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WHEN: Tuesday, September 11, 2007
9:00 a.m.–Noon

WHERE: Office of the Federal Register
Conference Room, Suite 700
800 North Capitol Street, NW.
Washington, DC 20002

RESERVATIONS: (202) 741–6008

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9355]

RIN 1545–BF66

Clarification of Section 6411 Regulations

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains final and temporary regulations clarifying that for purposes of allowing a tentative adjustment, the IRS may credit or reduce the tentative adjustment by an assessed tax liability, whether or not that tax liability was assessed before the date the application for tentative carryback was filed, and other unassessed tax liabilities in certain other circumstances. The portions of this document that are final regulations provide technical revisions that remove all references to IRS district director and service center director, as those positions no longer exist within the IRS. The offices of the district director and service center director were eliminated by the IRS reorganization implemented pursuant to the IRS Reform and Restructuring Act of 1998. The text of the temporary regulations serves as the text of the proposed regulations, set forth in the notice of proposed rulemaking on this subject in the Proposed Rules section in this issue of the **Federal Register**.

DATES: *Effective Date:* These regulations are effective August 27, 2007.

Applicability Date: These regulations apply with respect to applications for tentative refund filed on or after August 27, 2007.

FOR FURTHER INFORMATION CONTACT: Cynthia A. McGreevy, (202) 622–4910 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background and Explanation of Provisions

These regulations clarify the Income Tax Regulations (26 CFR part 1) under section 6411 relating to the computation and allowance of the tentative carryback adjustment. The tentative allowance is computed pursuant to § 1.6411–2 but applied pursuant to § 1.6411–3. These temporary regulations clarify that, for purposes of computing the allowance, the Commissioner will not consider amounts to which the taxpayer and the Commissioner are in disagreement. For purposes of applying the allowance, however, the Commissioner may credit or reduce the tentative adjustment by any assessed tax liabilities, unassessed liabilities determined in a statutory notice of deficiency, unassessed liabilities identified in a proof of claim filed in a bankruptcy proceeding, and other unassessed liabilities in rare and unusual circumstances. Regarding unassessed liabilities determined in a statutory notice of deficiency, see Rev. Rul. 2007–51. Regarding unassessed liabilities identified in a proof of claim filed in a bankruptcy proceeding, see Rev. Rul. 2007–52. See § 601.601(d)(2). The IRS plans to adopt procedures requiring IRS National Office review prior to a credit or reduction of the tentative adjustment by an unassessed liability that constitutes a rare and unusual circumstance.

These regulations also contain final regulations that remove all references to IRS district director or service center director, to account for the IRS's current organizational structure. The text of the temporary regulations serves as the text of the proposed regulations, published elsewhere in this issue of the **Federal Register**.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations. For the applicability of the Regulatory Flexibility Act (5 U.S.C. chapter 6) please refer to the Special Analyses section of the preamble of the cross-reference notice of proposed rulemaking published in the Proposed Rules section in this issue of the **Federal Register**. Pursuant to section 7805(f) of the Internal Revenue Code, these regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

Drafting Information

The principal author of these final and temporary regulations is Cynthia A. McGreevy of the Office of the Associate Chief Counsel (Procedure and Administration).

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Amendments to the Regulations

■ Accordingly, 26 CFR part 1 is to be amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *.

§ 1.6411–2 [Amended]

■ **Par. 2.** In the list below, for each section listed in the left column, remove the language in the middle column and add the language in the right column:

Section	Remove	Add
1.6411–2(a), first sentence	, unused investment credit, or unused WIN credit	, or unused investment credit
1.6411–2(a), fourth sentence	Internal Revenue Service	Commissioner
1.6411–2(a), last sentence	32	33
1.6411–2(b), third sentence	Internal Revenue Service	Commissioner

Section	Remove	Add
1.6411–2(b), fourth sentence	District director	Commissioner
1.6411–2(b), fourth sentence	Internal Revenue Service	Commissioner

■ **Par. 3.** Section 1.6411–2(c) is added to read as follows:

§ 1.6411–2 Computation of tentative carryback adjustment.

* * * * *

(c) *Effective/applicability date.* These regulations apply with respect to applications for tentative refund filed on or after August 27, 2007.

■ **Par. 4.** Section 1.6411–2T is added to read as follows:

§ 1.6411–2T Computation of tentative carryback adjustment (temporary).

(a) *Tax previously determined.* The taxpayer is to determine the amount of decrease, attributable to the carryback, in tax previously determined for each taxable year before the taxable year of the net operating loss, net capital loss, or unused investment credit. The tax previously determined is to be ascertained in accordance with the method prescribed in section 1314(a). Thus, the tax previously determined will be the tax shown on the return as filed, increased by any amounts assessed (or collected without assessment) as deficiencies before the date of the filing of the application for a tentative carryback adjustment, and decreased by any amounts abated, credited, refunded, or otherwise repaid prior to that date. Any items as to which the Commissioner and the taxpayer are in disagreement at the time of the filing of the application shall, for purposes of § 1.6411–2, be taken into account in ascertaining the tax previously determined only if, and to the extent that, they were reported in the return, or were reflected in any amounts assessed (or collected without assessment) as deficiencies, or in any amounts abated, credited, refunded, or otherwise repaid, before the date of filing the application. The tax previously determined, therefore, will reflect the foreign tax credit and the credit for tax withheld at source provided in section 33.

(b) *Decrease attributable to carryback.* After ascertaining the tax previously determined in the manner described in paragraph (a) of this section, the taxpayer shall determine the decrease in tax previously determined attributable to the carryback and any related adjustments on the basis of the items of tax taken into account in computing the tax previously determined. In determining any decrease attributable to the carryback or any related adjustment, items shall be taken into account under this subsection only to the extent that they were reported in the return, or were reflected in amounts assessed (or collected without assessment) as deficiencies, or in amounts abated, credited, refunded, or otherwise repaid, before the date of filing the application for a tentative carryback adjustment. If the Commissioner and the taxpayer are in disagreement as to the proper treatment of any item, it shall be assumed for purposes of determining the decrease in the tax previously determined that the item was correctly reported by the taxpayer unless, and to the extent that, the disagreement has resulted in the assessment of a deficiency (or the collection of an amount without an assessment), or the allowing or making of an abatement, credit, refund, or other repayment, before the date of filing the application. Thus, if the taxpayer claimed a deduction on its return of $50,000 for salaries paid its officers but the Commissioner proposes that the deduction should not exceed $20,000, and the Commissioner and the taxpayer have not agreed on the amount properly deductible before the date the application for a tentative carryback adjustment is filed, $50,000 shall be considered as the amount properly deductible for purposes of determining the decrease in tax previously determined in respect of the application for a tentative carryback adjustment. In determining the decrease in tax previously determined, any items which are affected by the carryback must be adjusted to reflect the carryback. Thus, unless otherwise provided, any deduction limited, for example, by adjusted gross income, such as the deduction for medical, dental, etc., expenses, is to be recomputed on the basis of the adjusted gross income as affected by the carryback. See § 1.6411–3T(d) for rules on the application of the decrease in tax to any tax liability.

(c) *Effective/applicability date.* (1) These regulations apply with respect to applications for tentative refund filed on or after August 27, 2007. (2) The applicability of this section expires on or before August 24, 2010.

■ **Par. 5.**

§ 1.6411–3 [Amended].

In the list below, for each section listed in the left column, remove the language in the middle column and add the language in the right column:

Section	Remove	Add
1.6411–3(a), first sentence	district director or director of a service center (either of whom are sometimes hereinafter referred to in this section as internal revenue officer)	Commissioner
1.6411–3(a)(2), first sentence	, unused investment credit, or unused WIN credit	, or unused investment credit
1.6411–3(b), first sentence	district director or director of a service center	Commissioner
1.6411–3(b), first sentence	he deems	Deemed
1.6411–3(b), second sentence	he	The Commissioner
1.6411–3(b), fourth sentence	Such internal revenue officer	The Commissioner
1.6411–3(b), fourth sentence	he may discover	discovered
1.6411–3(b), fifth sentence	he accordingly	the Commissioner accordingly
1.6411–3(b), fifth sentence	he may	May
1.6411–3(b), fifth sentence	, unused investment credit, or unused WIN credit	, or unused investment credit
1.6411–3(b), fifth sentence	, investment credit or WIN credit	, or investment credit
1.6411–3(b), sixth sentence	such internal revenue officer	the Commissioner
1.6411–3(b), sixth sentence	he	the Commissioner
1.6411–3(b), sixth sentence	his	the Commissioner's

Section	Remove	Add
1.6411–3(b), seventh sentence	such internal revenue officer	the Commissioner
1.6411–3(b), seventh sentence	he believes	the Commissioner believes
1.6411–3(b), seventh sentence	he will	the Commissioner will
1.6411–3(b), seventh sentence	such officer	the Commissioner
1.6411–3(c), first sentence	district director or director of a service center	Commissioner
1.6411–3(c), first sentence	he	the Commissioner
1.6411–3(c), second sentence	he deems	the Commissioner deems
1.6411–3(c), second sentence	by him	
1.6411–3(c), second sentence	he	the Commissioner
1.6411–3(c), third sentence	Such internal revenue officer's	The Commissioner's
1.6411–3(c), third sentence	he	the Commissioner
1.6411–3(c), fourth sentence	his	the Commissioner's
1.6411–3(c), fifth sentence	such internal revenue officer	the Commissioner
1.6411–3(d)(1), first sentence	district director or director of a service center	Commissioner
1.6411–3(d)(1)(iii), first sentence	including an amount the time for payment of which has been extended under section 6162, but	
1.6411–3(d)(2), first sentence	district director, or director of a service center	Commissioner
1.6411–3(d)(2), fifth sentence	such internal revenue officer	The Commissioner
1.6411–3(d)(2), fifth sentence	, unused investment credit, or unused WIN credit	, or unused investment credit
1.6411–3(d)(3), first sentence	district director or director of a service center	Commissioner

■ **Par. 6.** Section 1.6411–3(e) is added to read as follows:

§ 1.6411–3 Allowance of adjustments.

* * * * *

(e) *Effective/applicability date.* These regulations apply with respect to applications for tentative refund filed on or after August 27, 2007.

■ **Par. 7.** Section 1.6411–3T is added to read as follows:

§ 1.6411–3T Allowance of adjustments (temporary).

(a) *Time prescribed.* The Commissioner shall act upon any application for a tentative carryback adjustment filed under section 6411(a) within a period of 90 days from whichever of the following two dates is the later—

(1) The date the application is filed; or

(2) The last day of the month in which falls the last date prescribed by law (including any extension of time granted the taxpayer) for filing the return for the taxable year of the net operating loss, net capital loss, or unused investment credit from which the carryback results.

(b) *Examination.* Within the 90-day period described in paragraph (a) of this section, the Commissioner shall make, to the extent deemed practicable within this period, an examination of the application to discover omissions and errors of computation. The Commissioner shall determine within this period the decrease in tax previously determined, affected by the carryback or any related adjustments, upon the basis of the application and examination. The decrease shall be determined in the same manner as that provided in section 1314(a) for the determination by the taxpayer of the decrease in taxes previously determined which must be set forth in the application for a tentative carryback adjustment. The Commissioner, however, may correct any errors of computation or omissions discovered upon examination of the application. In determining the decrease in tax previously determined which is affected by the carryback or any related adjustment, the Commissioner may correct any mathematical error appearing on the application and may likewise correct any modification required by the law and incorrectly made by the taxpayer in computing the net operating loss, net capital loss, or unused investment credit, the resulting carrybacks, or the net operating loss deduction, capital loss deduction, or investment credit allowable. If the required modification has not been made by the taxpayer and the Commissioner has the necessary information to make the modification within the 90-day period, the Commissioner may, in the Commissioner's discretion, make the modification. In determining the decrease, however, the Commissioner will not, for example, change the amount claimed on the return as a deduction for depreciation because the Commissioner believes that the taxpayer has claimed an excessive amount; likewise, the Commissioner will not include in gross income any amount not so included by the taxpayer, even though the Commissioner believes that the amount is subject to tax and properly should be included in gross income.

(c) *Disallowance in whole or in part.* If the Commissioner finds that an application for a tentative carryback adjustment contains material omissions or errors of computation, the Commissioner may disallow such application in whole or in part without further action. If, however, the Commissioner deems that any error of computation can be corrected within the 90-day period, the Commissioner may do so and allow the application in whole or in part. The Commissioner's determination as to whether the Commissioner can correct any error of computation within the 90-day period shall be conclusive. Similarly, the Commissioner's action in disallowing, in whole or in part, any application for a tentative carryback adjustment shall be final and may not be challenged in any proceeding. The taxpayer may, however, file a claim for credit or refund under section 6402, and may maintain a suit based on the claim if it is disallowed or if the Commissioner does not act upon the claim within 6 months from the date it is filed.

(d) *Application of decrease.* (1) Each decrease determined by the Commissioner in any previously determined tax which is affected by the carryback or any related adjustments shall first be applied against any unpaid amount of the tax with respect to which such decrease was determined. The unpaid amount of tax may include one or more of the following:

(i) An amount with respect to which the taxpayer is delinquent.

(ii) An amount the time for payment of which has been extended under section 6164 and which is due and

payable on or after the date of the allowance of the decrease.

(iii) An amount (not including an amount the time for payment of which has been extended under section 6164) which is due and payable on or after the date of the allowance of the decrease, including any assessed liabilities, unassessed liabilities determined in a statutory notice of deficiency, unassessed liabilities identified in a proof of claim filed in a bankruptcy proceeding, and other unassessed liabilities in rare and unusual circumstances.

(2) If the unpaid amount of tax includes more than one unpaid amount, the Commissioner in his discretion, shall determine against which amount or amounts, and in what proportion, the decrease is to be applied. In general, however, the decrease will be applied against any amounts described in paragraphs (d)(1)(i) through (iii) of this section in the order named. If there are several amounts of the type described in paragraph (d)(1)(iii) of this section, any amount of the decrease which is to be applied against the amount will be applied by assuming that the tax previously determined minus the amount of the decrease to be so applied is ''the tax'' and that the taxpayer had elected to pay the tax in installments. The unpaid amount of tax against which a decrease may be applied under paragraph (d)(1) of this section may not include any amount of tax for any taxable year other than the year of the decrease. After making the application, the Commissioner will credit any remainder of the decrease against any unsatisfied amount of any tax for the taxable year immediately preceding the taxable year of the net operating loss, capital loss, or unused investment credit, the time for payment of which has been extended under section 6164.

(3) Any remainder of the decrease after the application and credits may, within the 90-day period, in the discretion of the Commissioner, be credited against any tax liability or installment thereof then due from the taxpayer (including assessed liabilities, unassessed liabilities determined in a statutory notice of deficiency, unassessed liabilities identified in a proof of claim filed in a bankruptcy proceeding, and other unassessed liabilities in rare and unusual circumstances), and, if not so credited, shall be refunded to the taxpayer within the 90-day period.

(e) *Effective/applicability date.* (1) These regulations apply with respect to applications for tentative refund filed on or after August 27, 2007.

(2) The applicability of this section expires on or before August 24, 2010.

Kevin M. Brown,

Deputy Commissioner for Services and Enforcement.

Approved: August 1, 2007.

Eric Solomon,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. E7–16878 Filed 8–24–07; 8:45 am]

BILLING CODE 4830–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[Docket No. EPA–R02–OAR–2006–0920; FRL–8441–7]

Approval and Promulgation of Implementation Plans; New Jersey; Low Emission Vehicle Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency is approving a state implementation plan revision submitted by the State of New Jersey. The State's revision adopts California's second generation low emission vehicle program for light-duty vehicles, LEV II, beginning with the 2009 model year. EPA is not taking action on two provisions of New Jersey's program: the zero-emission vehicle sales mandate and the greenhouse gas emission standards. The intended effect of this rulemaking is to approve a control strategy which will result in emissions reductions that will help New Jersey achieve attainment of national ambient air quality standard for ozone.

DATES: *Effective Date:* This rule will be effective September 26, 2007.

ADDRESSES: Copies of the State submittals are available at the following addresses for inspection during normal business hours:

Environmental Protection Agency, Region 2 Office, Air Programs Branch, 290 Broadway, 25th Floor, New York, New York 10007–1866.

New Jersey Department of Environmental Protection, Public Access Center, 401 East State Street, 1st Floor, Trenton, New Jersey 08625.

FOR FURTHER INFORMATION CONTACT: Matthew Laurita, *laurita.matthew@epa.gov* at the Environmental Protection Agency, Region 2 Office, Air Programs Branch, 290 Broadway, 25th Floor, New York, NY 10007–1866, telephone number (212) 637–3895, fax number (212) 637–3901.

SUPPLEMENTARY INFORMATION:

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I. Description of the SIP Revision

Section 209(a) of the Clean Air Act (CAA or the Act) prohibits states from adopting or enforcing standards relating to the control of emissions from new motor vehicles or new motor vehicle engines. However, under section 209(b) of the CAA, EPA shall grant a waiver of the section 209(a) prohibition to the State of California (unless EPA makes specified findings), thereby allowing California to adopt its own motor vehicle emissions standards. Section 177 of the CAA allows other states to adopt and enforce California's standards relating to the control of emissions from new motor vehicles, provided that, among other things, such state standards are identical to the California standards for which a waiver has been granted under CAA section 209(b). In addition to the identicality requirement, the state must adopt such standards at least two years prior to the commencement of the model year to which the standards will apply. All state implementation plan (SIP) revisions submitted to EPA for approval must also meet the requirements of CAA section 110.

In January 2004, the New Jersey Legislature passed legislation requiring the New Jersey Department of Environmental Protection (NJDEP) to adopt the California low emission vehicle (LEV) program, known as the LEV II program. Pursuant to this legislation, New Jersey promulgated regulations to adopt a LEV program identical to California's LEV II program. New Jersey's regulations were adopted on November 28, 2005. New Jersey's LEV program will affect light-duty motor vehicles manufactured in model year 2009 and later.

On June 2, 2006, New Jersey submitted a SIP revision to EPA, seeking federal approval of its LEV regulations. New Jersey's SIP revision submittal meets the requirements of sections 177 and 110 of the Act. EPA's approval of New Jersey's LEV program makes it federally-enforceable, further ensuring that planned emission reductions will continue to take place. For further information on New Jersey's LEV program see the March 21, 2007, Proposed Rulemaking (72 FR 13227).

II. Comments on the Proposed Rulemaking

EPA received two comments on the Proposed Rulemaking, published in the March 21, 2007 **Federal Register** (72 FR 13227). Both comments were supportive of EPA's proposed action to approve New Jersey's LEV program into the SIP. The comments and responses are included below.

Comment: EPA received a comment from a private citizen who was supportive of EPA's proposal to approve New Jersey's LEV program but expressed concerns over a lack of standards for small, non-road gasoline engines, such as for lawn mowers, ATVs, and jet skis.

Response: EPA notes the citizen's support of New Jersey's LEV program and notes that Subchapter 29 does not regulate small, non-road gasoline engines which were not a subject of the proposal. However, EPA has proposed emission standards for certain new non-road spark-ignition engines, equipment, and marine vessels (72 FR 28098). If implemented as proposed, these new standards will result in reductions of over 3.4 million tons of emissions by 2030.

Comment: NJDEP submitted comments in a letter dated April 20, 2007, in which NJDEP agreed with the proposed EPA action. However, NJDEP noted that on December 22, 2006, EPA issued a waiver of federal pre-emption to California, enabling California to implement the zero-emission vehicle (ZEV) component of its program through model year 2011. In light of EPA's granting this waiver, NJDEP requested that EPA act on the ZEV component of New Jersey's program, and approve it into the SIP through model year 2011, consistent with such waiver.

Response: EPA agrees with NJDEP and will propose to approve the ZEV component of New Jersey's LEV program in a separate notice-and-comment rulemaking. EPA is not taking action on the ZEV component in today's document, in order to allow the public an adequate opportunity to comment on this specific aspect of New Jersey's LEV program, since the March 21, 2007 Proposed Rulemaking (72 FR 13227) did not propose action on New Jersey's ZEV provisions.

III. Final EPA Action

EPA is approving New Jersey's LEV program, which is identical to the portions of California's LEV II program for which EPA has issued a waiver of pre-emption, with the exception that EPA is taking no action on the ZEV component of New Jersey's program. EPA has not issued a waiver to California to implement its greenhouse gas regulations, and therefore, EPA is also taking no action on the greenhouse gas portion of New Jersey's LEV program. Approval of New Jersey's LEV program further ensures that planned emissions reductions attributable to this program will be achieved. The New Jersey LEV program was adopted on November 28, 2005, published in the New Jersey State Register on January 17, 2006, is codified in Title 7, Chapter 27, Subchapter 29 of the New Jersey Administrative Code and replaces Subchapter 26, ''Ozone Transport Commission—Low Emission Vehicles Program'' which is now being removed from the SIP.

IV. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This action merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the CAA. This rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the CAA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

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**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

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 October 26, 2007. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: July 8, 2007.

Alan J. Steinberg,

Regional Administrator, Region 2.

■ Part 52, 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.*

Subpart FF—New Jersey

■ 2. Section 52.1570 is amended by adding new paragraph (c)(82) to read as follows:

§ 52.1570 Identification of plan.

* * * * *

(c) * * *

(82) Revisions to the State Implementation Plan submitted on June 2, 2006, by the New Jersey Department of Environmental Protection which consists of the adoption of California's second generation Low Emission Vehicle (LEV) program.

(i) Incorporation by reference:

(A) Regulation Subchapter 29 of Title 7, Chapter 27 of the New Jersey Administrative Code, entitled ''Low Emission Vehicle (LEV) Program,'' except sections 29.6, 29.7, and 29.13(g) (incorporation by reference of Title 13, Chapter 1, Article 2, Sections 1961.1 and 1962 of the California Code of Regulations only), adopted on November 28, 2005.

* * * * *

■ 3. Section 52.1605 is amended by removing the entry for Subchapter 26 and adding a new entry for Subchapter 29 under Title 7, Chapter 27 to read as follows:

§ 52.1605 EPA-approved New Jersey regulations.

State regulation	State effective date	EPA approved date	Comments
*	*	*	*
Title 7, Chapter 27			
*	*	*	*
Subchapter 29, ''Low Emission Vehicle (LEV) Program''.	January 27, 2006	August 27, 2007. [*Insert* **Federal Register** page citation].	Sections 29.6, 29.7, and 29.13(g) [Title 13, Chapter 1, Article 2, Sections 1961.1 and 1962 of the California Code of Regulations] relating to zero-emission vehicles and greenhouse gas emission standards are not incorporated into the SIP.
*	*	*	*

[FR Doc. E7–16815 Filed 8–24–07; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 65

[EPA–HQ–OAR–2007–0429; FRL–8459–5]

RIN 2060–A045

Revisions to Consolidated Federal Air Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The EPA is taking direct final action on the General Provisions for Consolidated Federal Air Rule to allow extensions to the deadline imposed for source owners and operators to conduct required performance tests in certain specified force majeure circumstances. On May 16, 2007, we published a final rule that revised the General Provisions for Standards of Performance for New Stationary Sources, for National Emission Standards for Hazardous Air Pollutants, and for National Emission Standards for Hazardous Air Pollutants for Source Categories to allow extensions to the deadline imposed for source owners and operators to conduct required performance tests in certain specified force majeure circumstances. We recently realized that we should have also revised the Consolidated Federal Air Rule to allow for similar extensions.

DATES: This rule is effective on November 26, 2007 without further notice, unless EPA receives adverse comment by September 26, 2007. If we receive adverse comment, we will publish a timely withdrawal in the **Federal Register** informing the public that some or all of the amendments in this rule will not take effect.

ADDRESSES: Submit your comments, identified under Docket ID No. EPA–HQ–OAR–2007–0429 by one of the following methods:

- *www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *E-mail: a-and-r-docket@epa.gov.*
- *Fax:* (202) 566–9744.
- *Mail:* Revisions to Consolidated Federal Air Rule, Environmental Protection Agency, Mailcode: 2822T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Please include a total of two copies.
- *Hand Delivery:* EPA Docket Center, 1301 Constitution Avenue, NW., EPA Headquarters Library, Room 3334, EPA West Building, Washington, DC 20460. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OAR–2007–0429. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which

means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov*, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm*.

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the Revisions to Consolidated Federal Air Rule Docket, EPA/DC, EPA West Building, EPA Headquarters Library, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Air Docket is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: Ms. Lula Melton, Air Quality Assessment Division (C304–02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–2910; fax number: (919) 541–4511; e-mail address *melton.lula@epa.gov*.

Table of Contents

I. Why Is EPA Using a Direct Final Rule?

The EPA is publishing this rule without a prior proposed rule because we view this as a non-controversial action and anticipate no adverse comment. The changes mirror those recently promulgated in the May 16, 2007 final rule revising the General Provisions for Standards of Performance for New Stationary Sources, for National Emission Standards for Hazardous Air Pollutants, and for National Emission Standards for Hazardous Air Pollutants for Source Categories (''Force Majeure Rule'') which allowed extensions to the deadline imposed for source owners and operators to conduct required performance tests in certain specified force majeure circumstances. Nonetheless, in the ''Proposed Rules'' section of this **Federal Register**, we are publishing a separate document that will serve as the proposed rule if relevant adverse comments are received on this direct final rule. We will not institute a second comment period on this action. Any parties interested in commenting, must do so at this time. For further information about commenting on this rule, see the **ADDRESSES** section of this document. If EPA receives adverse comment, we will publish a timely withdrawal in the **Federal Register** informing the public that this direct final rule will not take effect. We would address all public comments in any subsequent final rule based on the proposed rule.

II. Does This Action Apply to Me?

This action applies to any owner or operator of a source required to conduct performance testing to demonstrate compliance with applicable standards under the General Provisions for Consolidated Federal Air Rule.

III. Judicial Review

Under section 307(b)(1) of the Clean Air Act (CAA), judicial review of this direct final rule is available by filing a petition for review in the United States Court of Appeals for the District of Columbia Circuit by October 26, 2007. Only those objections to this final rule that were raised with reasonable specificity during the period for public comment may be raised during judicial review. Under section 307(b)(2) of the CAA, the requirements that are the subject of this direct final rule may not be challenged later in civil or criminal proceedings brought by EPA to enforce these requirements.

IV. This Action

The direct final rule allows source owners or operators, in the event of a force majeure, to petition the Administrator for an extension of the deadline(s) by which they are required to conduct an initial or subsequent performance test required by the Consolidated Federal Air Rule. Performance tests required as a result of enforcement orders or enforcement actions are not covered by this rule because enforcement agreements contain their own force majeure provisions. A ''force majeure'' is defined as an event that will be or has been caused by circumstances beyond the control of the affected facility, its contractors, or any entity controlled by the affected facility that prevents the owner or operator from complying with the regulatory requirement to conduct performance tests within the specified timeframe despite the affected facility's best efforts to fulfill the obligation. Examples of such events are acts of nature, acts of war or terrorism, or equipment failure or safety hazard beyond the control of the affected facility.

If an affected owner or operator intends to assert a claim that a force majeure is about to occur, occurs, or has occurred, the owner or operator must notify the Administrator, in writing, as soon as practicable following the date the owner or operator first knew, or through due diligence should have known, that the event may cause or caused a delay in testing beyond the regulatory deadline. The owner or operator must provide a written description of the event and a rationale for attributing the delay in testing beyond the regulatory deadline to the force majeure; describe the measures taken or to be taken to minimize the delay; and identify a date by which the owner or operator proposes to conduct the performance test. The test must be

conducted as soon as practicable after the force majeure occurs.

The decision as to whether or not to grant an extension to the performance test deadline is solely within the discretion of the Administrator. The Administrator will notify the owner or operator in writing of approval or disapproval of the request for an extension as soon as practicable. If an owner or operator misses its performance test deadline due to a force majeure event, and the request for an extension is subsequently approved, the owner or operator will not be held in violation for failure to conduct the performance test within the prescribed regulatory timeframe.

We recognize that there may be circumstances beyond a source owner's or operator's control constituting a force majeure event that could cause an owner or operator to be unable to conduct performance tests before the regulatory deadline. We developed this rule to provide a mechanism for consideration of these force majeure events and granting of extensions where warranted. Under current rules, a source owner or operator who is unable to comply with performance testing requirements within the allotted timeframe due to a force majeure is regarded as being in violation and subject to enforcement action. As a matter of policy, EPA often exercises enforcement discretion regarding such violations. However, where circumstances beyond the control of the source owner or operator constituting a force majeure prevent the performance of timely performance tests, we believe that it is appropriate to provide an opportunity to such owners and operators to make good faith demonstrations and obtain extensions of the performance testing deadline where approved by the Administrator in appropriate circumstances.

V. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

This action is not a ''significant regulatory action'' under the terms of Executive Order 12866 (58 FR 51735 October 4, 1993) and is therefore not subject to review under the EO.

B. Paperwork Reduction Act

The information collection requirements in this rule have been submitted for approval to the Office of Management and Budget (OMB) under the *Paperwork Reduction Act*, 44 U.S.C. 3501 *et seq.* The information collection requirements are not enforceable until OMB approves them.

The final rule requires a written notification only if a plant owner or operator needs an extension of a performance test deadline due to certain rare events, such as acts of nature, acts of war or terrorism, or equipment failure or safety hazard beyond the control of the affected facility. Since EPA believes such events will be rare, the projected cost and hour burden will be minimal.

The increased annual average reporting burden for this collection (averaged over the first 3 years of the ICR) is estimated to total 6 labor hours per year at a cost of $377.52. This includes one response per year from six respondents for an average of 1 hour per response. No capital/startup costs or operation and maintenance costs are associated with the final reporting requirements. 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.

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 in 40 CFR are listed in 40 CFR part 9. When this ICR is approved by OMB, the Agency will publish a technical amendment to 40 CFR part 9 in the **Federal Register** to display the OMB control number for the approved information collection requirements contained in this final rule.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute 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 organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of today's final rule on small entities, small entity is defined as: (1) A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. Extensions to deadlines for conducting performance tests will provide flexibility to small entities and reduce the burden on them by providing them an opportunity for additional time to comply with performance test deadlines during force majeure events. We expect force majeure events to be rare since these events include circumstances such as, acts of nature, acts of war or terrorism, and equipment failure or safety hazard beyond the control of the affected facility.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, Local, and Tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes

any regulatory requirements that may significantly or uniquely affect small governments, including Tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

EPA has determined that the final rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and Tribal governments, in the aggregate, or the private sector in any one year. The maximum total annual cost of this final rule for any year has been estimated to be less than $435. Thus, today's final rule is not subject to the requirements of Sections 202 and 205 of the UMRA.

EPA has determined that the final rule contains no regulatory requirements that might significantly or uniquely affect small governments. The final rule requires source owners and operators to provide a written notification to the Agency only if an extension to a performance test deadline is necessary due to rare force majeure events. Therefore, the final rule is not subject to the requirements of section 203 of the UMRA.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure (meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

This direct final rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. The final rule requirements will not supercede State regulations that are more stringent. In addition, the final rule requires a written notification only if a plant owner or operator needs an extension of a performance test deadline due to certain rare events, such as acts of nature, acts of war or terrorism, or equipment failure or safety hazard beyond the control of the affected facility. Since EPA believes such events will be rare, the projected cost and hour burden will be minimal. Thus, Executive Order 13132 does not apply to this rule.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' This direct final rule does not have tribal implications as specified in Executive Order 13175. This final rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

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 Executive Order 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 direct final rule is not subject to the Executive Order because it is not economically significant as defined in Executive Order 12866 and because the Agency does not have reason to believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This rule does not affect the underlying control requirements established by the applicable standards but only the timeframe associated with performance testing in limited circumstances.

H. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order (59 FR 7629, February 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this direct final rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment. This direct final rule does not relax the control requirements on affected sources. It merely allows an extension to the deadline for conducting performance tests in rare force majeure circumstances.

I. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This rule is not subject to Executive Order 13211, ''Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note), directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. New test methods are not being proposed in

this rulemaking, but EPA is allowing for extensions of the regulatory deadlines by which owners or operators are required to conduct performance tests when a force majeure is about to occur, occurs, or has occurred which prevents owners or operators from testing within the regulatory deadline. Therefore, NTTAA does not apply.

K. Congressional Review Act

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**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective on November 26, 2007.

List of Subjects in 40 CFR Part 65

Air pollution control, Environmental protection, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: August 17, 2007.

Stephen L. Johnson,

Administrator.

■ For the reasons stated in the preamble, title 40, chapter I, part 65 of the Code of Federal Regulations are amended as follows:

PART 65—[AMENDED]

■ 1. The authority citation for part 65 continues to read as follows:

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

Subpart A—[Amended]

■ 2. Section 65.2 is amended by adding, in alphabetical order, a definition for ''Force majeure'' to read as follows:

§ 65.2 Definitions.

* * * * *

Force majeure means, for purposes of § 65.157, an event that will be or has been caused by circumstances beyond the control of the affected facility, its contractors, or any entity controlled by the affected facility that prevents the owner or operator from complying with the regulatory requirement to conduct performance tests within the specified timeframe despite the affected facility's best efforts to fulfill the obligation. Examples of such events are acts of nature, acts of war or terrorism, or equipment failure or safety hazard beyond the control of the affected facility.

* * * * *

■ 3. Section 65.157 is amended as follows:

■ a. By revising paragraph (c) introductory text.

■ b. By adding paragraphs (c)(1)(viii) through (c)(1)(xi).

§ 65.157 Performance test and flare compliance determinations.

* * * * *

(c) Except as specified in paragraphs (c)(1)(viii), (c)(1)(ix), (c)(1)(x), and (c)(1)(xi) of this section, unless a waiver of performance testing or flare compliance determination is obtained under this section or the conditions of another subpart of this part, the owner or operator shall perform such tests specified in the following:

(1) * * *

(viii) If a force majeure is about to occur, occurs, or has occurred for which the affected owner or operator intends to assert a claim of force majeure, the owner or operator shall notify the Administrator, in writing as soon as practicable following the date the owner or operator first knew, or through due diligence should have known that the event may cause or caused a delay in testing beyond the regulatory deadline, but the notification must occur before the performance test deadline unless the initial force majeure or a subsequent force majeure event delays the notice, and in such cases, the notification shall occur as soon as practicable.

(ix) The owner or operator shall provide to the Administrator a written description of the force majeure event and a rationale for attributing the delay in testing beyond the regulatory deadline to the force majeure; describe the measures taken or to be taken to minimize the delay; and identify a date by which the owner or operator proposes to conduct the performance test. The performance test shall be conducted as soon as practicable after the force majeure occurs.

(x) The decision as to whether or not to grant an extension to the performance test deadline is solely within the discretion of the Administrator. The Administrator will notify the owner or operator in writing of approval or disapproval of the request for an extension as soon as practicable.

(xi) Until an extension of the performance test deadline has been approved by the Administrator under paragraphs (c)(1)(viii), (c)(1)(ix), and (c)(1)(x) of this section, the owner or operator of the affected facility remains strictly subject to the requirements of this part.

* * * * *

[FR Doc. E7–16840 Filed 8–24–07; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–R04–SFUND–2007–0719; FRL–8458–7]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List

AGENCY: Environmental Protection Agency.

ACTION: Direct final notice of deletion of the Standard Auto Bumper Site from the National Priorities List.

SUMMARY: The Environmental Protection Agency (EPA) Region 4 is publishing a direct final notice of deletion of the Standard Auto Bumper Site (Site), located in Hialeah, Florida, from the National Priorities List (NPL).

The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is appendix B of 40 CFR part 300, which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). This direct final deletion is being published by EPA with the concurrence of the State of Florida, through the Florida Department of Environmental Protection (FDEP) because EPA has determined that all appropriate response actions under CERCLA have been completed and, therefore, further remedial action pursuant to CERCLA is not appropriate.

DATES: This direct final deletion will be effective October 26, 2007 unless EPA receives adverse comments by September 26, 2007. If adverse comments are received, EPA will publish a timely withdrawal of the direct final deletion in the **Federal Register** informing the public that the deletion will not take effect.

ADDRESSES: Submit your comments, identified by EPA–R04–SFUND–2007–0613, by one of the following methods:

1. *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.

2. *E-mail: taylor.michael@epa.gov.*

3. *Fax:* (404) 562–8896.

4. *Mail:* EPA–R04–SFUND–2007–0719, Superfund Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960.

5. *Hand Delivery or Courier:* Michael Taylor, Remedial Project Manager, Superfund Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding Federal holidays.

Instructions: Direct your comments to EPA–R04–SFUND–2007–0719. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit through *http://www.regulations.gov* or e-mail, information that you consider to be CBI or otherwise protected. The *http://www.regulations.gov* Web site is an ''anonymous access'' systems, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov,* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the electronic docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the for further information contact section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30 excluding legal holidays.

Comprehensive information on this Site is available through the Region 4 public docket, which is available for viewing at the following repository location:

John F. Kennedy Memorial Library, Hialeah Public Library, 190 West 49th Street, Hialeah, Florida 33012, Hours: Monday through Thursday—10 a.m. until 8:45 p.m., and Friday–Saturday 9:30 a.m. until 4:45 p.m.

U.S. EPA Record Center, Attn: Ms. Debbie Jourdan, Atlanta Federal Center, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960, Phone: (404) 562–8862, Hours 8 a.m. to 4 p.m., Monday through Friday by appointment only.

FOR FURTHER INFORMATION CONTACT: Michael Taylor, Remedial Project Manager, Superfund Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960, Phone: (404) 562–8762, Electronic Mail: *taylor.michael@epa.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

EPA Region 4 is publishing this direct final notice of deletion of the Standard Auto Bumper, Superfund Site from the NPL.

The EPA identifies sites that appear to present a significant risk to public health or the environment and maintains the NPL as the list of those sites. As described in the § 300.425(e)(3) of the NCP, sites deleted from the NPL remain eligible for remedial actions if conditions at a deleted site warrant such action.

Because EPA considers this action to be noncontroversial and routine, EPA is taking it without prior publication of a notice of intent to delete. This action will be effective October 26, 2007 unless EPA receives adverse comments by September 26, 2007 on this document. If adverse comments are received within the 30-day public comment period on this document, EPA will publish a timely withdrawal of this direct final deletion before the effective date of the deletion and the deletion will not take effect. EPA will, as appropriate, prepare a response to comments and continue with the deletion process on the basis of the notice of intent to delete and the comments already received. There will be no additional opportunity to comment.

Section II of this document explains the criteria for deleting sites from the NPL. Section III discusses procedures that EPA is using for this action. Section IV discusses the Standard Auto Bumper, Superfund Site and demonstrates how it meets the deletion criteria. Section V discusses EPA's action to delete the Site from the NPL unless adverse comments are received during the public comment period.

II. NPL Deletion Criteria

Section 300.425(e) of the NCP provides that releases may be deleted from the NPL where no further response is appropriate. In making a determination to delete a Site from the NPL, EPA shall consider, in consultation with the State, whether any of the following criteria have been met:

i. Responsible parties or other persons have implemented all appropriate response actions required;

ii. All appropriate Fund-financed (Hazardous Substance Superfund Response Trust Fund) response under CERCLA has been implemented, and no further response action by responsible parties is appropriate; or

iii. The remedial investigation has shown that the release poses no significant threat to public health or the environment and, therefore, the taking of remedial measures is not appropriate.

Even if a site is deleted from the NPL, where hazardous substances, pollutants, or contaminants remain at the deleted site above levels that allow for unlimited use and unrestricted exposure, CERCLA section 121(c), 42 U.S.C. 9621(c) requires that a subsequent review of the site be conducted at least every five years after the initiation of the remedial action at the deleted site to ensure that the action remains protective of public health and the environment. If new information becomes available which indicates a need for further action, EPA may initiate remedial actions. Whenever there is a significant release from a site deleted from the NPL, the deleted site may be restored to the NPL without application of the hazard ranking system.

III. Deletion Procedures

The following procedures apply to deletion of the Site:

(1) The EPA consulted with the State of Florida on the deletion of the Site from the NPL prior to developing this direct final notice of deletion.

(2) Florida concurred with deletion of the Site from the NPL.

(3) Concurrently with the publication of this direct final notice of deletion, a notice of the availability of the parallel notice of intent to delete published today in the ''Proposed Rules'' section of the **Federal Register** is being published in a major local newspaper of general circulation at or near the Site and is being distributed to appropriate federal, state, and local government officials and other interested parties; the newspaper notice announces the 30-day public comment period concerning the notice of intent to delete the Site from the NPL.

(4) The EPA placed copies of documents supporting the deletion in the Site information repositories identified above.

(5) If adverse comments are received within the 30-day public comment period on this document, EPA will publish a timely notice of withdrawal of this direct final notice of deletion before its effective date and will prepare a response to comments and continue with the deletion process on the basis of the notice of intent to delete and the comments already received.

Deletion of a site from the NPL does not itself create, alter, or revoke any individual's rights or obligations. Deletion of a site from the NPL does not in any way alter EPA's right to take enforcement actions, as appropriate. The NPL is designed primarily for informational purposes and to assist EPA management. Section 300.425(e)(3) of the NCP states that the deletion of a site from the NPL does not preclude eligibility for future response actions, should future conditions warrant such actions.

IV. Basis for Site Deletion

The following information provides EPA's rationale for deleting the Site from the NPL:

Site Location

The Standard Auto Bumper Site is approximately 0.8 acres in size and located in an industrial/commercial area at 2500 West 3rd Court, Hialeah, Dade County, Florida.

Site History

The facility operated as a chrome plating facility from 1959 until the early 1990s. Prior to 1970 processed and untreated electroplating waste was discharged on the property behind the main building along a drainage ditch west of the property. This discharged waste percolated into the soil and groundwater. In 1972, the facility began pretreating the waste water before discharging it into the septic tank. The treatment system was constructed to convert hexavalent chromium to trivalent chromium. Pretreated waste water was routed to the Hialeah waste water treatment system in 1979. In early 1993, Standard Auto Bumper ceased operations and abandoned the facility. The Site property was taken by Miami-Dade county in 2004 due to non payment of property taxes. The property was sold in July 2005 for the taxes owed to the county. In August of 1985, the EPA conducted a site inspection and field investigation at the site. During this multi-media investigation groundwater samples, surface and subsurface soil samples were collected. Analytical data later revealed contamination of soil and groundwater. Chromium and nickel, substances used in the facility process, were detected in the soil and groundwater. In addition, the analytical data indicated the presence of cadmium, lead, cyanide, and copper.

The site is in the recharge zone of the Biscayne Aquifer, which supplies drinking water for Dade County. Four municipal well fields, the Upper and Lower Miami Springs, the Hialeah, and the John E. Preston, that supply drinking water to over 750,000 people, are within three miles of the site.

The site was included on the National Priority List in October of 1989 based upon the Hazard Ranking System (HRS) package from 1987.

Remedial Investigation and Feasibility Study (RI/FS)

In February of 1990, an Administrative Order on Consent for a Remedial Investigation/Feasibility Study (RI/FS) was signed by the EPA and Standard Auto Bumper. This agreement was later withdrawn by Standard Auto Bumper which resulted in the EPA completing the required site work.

This Superfund site was addressed in two operable units. Operable unit one dealt with the soil. Operable unit two addressed issues dealing with the groundwater. In 1991, the EPA conducted soil, sediment, surface water and groundwater sampling as part of the RI/FS. The RI/FS for OU1 was completed in August of 1992. The RI/FS for OU2 was completed in September of 1992.

Record of Decision Findings

The Record Of Decision (ROD) for OU1 was signed by EPA on September 28, 1992. The ROD for OU1 describes the contamination at the Site and the approved cleanup method to be used at the Site. The remedial objective for OU1 was to prevent current or future exposure to the soil contaminated with nickel and chromium through treatment and/or containment, and to reduce the migration of these contaminants from the soil to groundwater. The ROD required all soils above the cleanup standards to be excavated and disposed at an offsite permitted landfill facility. The ROD also required up to five years of groundwater monitoring.

The ROD for OU2 was issued by EPA on December 10, 1993. The remedial objective for OU2 was to prevent current and future exposure to contaminated groundwater from nickel and other inorganic compounds. This remedy addressed groundwater contamination through natural attenuation, groundwater use controls, and groundwater monitoring for a minimum of 18 months. The remedy was designed to follow the OU1 source removal and the required groundwater monitoring was to be conducted as part of the OU1 groundwater monitoring plan.

Characterization of Risk

The OU1 soil posed a threat to human health and the environment due to ingestion of contaminated surface soils by children of potential future residents and the soil contamination's impact on the groundwater.

The OU2 groundwater posed a threat to human health and the environment due to ingestion of contaminated groundwater by future residents. The groundwater contaminants of concern identified in the site's baseline risk assessment were barium, manganese, nickel and zinc.

The environmental risks were also considered for site impact on the surrounding habitat. The site does not provide for many habitat resources for wildlife, due to the industrial setting of the site. Contamination from the site from surface water runoff is not likely due to local businesses, highways, and elevated railroad tracks that exist between the site and nearby canal.

Response Actions

An Administrative Order on Consent was signed on May 4, 1989, between the EPA and Standard Auto Bumper for a Removal action. This Order addressed soil contamination and not groundwater. Contaminated soil was excavated during the summer of 1989.

In October of 1992, the EPA issued a notice letter to the PRP pursuant to 122(a) of CERCLA for conducting the Remedial Design and Remedial Action (RD/RA) for OU1. There was no response from the PRP resulting in EPA conducting the OU1 RD/RA. The OU1 RD/RA conducted by EPA in 1993 and 1994 consisted of removal of the tanks, process water and drums along with approximately 10,000 tons of contaminated soils. Contaminated soils immediately adjacent to or underlying the Gilda Bakery and Quality manufacturing buildings as well as under West 3rd Court were inaccessible and left in place.

OU1 soil contamination remaining on site and off site in areas inaccessible for removal during OU1 are being addressed through institutional controls as required by CERCLA. Proper notification and facility information has been provided to potentially affected parties adjacent to the SAB site. A flagging system has been implemented through Florida Department of Environmental Resources Management (DERM) which utilizes the County permitting requirements for facility structural changes and improvements. Any permit request or change in structure on the adjacent properties will prompt notification to FDEP and the EPA to assure that appropriate steps are taken to address contaminated soils still remaining underneath the building foundations, where necessary. In addition to the flagging system, FDEP-Bureau of Waste Cleanup maintains a registry database for tracking former waste sites where remedial action includes use of institutional controls.

OU2 groundwater monitoring was conducted by EPA in 1994 and from May 1995 through February 2001 by FDEP as required under CERCLA. Groundwater sampling in February 2001 confirmed that groundwater met federal and state drinking water standards. The Pollution Remediation Section of the Florida Department of Environmental Resources Management (DERM) concurred that sufficient groundwater monitoring for the chemicals of concern has occurred in accordance with the requirements of Chapter 24, Code of Miami-Dade County. In addition, there are no further requirements to address groundwater contamination at the site.

The new owner agreed to place a restrictive covenant on the property deed that would maintain current and future property use consistent with the remedial action. In addition to the institutional control, the new owner agreed to close a monitoring well on site. Institutional controls have been initiated.

All appropriate Fund-financed response under CERCLA has been implemented. No further response action is necessary.

Cleanup Standards

The OU1 ROD determined that all soil concentrations for total chromium, hexavalent chromium or nickel above 519 ppm, 52 ppm or 370 ppm would be excavated and disposed at an offsite permitted landfill facility.

The OU1 ROD determined that monitoring was required to ensure that drinking water Maximum Contaminant Levels (MCLs) were achieved.

Operation and Maintenance

FDEP conducted the required operation and maintenance and groundwater monitoring activities at the site subsequent to completion of the removal and remedial actions at the site.

Five-Year Review

A statutory five-year review of the remedy was conducted in November of 1999 and determined that the remedy for the Site remained protective of human health and the environment. A second five-year review was conducted in 2005. The remedy for the Site continues to be protective of human health and the environment. Five-year reviews will be conducted in the future to assure the continued protectiveness of the remedy.

Community Involvement

Public participation activities have been satisfied as required in CERCLA section 113(k), 42 U.S.C. 9613(k), and CERCLA section 117, 42 U.S.C. 9617. Documents in the deletion docket which EPA relied on for recommendation of the deletion from the NPL are available to the public in the information repositories.

V. Deletion Action

The EPA, with concurrence of the State of Florida has determined that all appropriate responses under CERCLA have been completed, and that no further response actions, under CERCLA, are necessary. Therefore, EPA is deleting the Site from the NPL.

Because EPA considers this action to be noncontroversial and routine, EPA is taking it without prior publication. This action will be effective October 26, 2007 unless EPA receives adverse comments by September 26, 2007. If adverse comments are received within the 30-day public comment period, EPA will publish a timely withdrawal of this direct final notice of deletion before the effective date of the deletion and it will not take effect and, EPA will prepare a response to comments and continue with the deletion process on the basis of the notice of intent to delete and the comments already received. There will be no additional opportunity to comment.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: August 13, 2007.

J.I. Palmer, Jr.,

Regional Administrator, Region 4.

■ 40 CFR part 300 is amended as follows:

PART 300—[AMENDED]

■ 1. The authority citation for part 300 continues to read as follows:

Authority: 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601–9657; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p.351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p.193.

Appendix B—[Amended]

■ 2. Table 1 of Appendix B to part 300 is amended by removing the entry for the ''Standard Auto Bumper Corp'' site in Hialeah, FL.

[FR Doc. E7–16685 Filed 8–24–07; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 061020273–7001–03]

RIN 0648–XC21

Fisheries of the Northeastern United States; Summer Flounder Fishery; Commercial Quota Harvested for Connecticut

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS announces that the 2007 summer flounder commercial quota allocated to the State of Connecticut has been harvested. Vessels issued a commercial Federal fisheries permit for the summer flounder fishery may not land summer flounder in Connecticut for the remainder of

calendar year 2007, unless additional quota becomes available through a transfer from another state. Regulations governing the summer flounder fishery require publication of this notification to advise Connecticut that the quota has been harvested and to advise vessel permit holders and dealer permit holders that no commercial quota is available for landing summer flounder in Connecticut.

DATES: Effective 0001 hours, August 25, 2007 through 2400 hours, December 31, 2007.

FOR FURTHER INFORMATION CONTACT: Emily Bryant, Fishery Management Specialist, (978) 281–9244.

SUPPLEMENTARY INFORMATION: Regulations governing the summer flounder fishery are found at 50 CFR part 648. The regulations require annual specification of a commercial quota that is apportioned on a percentage basis among the coastal states from North Carolina through Maine. The process to set the annual commercial quota and the percent allocated to each state is described in § 648.100.

The initial total commercial quota for summer flounder for the 2007 calendar year was set equal to 7,789,800 lb (3,533 mt) (71 FR 75134, December 14, 2006). This quota was increased through an emergency action to 10,267,098 lb (4,658 mt) (72 FR 2458, January 19, 2007). The percent allocated to vessels landing summer flounder in Connecticut is 2.25708 percent, resulting in a commercial quota of 231,739 lb (106 mt). The 2007 allocation was reduced to 226,464 lb (103 mt) when research set-aside was deducted and then reduced to 209,994 (96 mt) after the 2006 overages had been applied.

Section 648.101(b) requires the Administrator, Northeast Region, NMFS (Regional Administrator) to monitor state commercial quotas and to determine when a state's commercial quota has been harvested. NMFS then publishes a notification in the **Federal Register** to advise the state and to notify Federal vessel and dealer permit holders that, effective upon a specific date, the state's commercial quota has been harvested and no commercial quota is available for landing summer flounder in that state. The Regional Administrator has determined, based upon dealer reports and other available information, that Connecticut has harvested its quota for 2007.

The regulations at § 648.4(b) provide that Federal permit holders agree, as a condition of the permit, not to land summer flounder in any state that the Regional Administrator has determined no longer has commercial quota available. Therefore, effective 0001 hours, August 25, 2007, further landings of summer flounder in Connecticut by vessels holding summer flounder commercial Federal fisheries permits are prohibited for the remainder of the 2007 calendar year, unless additional quota becomes available through a transfer and is announced in the **Federal Register**. Effective 0001 hours, August 25, 2007, federally permitted dealers are also notified that they may not purchase summer flounder from federally permitted vessels that land in Connecticut for the remainder of the calendar year, or until additional quota becomes available through a transfer from another state.

Classification

This action is required by 50 CFR part 648 and is exempt from review under Executive Order 12866.

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

Dated: August 21, 2007.

Emily H. Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 07–4189 Filed 8–22–07; 3:07 pm]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 070213032–7032–01]

RIN 0648–XC22

Fisheries of the Exclusive Economic Zone Off Alaska; Pollock in Statistical Area 630 of the Gulf of Alaska

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for pollock in Statistical Area 630 of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the C season allowance of the 2007 total allowable catch (TAC) of pollock for Statistical Area 630 of the GOA.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), August 28, 2007, through 1200 hrs, A.l.t., October 1, 2007.

FOR FURTHER INFORMATION CONTACT: Jennifer Hogan, 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 C season allowance of the 2007 TAC of pollock in Statistical Area 630 of the GOA is 4,889 metric tons (mt) as established by the 2007 and 2008 harvest specifications for groundfish of the GOA (72 FR 9676, March 5, 2007). In accordance with § 679.20(a)(5)(iv)(B) the Administrator, Alaska Region, NMFS (Regional Administrator), hereby decreases the C season pollock allowance by 1,338 mt, the amount of the B season allowance of the pollock TAC that was exceeded in Statistical Area 630. Therefore, the revised C season allowance of the pollock TAC in Statistical Area 630 is 3,551 mt (4,889 mt minus 1,338 mt).

In accordance with § 679.20(d)(1)(i), the Regional Administrator has determined that the C season allowance of the 2007 TAC of pollock in Statistical Area 630 of the GOA will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 3,251 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 has been reached. Consequently, NMFS is prohibiting directed fishing for pollock in Statistical Area 630 of the GOA.

After the effective date of this closure the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the closure of pollock in Statistical Area 630 of the GOA. NMFS was unable to publish a notice providing time for public comment

because the most recent, relevant data only became available as of August 20, 2007.

The AA also finds good cause to waive the 30–day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

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

Dated: August 21, 2007.

Alan D. Risenhoover,

Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. E7–16914 Filed 8–24–07; 8:45 am]

BILLING CODE 3510–22–S

Proposed Rules

Federal Register
Vol. 72, No. 165
Monday, August 27, 2007

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 TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2007–28955; Directorate Identifier 2007–CE–067–AD]

RIN 2120–AA64

Airworthiness Directives; Diamond Aircraft Industries GmbH Model DA 42 Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for the products listed above. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

Recently, a double in-flight engine shut down incident occurred on a DA42 aircraft equipped with TAE125–01 engines. The BFU (German Accident Investigation Body) found the root cause to be a violation of the Airplane Flight Manual procedures (taking-off with an insufficiently charged main aircraft battery) and momentary low voltage in the electrical system of the aircraft when retracting the main landing gear. This has been the subject of Diamond Service Information (SI) 42–040 and a subsequent EASA Safety Information Notice, SIN 2007–08, issued on 18 April 2007.

The TAE125–01 and TAE125–02–99 engines, approved for installation on the DA42, are FADEC (Full Authority Digital Engine Control) controlled and are not totally independent from the aircraft electrical power supply. A significant drop of the voltage causes simultaneously a reset of the FADEC on both engines with subsequent feathering of the propeller blades. In the case of an empty battery this scenario may be considered as catastrophic at the aircraft level.

The proposed AD would require actions that are intended to address the unsafe condition described in the MCAI.

DATES: We must receive comments on this proposed AD by September 26, 2007.

ADDRESSES: You may send comments by any of the following methods:

- *DOT Docket Web Site:* Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Follow the instructions for submitting comments.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://dms.dot.gov;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Peter L. Rouse, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4135; fax: (816) 329–4090.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2007–28955; Directorate Identifier 2007–CE–067–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://dms.dot.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued AD No: 2007–0183, dated July 2, 2007 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

Recently, a double in-flight engine shut down incident occurred on a DA42 aircraft equipped with TAE125–01 engines. The BFU (German Accident Investigation Body) found the root cause to be a violation of the Airplane Flight Manual procedures (taking-off with an insufficiently charged main aircraft battery) and momentary low voltage in the electrical system of the aircraft when retracting the main landing gear. This has been the subject of Diamond Service Information (SI) 42–040 and a subsequent EASA Safety Information Notice, SIN 2007–08, issued on 18 April 2007.

The TAE125–01 and TAE125–02–99 engines, approved for installation on the DA42, are FADEC (Full Authority Digital Engine Control) controlled and are not totally independent from the aircraft electrical power supply. A significant drop of the voltage causes simultaneously a reset of the FADEC on both engines with subsequent feathering of the propeller blades. In the case of an empty battery this scenario may be considered as catastrophic at the aircraft level.

The Thielert Aircraft Engines (TAE) Installation Manuals IM–02–01 Issue 4 and IM–02–02 Issue 1 have been revised to address this issue, which is the subject of EASA Airworthiness Directive (AD) 2007–0182.

The present AD, regarding the new specifications introduced by the TAE Installation Manuals, mandates installation of additional Engine Control Unit (ECU) Backup Batteries to supply electrical power to the ECU, preventing high transient power drains from causing a short-term voltage drop when insufficient power from the main battery might exist.

You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

Diamond Aircraft Industries GmbH has issued Optional Service Bulletin No. OSB–42–050, dated August 13, 2007; and Work Instruction WI–OSB–42–050, Revision 1, dated August 20, 2007. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of the Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with this State of Design Authority, they have notified us of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all information and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

Differences Between This Proposed AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We have proposed different actions in this AD from those in the MCAI in order to follow FAA policies. We believe that the batteries specified in the MCAI do not fully address the unsafe condition for U.S. registered airplanes. The batteries specified in the MCAI only provide approximately 10 minutes of backup electrical power to the engine full authority digital engine controls (FADECs) in the event of an aircraft electrical failure. The FAA requires a minimum of 30 minutes of backup electrical power for the engine FADECs in the event of an aircraft electrical failure. To fully address the unsafe condition, Diamond Aircraft Industries GmbH has developed different part numbers and procedures for U.S. registered airplanes. These procedures require the installation of larger capacity batteries than the MCAI required. We have discussed this difference with EASA and they accepted that the FAA's view is different to require installation of larger capacity batteries.

Costs of Compliance

Based on the service information, we estimate that this proposed AD would affect about 86 products of U.S. registry. We also estimate that it would take about 13 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is $80 per work-hour. Where the service information lists required parts costs that are covered under warranty, we have assumed that there will be no charge for these costs. As we do not control warranty coverage for affected parties, some parties may incur costs higher than estimated here.

Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $89,440, or $1,040 per product.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new AD:

Diamond Aircraft Industries GmbH: Docket No. FAA–2007–28955; Directorate Identifier 2007–CE–067–AD.

Comments Due Date

(a) We must receive comments by September 26, 2007.

Affected ADs

(b) None.

Applicability

(c) This AD applies to DA 42 airplanes, all serial numbers, certificated in any category.

Subject

(d) Air Transport Association of America (ATA) Code 72: Engine.

Reason

(e) The mandatory continuing airworthiness information (MCAI) states:

Recently, a double in-flight engine shut down incident occurred on a DA42 aircraft equipped with TAE125–01 engines. The BFU (German Accident Investigation Body) found the root cause to be a violation of the Airplane Flight Manual procedures (taking-off with an insufficiently charged main aircraft battery) and momentary low voltage in the electrical system of the aircraft when retracting the main landing gear. This has been the subject of Diamond Service Information (SI) 42–040 and a subsequent EASA Safety Information Notice, SIN 2007–08, issued on 18 April 2007.

The TAE125–01 and TAE125–02–99 engines, approved for installation on the DA42, are FADEC (Full Authority Digital Engine Control) controlled and are not totally independent from the aircraft electrical power supply. A significant drop of the voltage causes simultaneously a reset of the FADEC on both engines with subsequent feathering of the propeller blades. In the case of an empty battery this scenario may be considered as catastrophic at the aircraft level.

The Thielert Aircraft Engines (TAE) Installation Manuals IM–02–01 Issue 4 and

IM–02–02 Issue 1 have been revised to address this issue, which is the subject of EASA Airworthiness Directive (AD) 2007–0182.

The present AD, regarding the new specifications introduced by the TAE Installation Manuals, mandates installation of additional Engine Control Unit (ECU) Backup Batteries to supply electrical power to the ECU, preventing high transient power drains from causing a short-term voltage drop when insufficient power from the main battery might exist.

Actions and Compliance

(f) Unless already done, do the following actions within the next 100 hours time-in-service after the effective date of this AD or within 30 days after the effective date of this AD, whichever occurs first:

(1) Modify the engine electrical system by installing additional engine control unit (ECU) backup batteries following Diamond Aircraft Industries GmbH Work Instruction WI–OSB–42–050, Revision 1, dated August 20, 2007, as referenced in Diamond Aircraft Industries GmbH Optional Service Bulletin No. OSB–42–050, dated August 13, 2007.

(2) Incorporate Diamond Aircraft Temporary Revision AMM–TR–O–M–42–129, dated July 11, 2007, into the FAA-approved maintenance program (e.g., maintenance manual). The owner/operator holding at least a private pilot certificate as authorized by section 43.7 of the Federal Aviation Regulations (14 CFR 43.7) may do this action. Make an entry in the aircraft records showing compliance with this portion of the AD following section 43.9 of the Federal Aviation Regulations (14 CFR 43.9).

(3) Update the airplane flight manual (AFM) by inserting a copy of Diamond Aircraft Temporary Revision TR–OÄM–42–129, dated July 11, 2007, into the AFM. The owner/operator holding at least a private pilot certificate as authorized by section 43.7 of the Federal Aviation Regulations (14 CFR 43.7) may do this action. Make an entry in the aircraft records showing compliance with this portion of the AD following section 43.9 of the Federal Aviation Regulations (14 CFR 43.9).

FAA AD Differences

Note: This AD differs from the MCAI and/or service information as follows: We believe that the batteries specified in the MCAI do not fully address the unsafe condition for U.S. registered airplanes. The batteries specified in the MCAI only provide approximately 10 minutes of backup electrical power to the engine full authority digital engine controls (FADECs) in the event of an aircraft electrical failure. The FAA requires a minimum of 30 minutes of backup electrical power for the engine FADECs in the event of an aircraft electrical failure. To fully address the unsafe condition, Diamond Aircraft Industries has developed different part numbers and procedures for U.S. registered airplanes. These procedures require the installation of larger capacity batteries than the MCAI required. We have discussed this difference with EASA and they accepted that the FAA's view is different to require installation of larger capacity batteries.

Other FAA AD Provisions

(g) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Peter L. Rouse, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4135; fax: (816) 329–4090. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements:* For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120–0056.

Related Information

(h) Refer to MCAI European Aviation Safety Agency (EASA) AD No. 2007–0183, dated July 2, 2007; Diamond Aircraft Industries GmbH Optional Service Bulletin No. OSB–42–050, dated August 13, 2007; Diamond Aircraft Industries GmbH Work Instruction WI–OSB–42–050, Revision 1, dated August 20, 2007; Diamond Aircraft Temporary Revision AMM–TR–OÄM–42–129, dated July 11, 2007; and Diamond Aircraft Temporary Revision TR–OÄM–42–129, dated July 11, 2007, for related information.

Issued in Kansas City, Missouri, on August 21, 2007.

Brian A. Yanez,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. E7–16891 Filed 8–24–07; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 121

[Docket No. FAA–2002–14081, Notice No. 03–02]

RIN 2120–AH67

Transponder Continuous Operation

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM), withdrawal.

SUMMARY: The FAA is withdrawing the NPRM published on January 14, 2003, that proposed to require airplanes operated in domestic, flag, and supplemental operations to ensure immediate activation and continuous transmission of the designated hijack alert code to air traffic control (ATC) during a hijack situation. After September 11, 2001, the increased threat of hijacking and realization that a plane could be used as a weapon became the basis for the proposed rule. The intent was to provide the flight crew of commercial airplanes with the ability to initiate an immediate national security response in the event of a hijacking. The overwhelming majority of comments opposed the proposal for several reasons. Because of the reasons given, including completed security enhancements to strengthen flightdeck doors, we are withdrawing the proposal. Current regulations ensure an adequate level of aviation security.

FOR FURTHER INFORMATION CONTACT: Richard E. Jennings, Aircraft Certification Service, Aircraft Engineering Division, AIR–130, Federal Aviation Administration, 470 L'Enfant Plaza, Suite 4102, Washington, DC 20024; telephone (202) 385–6090; e-mail *Richard.Jennings@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

On January 14, 2003, the FAA published a Notice of Proposed Rulemaking (Notice No. 03–02, 68 FR 1942). The NPRM proposed to amend the instrument and equipment requirements in 14 CFR 121.345 for airplanes operated in domestic, flag, and supplemental operations. Under 121.345 currently, air carrier aircraft must be equipped with an air traffic control (ATC) transponder, which in normal operation provides radar beacon identity code and altitude for ATC use in controlling aircraft in en route and terminal areas of operation.

In response to the devastating events of September 11, 2001, the FAA

initiated a complete review of aircraft and airport security procedures that produced several recommendations to improve security and safety during flight. The Secretary of Transportation established the Rapid Response Teams (Team) for Aircraft and Airport Security to identify weaknesses in the nation's security and produce recommendations for improving aircraft and airport security. The Team consisted of individuals from the aviation industry, including airplane designers and manufacturers, airline operators, airline pilots, and flight attendants. On October 1, 2001, the Team submitted its report on aircraft security to the Secretary of Transportation. The report (available in Docket No. FAA–2002–14081) included 17 recommendations to help counter a situation in which an airplane might be hijacked and used as a weapon.

In response to recommendation No. 16 regarding transponders, the FAA established the FAA-Industry Transponder Task Force. The Task Force examined options for enabling the flight crew to set and lock a designated hijack code during an emergency situation, and to secure the ATC transponder from being disabled by a hijacker.

Notice No. 03–02 was based, in part, on the efforts and recommendations of the Task Force. The proposed rule would have required all airplanes operated under part 121 to be capable of immediately notifying ATC of a hijack situation. It would have required that the ATC transponder continuously transmit the emergency code once activated, without the possibility of interruption.

During normal operations a flight crew could manually dial in a new ATC transponder beacon code in 5 to 10 seconds. The International Civil Aviation Organization (ICAO) has designated a code for unlawful interference (''7500'' or ''hijack code'') to be used during a hijacking. Under the stressful conditions of a hijacking and the presence of an intruder on the flightdeck, activation of this ''hijack code'' would likely take longer than 10 seconds. The four planes that were hijacked on September 11, 2001, were unable to enter the hijack code to alert ATC of the trouble and therefore delayed ATC awareness.

In addition, three of the four planes stopped responding to ATC interrogations minutes after departing from their assigned routes. Under current requirements, the airplane's ATC transponder is not prevented from being switched to the ''standby'' position, or having its circuit breaker ''pulled,'' disabling the transponder's response to an ATC secondary ground radar beacon interrogation.

For these reasons, we proposed that airplanes operating under part 121 must have the capability to allow each flight crewmember to quickly activate the ATC transponder ''hijack code'' through a single action that includes protection from inadvertent activation. Once activated, the ATC transponder would have been able to:

- Continue to report the airplane's altitude.
- Provide visual indication to the flight crew that the activation has occurred.
- Be protected from any person onboard the plane attempting to disable the transponder or change its code during the remainder of the flight.

This rule would have been incorporated into 14 CFR part 121 by creating § 121.346. The comment period closed on April 18, 2003.

Discussion of Comments

The FAA received 146 comments on this NPRM. Comments were received from industry operators, air carriers, trade associations, pilots, and manufacturers. The overwhelming majority opposed the proposed rule. Most commenters felt that the continuous transponder rule was unnecessary because of the improved security measures implemented since the September 11, 2001, terrorist hijackings. We agree with these comments, and the FAA finalized the other security improvements since the NPRM was written. One hundred and twenty-six commenters opposed the proposed rule. Nine commenters expressed support for the rule. Ten commenters supported only part of the proposed rule or took a neutral position.

Opposition was almost universal from industry operators, air carriers, and trade associations. Nearly every commenter cited recently completed security improvements like strengthened flightdeck doors and more thorough screening of passengers and baggage as justification for their opposition. They believe that installing continuous ATC transponders would not increase safety or security, and that the cost of compliance would be harmful to the industry at this time. Commenters also believed the FAA underestimated the cost of compliance in the NPRM, stating that many planes would need rewiring or replacement of current ATC transponder equipment.

The Air Transport Association (ATA) submitted a lengthy comment that recommended withdrawing the NPRM. ATA noted that Congress gave discretion for ATC transponder modifications and did not specifically mandate a change. Rather than implement this rule, ATA would prefer that the FAA focus on improving ATC equipment to monitor more types of air traffic. Like the majority of commenters, they felt that the flightdeck is now secure with new strengthened flightdeck doors. ATA also questioned the analysis of benefits in the proposal and claimed the NPRM did not satisfy the requirements of the Administrative Procedures Act. They also question the ''propriety of continuing unfunded mandates for aircraft modifications under the umbrella of national security.'' Finally, ATA conducted a survey of its members (the majority of U.S. scheduled air carriers) to compare the cost estimates presented in the NPRM to show that the FAA underestimated the cost to the industry. Before issuing the NPRM, with the help and input from the industry, the FAA estimated the total 3-year cost at approximately $88.1 million in the NPRM. The ATA survey estimated it would cost $258.8 million to comply with the rule. The FAA concedes that the cost to comply may exceed our estimate in the NPRM but we cannot verify the accuracy or source for ATA's numbers, even though a detailed summary of the survey was included in the comment.

Twenty international air carriers and associations from Europe, South America, Asia, and Canada submitted comments opposing the proposal. One common reason they expressed was that there was no such ICAO requirement for ATC transponders and that the lack of harmonization could have a ''negative impact'' on flight safety for international operators. The International Air Transport Association (IATA) and International Air Carriers Association (IACA) both stated this as one reason for their opposition.

IATA added concerns that unintentional hijack-code selection would certainly occur, and they are also concerned that many pilots said they would be reluctant to use the hijacking code if it resulted in a possible military response. IATA believes an unintentionally activated ATC transponder would put passengers at greater, rather than reduced, risk. The inability to turn the ATC transponder off would increase risk even more, they contend. IACA felt that no benefit would be gained by adding the continuous ATC transponder because of the reinforced flightdeck doors. These doors are meant to deny potential hijackers access to the flightdeck, thereby providing pilots enough time to initiate the hijacking code and

communicate with ATC, they argued. British Airways, Austrian Airlines, Singapore Airlines, Lufthansa, and Swiss International Air Lines echoed concerns about accidental ATC transponder activation and the belief that recent enhancements have secured the flightdeck.

The Aircraft Owners and Pilots Association (AOPA) and National Air Transportation Association (NATA) commented separately on the rule's applicability to general aviation aircraft. Both groups summarized the comments of many of those in opposition by strongly opposing the application of this rule to general aviation operations. The FAA asked interested persons to comment on the applicability of this rule to aircraft operated under 14 CFR parts 91, 125, 129, and 135. AOPA noted that general aviation pilots personally know the passengers that are on board the aircraft, therefore eliminating the possibility of a passenger hijacking the plane. They also contend general aviation aircraft are primarily used for personal or business transportation and that these aircraft pose no greater threat than an average automobile. NATA cited ''multiple discussions with security officials at all levels of government,'' and based on these discussions they assert that there is no specific or credible terrorist threat related to these aircraft operations.'' Many individual pilots and general aviation supporters believed that there was no record of a general aviation aircraft ever being hijacked. Three commenters suggested a continuous ATC transponder might be better suited for Ryder trucks or cars.

The Air Line Pilots Association (ALPA) submitted one of few comments in favor of the NPRM. ALPA agreed that the rule would ensure acceptable aviation security, but also wished to distinguish the difference between safety and security. ALPA cited strengthened flightdeck doors as a preventive safety measure, but they believe the ATC transponder modification should not be seen as a similar measure. They pointed out that modifying the flightdeck doors and other security changes are aimed at preventing a hijacking, while the ATC transponder modification would deter disaster should an aircraft become commandeered. Because they believe this is a security issue and not a safety issue, ALPA felt that the government should fund the changes.

The FAA received 15 comments in favor of the proposed rule. The comments in favor of the proposal came from pilots and interested individuals for the most part. Seven commenters felt the proposed rule was appropriate and that it would provide additional needed security after September 11, 2001. Six commenters were opposed to the proposed rule if it were applied to general aviation aircraft but felt the application to commercial aircraft was ''great'' and ''very positive.''

Reason for Withdrawal

We are withdrawing Notice No. 03–02 because the level of security provided by the proposed rulemaking has been accomplished by other completed rules and because of reasons given in overwhelming opposition to the proposal. Several recently implemented security measures in response to the hijackings of September 11, 2001, such as strengthened flightdeck doors, make the modification of the ATC transponder equipment unnecessary. Due to the current security of the flightdeck against intrusion, measures to prevent the disabling of the ATC transponder are unnecessary. Likewise, current safety and security requirements allow pilots time to transmit the necessary hijack alert code and to communicate any danger to air traffic control.

The Transportation Security Administration (TSA) carefully evaluated the NPRM and considered changes that have already been made to the commercial aviation system. TSA does not see sufficient added security value to justify proceeding with this type of aircraft modification at this time. This position has been fully coordinated within TSA and the Department of Homeland Security.

Conclusion

Withdrawal of Notice No. 03–02 does not preclude the FAA from issuing another notice on the subject matter in the future or committing the agency to any future course of action.

The FAA has determined that this regulatory course of action is no longer necessary. Therefore, the FAA withdraws Notice No. 03–02, published at 68 FR 1982 on January 14, 2003.

Issued in Washington, DC, on June 20, 2007.

John J. Hickey,

Director, Aircraft Certification Service.

[FR Doc. E7–16846 Filed 8–24–07; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–118886–06]

RIN 1545–BF65

Clarification to Section 6411 Regulations

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations.

SUMMARY: In the Rules and Regulations section of this issue of the **Federal Register**, the IRS is issuing temporary regulations relating to the computation and allowance of the tentative carryback adjustment under section 6411 of the Internal Revenue Code. Those temporary regulations clarify that for purposes of allowing the tentative adjustment, the IRS may credit or reduce the tentative adjustment by an assessed tax liability, whether or not that tax liability was assessed before the date the application for tentative carryback is filed, and other unassessed liabilities in certain other circumstances. Those regulations also remove all references to IRS district director or service center director, as these positions no longer exist within the IRS. The offices of the district director and service center director were eliminated by the IRS reorganization implemented pursuant to the IRS Reform and Restructuring Act of 1998. The text of the temporary regulations serves as the text of these proposed regulations.

DATES: Written and electronic comments and requests for a public hearing must be received by November 26, 2007.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–118886–06), room 5203, Internal Revenue Service, PO Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–118886–06), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC, or sent electronically via the Federal eRulemaking Portal at *www.regulations.gov* (IRS REG–118886–06).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Cynthia A. McGreevy, (202) 622–4910; concerning submissions of comments,

Richard Hurst, (202) 622–7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background and Explanation of Provisions

These proposed regulations clarify the Income Tax Regulations (26 CFR part 1) under section 6411 relating to the computation and allowance of the tentative carryback adjustment. The tentative allowance is computed pursuant to § 1.6411–2 but applied pursuant to § 1.6411–3. These regulations clarify that for purposes of computing the allowance, the Commissioner will not consider amounts to which the taxpayer and the Commissioner are in disagreement. For purposes of applying the allowance, however, the Commissioner may credit or reduce the tentative adjustment by any assessed tax liabilities, unassessed liabilities determined in a statutory notice of deficiency, unassessed liabilities identified in a proof of claim filed in a bankruptcy proceeding, and other unassessed liabilities in rare and unusual circumstances. Regarding unassessed liabilities determined in a statutory notice of deficiency, see Rev. Rul. 2007–51. Regarding unassessed liabilities identified in a proof of claim filed in a bankruptcy proceeding, see Rev. Rul. 2007–52. See § 601.601(d)(2). The IRS plans to adopt procedures requiring IRS National Office review prior to a credit or reduction of the tentative adjustment by an unassessed liability that constitutes a rare and unusual circumstance.

In the Rules and Regulations section of this issue of the **Federal Register**, the IRS is issuing temporary regulations relating to the computation and allowance of the tentative carryback adjustment under section 6411 of the Internal Revenue Code. The text of those temporary regulations also serves as the text of these proposed regulations. The preamble to the temporary regulations explains the temporary regulations and these proposed regulations.

Proposed Effective Date

These proposed amendments to §§ 1.6411–2 and 1.6411–3 apply with respect to applications for tentative refund filed on or after the date these rules are published as final regulations in the **Federal Register**. No implication is intended concerning whether or not a rule to be adopted in these regulations is applicable law for applications filed prior to that date.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because these regulations do not impose a collection of information on small entities, the provisions of the Regulatory Flexibility Act (5 U.S.C. chapter 6) do not apply. Pursuant to section 7805(f) of the Internal Revenue Code, these regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

Comments and Requests for a Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any electronic and written comments (a signed original and eight (8) copies) that are submitted timely to the IRS. The IRS and Treasury Department specifically request comments on the clarity of the proposed regulations and how they can be made easier to understand. All comments will be available for public inspection and copying. A public hearing may be scheduled if requested in writing by a person who timely submits comments. If a public hearing is scheduled, notice of the date, time, and place for the hearing will be published in the **Federal Register**.

Drafting Information

The principal author of these regulations is Cynthia A. McGreevy of the Office of the Associate Chief Counsel (Procedure and Administration).

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

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

Authority: 26 U.S.C. 7805 * * *

Par. 2. Section 1.6411–2 is revised to read as follows:

§ 1.6411–2 Computation of tentative carryback adjustment.

(a) [The text of proposed § 1.6411–2(a) is the same as the text of § 1.6411–2T(a) published elsewhere in this issue of the **Federal Register**].

(b) [The text of proposed § 1.6411–2(b) is the same as the text of § 1.6411–2T(b) published elsewhere in this issue of the **Federal Register**].

Par. 3. Section 1.6411–3 is revised to read as follows:

§ 1.6411–3 Allowance of adjustments.

(a) [The text of proposed § 1.6411–3(a) is the same as the text of § 1.6411–3T(a) published elsewhere in this issue of the **Federal Register**].

(b) [The text of proposed § 1.6411–3(b) is the same as the text of § 1.6411–3T(b) published elsewhere in this issue of the **Federal Register**].

(c) [The text of proposed § 1.6411–3(c) is the same as the text of § 1.6411–3T(c) published elsewhere in this issue of the **Federal Register**].

(d) [The text of proposed § 1.6411–3(d) is the same as the text of § 1.6411–3T(d) published elsewhere in this issue of the **Federal Register**].

Kevin M. Brown,

Deputy Commissioner for Services and Enforcement.

[FR Doc. E7–16876 Filed 8–24–07; 8:45 am]

BILLING CODE 4830–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 65

[EPA–HQ–OAR–2007–0429; FRL–8459–6]

RIN 2060–A045

Revisions to Consolidated Federal Air Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is proposing to revise the General Provisions for Consolidated Federal Air Rule. On May 16, 2007, we published a final rule that revised the General Provisions for Standards of Performance for New Stationary Sources, for National Emission Standards for Hazardous Air Pollutants, and for National Emission Standards for Hazardous Air Pollutants for Source Categories to allow extensions to the deadline imposed for source owners and operators to conduct initial or other required performance tests in certain specified force majeure circumstances. We recently realized that we should have also revised the Consolidated Federal Air Rule to allow similar extensions.

DATES: Written comments must be received by September 26, 2007.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2007–0429 by mail to Revisions to Consolidated Federal Air Rule, Environmental Protection Agency, Mailcode: 2822T, 1200 Pennsylvania Ave., NW., Washington, DC 20460. Please include a total of two copies. Comments may also be submitted electronically or through hand delivery/courier by following the detailed instructions in the **ADDRESSES** section of the direct final rule located in the rules section of this **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Ms. Lula Melton, Air Quality Assessment Division (C304–02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–2910; fax number: (919) 541–4511; e-mail address ''*melton.lula@epa.gov.*''

SUPPLEMENTARY INFORMATION:

I. Why Is EPA Issuing This Proposed Rule?

This document proposes to take action on Revisions to the Consolidated Federal Air Rule. We have published a direct final rule to revise the Consolidated Federal Air Rule to allow extensions to the deadline imposed for source owners and operators to conduct performance tests in certain specified force majeure circumstances in the ''Rules and Regulations'' section of this **Federal Register**. These revisions would mirror those contained in a May 16, 2007 final rule revising the General Provisions for Standards of Performance for New Stationary Sources, for National Emission Standards for Hazardous Air Pollutants, and for National Emission Standards for Hazardous Air Pollutants for Source Categories to allow extensions to the deadline imposed for source owners and operators to conduct initial or other required performance tests in certain specified force majeure circumstances. We recently realized that we should have also revised the Consolidated Federal Air Rule for the same reasons. We view this as a non-controversial action and anticipate no adverse comment. We have explained our reasons for this action in the preamble to the direct final rule.

If we receive no adverse comment, we will not take further action on this proposed rule. If we receive adverse comment, we will withdraw the direct final rule, and it will not take effect. We would address all public comments in any subsequent final rule base on this proposed rule. We do not intend to institute a second comment period on this action. Any parties interested in commenting must do so at this time.

The regulatory text for the proposal is identical to that for the direct final rule published in the ''Rules and Regulations'' section of this **Federal Register**. For further supplementary information, the detailed rationale for the proposal and the regulatory revisions, see the direct final rule published in a separate part of this **Federal Register**.

II. Does This Action Apply to Me?

This action applies to any owner or operator of a source required to conduct performance testing to demonstrate compliance with applicable standards under the General Provisions for Consolidated Federal Air Rule.

III. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Reviews

This action is not a ''significant regulatory action'' under the terms of Executive Order 12866 (58 FR 51735 October 4, 1993) and is therefore not subject to review under the EO.

B. Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the *Paperwork Reduction Act*, 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) document prepared by EPA has been assigned EPA ICR No. xxxx.

The proposed rule would require a written notification only if a plant owner or operator needs an extension of a performance test deadline due to certain rare events, such as acts of nature, acts of war or terrorism, or equipment failure or safety hazard beyond the control of the affected facility. Since EPA believes such events will be rare, the projected cost and hour burden will be minimal.

The increased annual average reporting burden for this collection (averaged over the first 3 years of the ICR) is estimated to total 6 labor hours per year at a cost of $377.52. This includes one response per year from six respondents for an average of 1 hour per response. No capital/startup costs or operation and maintenance costs are associated with the proposed reporting requirements. 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.

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 in 40 CFR are listed in 40 CFR part 9.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute 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.

For purposes of assessing the impacts of today's proposed rule on small entities, small entity is defined as: (1) A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. Extensions to deadlines for conducting performance tests will provide flexibility to small entities and reduce the burden on them by providing them an opportunity for additional time to comply with performance test deadlines during force majeure events. Furthermore, we expect force majeure events to be rare since these events include circumstances such as acts of nature, acts of war or terrorism, or equipment failure or safety hazard beyond the control of the affected facility.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, Local, and Tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including Tribal governments, it must have developed, under section 203 of the UMRA, a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

EPA has determined that the proposed rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and Tribal governments, in the aggregate, or the private sector in any one year. The maximum total annual cost of this proposed rule for any year has been estimated to be less than $435.00. Thus, today's proposed rule is not subject to the requirements of sections 202 and 205 of the UMRA.

EPA has determined that the proposed rule contains no regulatory requirements that might significantly or uniquely affect small governments. The proposed rule requires source owners and operators to provide a written notification to the Agency only if an extension to a performance test deadline is necessary due to a rare force majeure event. Therefore, the proposed rule is not subject to the requirements of section 203 of the UMRA.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

This proposed rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. The proposed rule requirements will not supersede State regulations that are more stringent. In addition, the proposed rule requires a written notification only if a plant owner or operator needs an extension of a performance test deadline due to certain rare events, such as acts of nature, acts of war or terrorism, or equipment failure or safety hazard beyond the control of the affected facility. Since EPA believes that such events will be rare, the projected cost and hour burden will be minimal. Thus, Executive Order 13132 does not apply to this rule.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' This proposed rule does not have tribal implications as specified in Executive Order 13175. This proposed rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

Executive Order 13045 (62 FR 19885, April 23, 1997) applies to any rule that: (1) Is determined to be ''economically significant'' as defined under Executive Order 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.

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of the Executive Order has the potential to influence the regulation. This proposed rule is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866 and because the Agency does not have reason to believe that the environmental health or safety risks addressed by this action present a disproportionate risk to children. This rule does not affect the underlying control requirements established by the applicable standards but only the timeframe associated with performance testing in limited circumstances.

H. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes Federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this proposed rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of

protection provided to human health or the environment. The rule merely allows extensions to performance test deadlines in rare force majeure events.

I. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

The proposed rule is not a ''significant energy action'' as defined in Executive Order 13211, ''Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note), directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. New test methods are not being proposed in this rulemaking, but EPA is allowing for extensions of the regulatory deadlines by which owners or operators are required to conduct performance tests when a force majeure is about to occur, occurs, or has occurred which prevents owners or operators from testing within the regulatory deadline. Therefore, NTTAA does not apply.

List of Subjects in 40 CFR Part 65

Air pollution control, Environmental protection, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: August 17, 2007.

Stephen L. Johnson,

Administrator.

[FR Doc. E7–16835 Filed 8–24–07; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[EPA–HQ–OAR–2006–1016; FRL–8461–2]

RIN 2060–A030

Protection of Stratospheric Ozone: The 2008 Critical Use Exemption From the Phaseout of Methyl Bromide

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing an exemption to the phaseout of methyl bromide to meet the needs of 2008 critical uses. Specifically, EPA is proposing uses that qualify for the 2008 critical use exemption and the amount of methyl bromide that may be produced, imported, or supplied from existing stocks for those uses in 2008. EPA is taking action under the authority of the Clean Air Act to reflect recent consensus decisions taken by the Parties to the Montreal Protocol on Substances that Deplete the Ozone Layer (Protocol) at the 18th Meeting of the Parties (MOP). EPA is seeking comment on the list of critical uses and on EPA's determination of the amounts of methyl bromide needed to satisfy those uses.

DATES: Comments must be submitted by September 26, 2007. Any party requesting a public hearing must notify the contact person listed below by 5 p.m. Eastern Standard Time on September 4, 2007. If a hearing is requested it will be held on September 11, 2007 and comments will be due to the Agency October 11, 2007. EPA will post information regarding a hearing, if one is requested, on the Ozone Protection Web site *http://www.epa.gov/ozone*. Persons interested in attending a public hearing should consult with the contact person below regarding the location and time of the hearing.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2006–1016, by one of the following methods:

- *www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *E-mail: a-and-r-Docket@epa.gov.*
- *Fax:* 202–566–1741.
- *Mail:* Docket #, Air and Radiation Docket and Information Center, U.S. Environmental Protection Agency, Mail Code: 6102T, 1200 Pennsylvania Ave., NW., Washington, DC 20460.
- *Hand Delivery:* Docket # EPA–HQ–OAR–2006–1016, Air and Radiation Docket at EPA West, 1301 Constitution Avenue, NW., Room B108, Mail Code 6102T, Washington, DC 20460. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OAR–2006–1016. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or e-mail. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *www.regulations.gov* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm*.

FOR FURTHER INFORMATION CONTACT: For further information about this proposed rule, contact Aaron Levy by telephone at (202) 343–9215, or by e-mail at *levy.aaron@epa.gov* or by mail at Aaron Levy, U.S. Environmental Protection Agency, Stratospheric Protection Division, Stratospheric Program Implementation Branch (6205J), 1200 Pennsylvania Avenue, NW., Washington, DC 20460. You may also visit the Ozone Depletion Web site of EPA's Stratospheric Protection Division at *www.epa.gov/ozone* for further information about EPA's Stratospheric Ozone Protection regulations, the science of ozone layer depletion, and other related topics.

SUPPLEMENTARY INFORMATION: This proposed rule concerns Clean Air Act

(CAA) restrictions on the consumption, production, and use of methyl bromide (a class I, Group VI controlled substance) for critical uses during calendar year 2008. Under the Clean Air Act, methyl bromide consumption (consumption is defined under the CAA as production plus imports minus exports) and production was phased out on January 1, 2005 apart from allowable exemptions, namely the critical use exemption and the quarantine and pre-shipment exemption. With this action, EPA is proposing and seeking comment on the uses that will qualify for the 2008 critical use exemption as well as specific amounts of methyl bromide that may be produced, imported, or sold from stocks for proposed critical uses in 2008.

Table of Contents

I. General Information

A. Regulated Entities

Entities potentially regulated by this proposed action are those associated with the production, import, export, sale, application, and use of methyl bromide covered by an approved critical use exemption. Potentially regulated categories and entities include:

Category	Examples of regulated entities
Industry	Producers, importers and exporters of methyl bromide; applicators, distributors of methyl bromide; users of methyl bromide, e.g., farmers of vegetable crops, fruits and seedlings, owners of stored food commodities and structures such as grain mills and processors, and agricultural researchers.

The above table is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be regulated by this proposed action. This table lists the types of entities that EPA is aware could potentially be regulated by this proposed action. To determine whether your facility, company, business, or organization is regulated by this proposed action, you should carefully examine the regulations promulgated at 40 CFR Part 82, Subpart A. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding section.

B. What Should I Consider When Preparing My Comments?

1. *Confidential Business Information.* Do not submit this information to EPA through *www.regulations.gov* or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2.

2. *Tips for Preparing Your Comments.* When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions—The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns, and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified.

II. What Is Methyl Bromide?

Methyl bromide is an odorless, colorless, toxic gas which is used as a broad-spectrum pesticide and is controlled under the CAA as a class I ozone-depleting substance (ODS). Methyl bromide is used in the U.S. and throughout the world as a fumigant to control a variety of pests such as insects, weeds, rodents, pathogens, and nematodes. Additional characteristics and details about the uses of methyl bromide can be found in the proposed rule on the phaseout schedule for methyl bromide published in the **Federal Register** on March 18, 1993 (58 FR 15014) and the final rule published in the **Federal Register** on December 10, 1993 (58 FR 65018). Information on methyl bromide can be found at *http://www.epa.gov/ozone/mbr* and *http://www.unep.org/ozone* or by contacting the Stratospheric Ozone Hotline at 1–800–296–1996.

Because it is a pesticide, methyl bromide is also regulated by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and other statutes and regulatory authority, as well as by States under their own statutes and regulatory authority. Under FIFRA, methyl bromide is a restricted use pesticide. Restricted use pesticides are subject to certain Federal and State requirements governing their sale, distribution, and use. Nothing in this proposed rule implementing the Clean Air Act is intended to derogate from provisions in any other Federal, State, or local laws or regulations governing actions including, but not limited to, the sale, distribution, transfer, and use of methyl bromide. All entities that would be affected by provisions of this proposal must continue to comply with FIFRA and other pertinent statutory and regulatory requirements for pesticides (including, but not limited to, requirements pertaining to restricted use pesticides) when importing, exporting, acquiring, selling, distributing, transferring, or using methyl bromide for critical uses. The regulations in this proposed action are intended only to implement the CAA restrictions on the production, consumption, and use of methyl bromide for critical uses exempted from the phaseout of methyl bromide.

III. What Is the Background to the Phaseout Regulations for Ozone-Depleting Substances?

The current regulatory requirements of the Stratospheric Ozone Protection Program that limit production and consumption of ozone-depleting substances can be found at 40 CFR part 82, subpart A. The regulatory program was originally published in the **Federal Register** on August 12, 1988 (53 FR 30566), in response to the 1987 signing and subsequent ratification of the Montreal Protocol on Substances That Deplete the Ozone Layer (Protocol). The Protocol is the international agreement aimed at reducing and eliminating the production and consumption of stratospheric ozone-depleting substances. The U.S. was one of the original signatories to the 1987 Montreal Protocol and the U.S. ratified the Protocol on April 12, 1988. Congress then enacted, and President George H.W. Bush signed into law, the Clean Air Act Amendments of 1990 (CAAA of 1990) which included Title VI on Stratospheric Ozone Protection, codified as 42 U.S.C. Chapter 85, Subchapter VI, to ensure that the United States could satisfy its obligations under the Protocol. EPA issued new regulations to implement this legislation and has made several amendments to the regulations since that time.

Methyl bromide was added to the Protocol as an ozone-depleting substance in 1992 through the Copenhagen amendment to the Protocol. The Parties agreed that each industrialized country's level of methyl bromide production and consumption in 1991 should be the baseline for establishing a freeze in the level of methyl bromide production and consumption for industrialized countries. EPA published a final rule in the **Federal Register** on December 10, 1993 (58 FR 65018), listing methyl bromide as a class I, Group VI controlled substance, freezing U.S. production and consumption at this 1991 level of 25,528,270 kilograms, and, in 40 CFR 82.7 of the rule, setting forth the percentage of baseline allowances for methyl bromide granted to companies in each control period (each calendar year) until 2001, when the complete phaseout would occur. This phaseout date was established in response to a petition filed in 1991 under sections 602(c)(3) and 606(b) of the CAAA of 1990, requesting that EPA list methyl bromide as a class I substance and phase out its production and consumption. This date was consistent with section 602(d) of the CAAA of 1990, which for newly listed class I ozone-depleting substances provides that ''no extension [of the phaseout schedule in section 604] under this subsection may extend the date for termination of production of any class I substance to a date more than 7 years after January 1 of the year after the year in which the substance is added to the list of class I substances.'' EPA based its action on scientific assessments and actions by the Parties to the Montreal Protocol to freeze the level of methyl bromide production and consumption for industrialized countries at the 1992 Meeting of the Parties in Copenhagen.

At their 1995 meeting, the Parties made adjustments to the methyl bromide control measures and agreed to reduction steps and a 2010 phaseout date for industrialized countries with exemptions permitted for critical uses. At that time, the U.S. continued to have a 2001 phaseout date in accordance with the CAAA of 1990 language. At their 1997 meeting, the Parties agreed to further adjustments to the phaseout schedule for methyl bromide in industrialized countries, with reduction steps leading to a 2005 phaseout for industrialized countries.

IV. What Is the Legal Authority for Exempting the Production and Import of Methyl Bromide for Critical Uses Authorized by the Parties to the Montreal Protocol?

In October 1998, the U.S. Congress amended the CAA to prohibit the termination of production of methyl bromide prior to January 1, 2005, to require EPA to bring the U.S. phaseout of methyl bromide in line with the schedule specified under the Protocol, and to authorize EPA to provide exemptions for critical uses. These amendments were contained in Section 764 of the 1999 Omnibus Consolidated and Emergency Supplemental Appropriations Act (Pub. L. 105–277, October 21, 1998) and were codified in Section 604 of the CAA, 42 U.S.C. 7671c. The amendment that specifically addresses the critical use exemption appears at Section 604(d)(6), 42 U.S.C. 7671c(d)(6). EPA revised the phaseout schedule for methyl bromide production and consumption in a direct final rulemaking on November 28, 2000 (65 FR 70795), which allowed for the phased reduction in methyl bromide consumption and extended the phaseout to 2005. EPA again amended the revised phaseout to allow for an exemption for quarantine and preshipment purposes on July 19, 2001 (66 FR 37751) with an interim final rule and with a final rule on January 2, 2003 (68 FR 238).

On December 23, 2004 (69 FR 76982), EPA published a final rule titled ''Protection of Stratospheric Ozone: Process for Exempting Critical Uses From the Phaseout of Methyl Bromide'' (the ''Framework Rule'') in the **Federal Register** that established the framework for the critical use exemption; set forth a list of approved critical uses for 2005; and specified the amount of methyl bromide that could be supplied in 2005 from stocks and new production or import to meet the needs of approved critical uses. EPA then promulgated a second rule that added additional uses to the exemption program for 2005 and allocated additional stock allowances (70 FR 73604). EPA published a final rule on February 6, 2006, to exempt production and import of methyl bromide for 2006 critical uses and indicated which uses met the criteria for the exemption program for that year (71 FR 5985). EPA published another final rule on December 14, 2006, to exempt production and import of methyl bromide for critical uses in 2007 and indicated which uses met the criteria for critical uses for that year (71 FR 75386). Under authority of section 604(d)(6) of the CAA, EPA is proposing in this

action the uses that will qualify as approved critical uses in 2008 and the amount of methyl bromide required to satisfy those uses.

This proposed action reflects Decision XVIII/13, taken at the Eighteenth Meeting of the Parties in October 2006. In accordance with Article 2H(5), the Parties have issued several Decisions pertaining to the critical use exemption. These include Decisions IX/6 and Ex. I/4, which set forth criteria for review of proposed critical uses. The status of Decisions is addressed in *NRDC* v. *EPA*, (464 F.3d 1, D.C. Cir. 2006) and in EPA's ''Supplemental Brief for the Respondent,'' filed in *NRDC* v. *EPA* and available in the docket for this action. In this proposed rule, EPA is honoring commitments made by the United States in the Montreal Protocol context.

V. What Is the Critical Use Exemption Process?

A. Background of the Process

Starting in 2002, EPA began notifying applicants of the process for obtaining a critical use exemption to the methyl bromide phaseout. On May 8, 2003, the Agency published its first notice in the **Federal Register** (68 FR 24737) announcing the availability of the application for a critical use exemption and the deadline for submission of the requisite data. Applicants were informed that they may apply as individuals or as part of a group of users (a ''consortium'') who face the same limiting critical conditions (i.e. specific conditions that establish a critical need for methyl bromide). EPA has repeated this process annually since then. The critical use exemption is designed to permit production and import of methyl bromide for uses that do not have technically and economically feasible alternatives.

The criteria for the exemption initially appeared in Decision IX/6 of the Parties to the Protocol. In that Decision, the Parties agreed that ''a use of methyl bromide should qualify as 'critical' only if the nominating Party determines that: (i) The specific use is critical because the lack of availability of methyl bromide for that use would result in a significant market disruption; and (ii) there are no technically and economically feasible alternatives or substitutes available to the user that are acceptable from the standpoint of environment and public health and are suitable to the crops and circumstances of the nomination.'' These criteria are reflected in EPA's definition of ''critical use'' at 40 CFR 82.3.

In response to the yearly requests for critical use exemption applications published in the **Federal Register**, applicants have provided data on the technical and economic feasibility of using alternatives to methyl bromide. Applicants further submit data on their use of methyl bromide, on research programs into the use of alternatives to methyl bromide, and on efforts to minimize use and emissions of methyl bromide.

EPA's Office of Pesticide Programs reviews the data submitted by applicants, as well as data from governmental and academic sources, to establish whether there are technically and economically feasible alternatives available for a particular use of methyl bromide and whether there would be significant market disruption if no exemption were available. In addition, EPA reviews other parameters of the exemption applications such as dosage and emissions minimization techniques and applicants' research or transition plans. This assessment process culminates with the development of a document referred to as the ''Critical Use Nomination'' or CUN. The U.S. Department of State submits the CUN annually to the United Nations Environment Programme (UNEP) Ozone Secretariat. The CUNs of various countries are subsequently reviewed by the Methyl Bromide Technical Options Committee (MBTOC) and the Technical and Economic Assessment Panel (TEAP), which are independent advisory bodies to Parties to the Montreal Protocol. These bodies make recommendations to the Parties on the nominations. The Parties then take a Decision to authorize a critical use exemption for a particular country. The Decision also identifies how much methyl bromide may be supplied for the exempted critical uses. As required in Section 604(d)(6) of the Clean Air Act, for each exemption period, EPA consults with the United States Department of Agriculture and other departments and institutions of the Federal government that have regulatory authority related to methyl bromide, and provides an opportunity such as this for public comment on the amounts of methyl bromide that the Agency has determined to be necessary for critical uses and the uses that the Agency has determined meet the criteria of the critical use exemption.

For more information on the domestic review process and methodology employed by the Office of Pesticide Programs, please refer to a detailed memo titled *''Development of 2003 Nomination for a Critical Use Exemption for Methyl Bromide for the United States of America''* available on the docket for this rulemaking. While the particulars of the data continue to evolve and clerical matters are further streamlined, the technical review itself has remained the same since the inception of the exemption program.

On January 24, 2006, the U.S. Government (USG) submitted the fourth *Nomination for a Critical Use Exemption for Methyl Bromide for the United States of America* to the Ozone Secretariat of the United Nations Environment Programme. This fourth nomination contained the request for 2008 critical uses. In March 2006, MBTOC sent questions to the USG concerning technical and economic issues in the nomination. In April 2006 the USG transmitted responses to MBTOC's requests for clarification. The USG received MBTOC's second-round of questions in June 2006, and sent responses to MBTOC in August 2006. These documents, together with reports by the advisory bodies noted above, can be accessed in the public docket for this rulemaking. The determination in this proposed rule reflects the analysis contained in those documents.

B. How Does This Proposed Rulemaking Relate to Previous Critical Use Exemption Rulemakings?

The December 23, 2004 Framework Rule (69 FR 76982) established the operational framework for the critical use exemption program in the U.S., including trading provisions and recordkeeping and reporting obligations. The Framework Rule defined the terms ''critical use allowances'' (CUAs) and ''critical stock allowances'' (CSAs) at 40 CFR 82.3. Today's action proposes the uses that will qualify as critical uses for 2008 and the amounts of CUAs and CSAs to be allocated for those uses. The uses that EPA is proposing to qualify as 2008 critical uses are the uses which USG included in the fourth CUN, and which were approved by the Parties in Decision XVIII/13. In this action, EPA is also proposing to refine its approach for determining the amount of CSAs to allocate in 2008 and each year thereafter. EPA discusses this proposal in detail in Section V.D. of this preamble.

C. Proposed Critical Uses

In Decision XVIII/13, taken in October 2006, the Parties to the Protocol agreed as follows: ''For the agreed critical-use categories for 2008, set forth in table C of the annex to the present decision for each Party to permit, subject to the conditions set forth in the present decision and decision Ex. I/4, to the extent that those conditions are applicable, the levels of production and consumption for 2008 set forth in table

D of the annex to the present decision which are necessary to satisfy critical uses * * *.''

The following uses are those set forth in table C of the annex to Decision XVIII/13: Commodities, Cocoa beans (NPMA [1] subset), NPMA food processing structures (cocoa beans removed), Mills and processors, Smokehouse ham, Cucurbits—field, Eggplant—field, Forest nursery, Nursery stock—fruit, nut, flower, Orchard replant, Ornamentals, Peppers—field, Strawberry—field, Strawberry runners, Tomatoes—field, Sweet potato slips. The agreed critical-use levels for 2008 total 5,355,946 kilograms (kg), which is equivalent to 21.0% of the U.S. 1991 methyl bromide consumption baseline of 25,528,270 kg. However, the maximum amount of allowable new production and import as set forth in table D of Decision XVIII/13 is 4,595,040 kg (18.0% of baseline). For the reasons described in Section V.D. of this preamble, EPA is proposing to allow limited amounts of new production or import of methyl bromide for critical uses for 2008 up to the amount of 3,101,076 kg (12.2% of baseline), with 1,715,438 kg (6.7% of baseline) coming from stocks. To clarify, while the Parties require only 760,906 kg of stockpile consumption if the entire U.S. allotment is utilized, EPA is proposing consumption of 1,715,438 kg of stockpiles for critical uses.

In this proposed rule, EPA is proposing to modify Columns B and C of Appendix L to 40 CFR Part 82, Subpart A to reflect the agreed critical-use categories identified in Decision XVIII/13 for the 2008 control period (calendar year). The Agency is proposing to amend the table of critical uses based, in part, on the technical analysis contained in the 2008 U.S. nomination that assesses data submitted by applicants to the critical use exemption program as well as public and proprietary data on the use of methyl bromide and its alternatives. EPA is seeking comment on the technical analysis (which is provided in the docket) and seeks information regarding changes to the registration or use of alternatives that may have transpired after the 2008 U.S. nomination was written. Such information has the potential to alter the technical or economic feasibility of an alternative and could thus cause EPA to modify the analysis that underpins EPA's determination as to which uses and what amounts of methyl bromide qualify for the critical use exemption. EPA notes that while we may, in response to comments, reduce the proposed quantities of critical use methyl bromide, or decide not to approve uses authorized by the Parties, we do not intend to increase the quantities or add new uses in the final rule beyond those authorized by the Parties. Therefore, if there has been a change in registration of an alternative that results in that alternative no longer being available to a particular use, EPA does not intend to add uses or amounts of methyl bromide to the critical use exemption program beyond those identified here. Under such circumstances, the user should apply to EPA, requesting that the U.S. nominate its use for a critical use exemption in the future. Based on the information described above, EPA is proposing that the uses in Table I: Approved Critical Uses, with the limiting critical conditions specified, qualify to obtain and use critical use methyl bromide in 2008.

TABLE I.—APPROVED CRITICAL USES

Column A	Column B	Column C
Approved critical uses	Approved critical user and location of use	Limiting critical conditions—that either exist, or that the approved critical user reasonably expects could arise without methyl bromide fumigation:
Pre-Plant Uses:		
Cucurbits	(a) Michigan growers	Moderate to severe soilborne disease infestation. A need for methyl bromide for research purposes.
	(b) Southeastern U.S. limited to growing locations in Alabama, Arkansas, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, and Virginia.	Moderate to severe yellow or purple nutsedge infestation. Moderate to severe soilborne disease infestation. Moderate to severe root knot nematode infestation. A need for methyl bromide for research purposes.
	(c) Georgia growers	Moderate to severe yellow or purple nutsedge infestation. Moderate to severe soilborne disease infestation. Moderate to severe root knot nematode infestation. A need for methyl bromide for research purposes.
Eggplant	(a) Florida growers	Moderate to severe yellow or purple nutsedge infestation. Moderate to severe soilborne disease infestation. Restrictions on alternatives due to karst topographical features and soils not supporting seepage irrigation. A need for methyl bromide for research purposes.
	(b) Georgia growers	Moderate to severe yellow or purple nutsedge infestation. Moderate to severe nematode infestation. Moderate to severe pythium collar, crown and root rot. Moderate to severe southern blight infestation. Restrictions on alternatives due to karst topographical features. A need for methyl bromide for research purposes.
	(c) Michigan growers	Moderate to severe soilborne disease infestation. A need for methyl bromide for research purposes.

[1] NPMA stands for National Pest Management Association.

TABLE I.—APPROVED CRITICAL USES—Continued

Column A	Column B	Column C
Approved critical uses	Approved critical user and location of use	Limiting critical conditions—that either exist, or that the approved critical user reasonably expects could arise without methyl bromide fumigation:
Forest Nursery Seedlings.	(a) Growers in Alabama, Arkansas, Georgia, Louisiana, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, and Virginia.	Moderate to severe yellow or purple nutsedge infestation. Moderate to severe soilborne disease infestation. Moderate to severe nematode infestation.
	(b) International Paper and its subsidiaries limited to growing locations in Alabama, Arkansas, Georgia, South Carolina, and Texas.	Moderate to severe yellow or purple nutsedge infestation. Moderate to severe soilborne disease infestation.
	(c) Public (government-owned) seedling nurseries in Illinois, Indiana, Kentucky, Maryland, Missouri, New Jersey, Ohio, Pennsylvania, West Virginia, and Wisconsin.	Moderate to severe weed infestation including purple and yellow nutsedge infestation. Moderate to severe Canada thistle infestation. Moderate to severe nematode infestation. Moderate to severe soilborne disease infestation.
	(d) Weyerhaeuser Company and its subsidiaries limited to growing locations in Alabama, Arkansas, North Carolina, and South Carolina.	Moderate to severe yellow or purple nutsedge infestation. Moderate to severe soilborne disease infestation. Moderate to severe nematode or worm infestation.
	(e) Weyerhaeuser Company and its subsidiaries limited to growing locations in Oregon and Washington.	Moderate to severe yellow nutsedge infestation. Moderate to severe soilborne disease infestation.
	(f) Michigan growers	Moderate to severe soilborne disease infestation. Moderate to severe Canada thistle infestation. Moderate to severe nutsedge infestation. Moderate to severe nematode infestation.
	(g) Michigan herbaceous perennials growers	Moderate to severe nematode infestation. Moderate to severe soilborne disease infestation. Moderate to severe yellow nutsedge and other weed infestation.
Orchard Nursery Seedlings.	(a) Members of the Western Raspberry Nursery Consortium limited to growing locations in California and Washington.	Moderate to severe nematode infestation. Presence of medium to heavy clay soils. Prohibition on use of 1,3-dichloropropene products because local township limits on use of this alternative have been reached. A need for methyl bromide for research purposes.
	(b) Members of the California Association of Nursery and Garden Centers representing Deciduous Tree Fruit Growers.	Moderate to severe nematode infestation. Presence of medium to heavy clay soils. Prohibition on use of 1,3-dichloropropene products because local township limits on use of this alternative have been reached. A need for methyl bromide for research purposes.
	(c) California rose nurseries	Moderate to severe nematode infestation. Prohibition on use of 1,3-dichloropropene products because local township limits on use of this alternative have been reached. A need for methyl bromide for research purposes.
Strawberry Nurseries	(a) California growers	Moderate to severe soilborne disease infestation. Moderate to severe yellow or purple nutsedge infestation. Moderate to severe nematode infestation. A need for methyl bromide for research purposes.
	(b) North Carolina and Tennessee growers	Moderate to severe black root rot. Moderate to severe root-knot nematode infestation. Moderate to severe yellow and purple nutsedge infestation. A need for methyl bromide for research purposes.
Orchard Replant	(a) California stone fruit growers	Moderate to severe nematode infestation. Moderate to severe soilborne disease infestation. Replanted (non-virgin) orchard soils to prevent orchard replant disease. Presence of medium to heavy soils. Prohibition on use of 1,3-dichloropropene products because local township limits on use of this alternative have been reached.

TABLE I.—APPROVED CRITICAL USES—Continued

Column A	Column B	Column C
Approved critical uses	Approved critical user and location of use	Limiting critical conditions—that either exist, or that the approved critical user reasonably expects could arise without methyl bromide fumigation:
	(b) California table and raisin grape growers	Moderate to severe nematode infestation. Moderate to severe soilborne disease infestation. Replanted (non-virgin) orchard soils to prevent orchard replant disease. Medium to heavy soils. Prohibition on use of 1,3-dichloropropene products because local township limits for this alternative have been reached.
	(c) California wine grape growers	Moderate to severe nematode infestation. Moderate to severe soilborne disease infestation. Replanted (non-virgin) orchard soils to prevent orchard replant disease. Medium to heavy soils. Prohibition on use of 1,3-dichloropropene products because local township limits for this alternative have been reached.
	(d) California walnut growers	Moderate to severe nematode infestation. Moderate to severe soilborne disease infestation. Replanted (non-virgin) orchard soils to prevent orchard replant disease. Medium to heavy soils. Prohibition on use of 1,3-dichloropropene products because local township limits for this alternative have been reached.
	(e) California almond growers	Moderate to severe nematode infestation. Moderate to severe soilborne disease infestation. Replanted (non-virgin) orchard soils to prevent orchard replant disease. Medium to heavy soils. Prohibition on use of 1,3-dichloropropene products because local township limits for this alternative have been reached.
Ornamentals	(a) California growers	Moderate to severe soilborne disease infestation. Moderate to severe nematode infestation. Prohibition on use of 1,3-dichloropropene products because local township limits for this alternative have been reached. A need for methyl bromide for research purposes.
	(b) Florida growers	Moderate to severe weed infestation. Moderate to severe soilborne disease infestation. Moderate to severe nematode infestation. Restrictions on alternatives due to karst topographical features and soils not supporting seepage irrigation. A need for methyl bromide for research purposes.
Peppers	(b) Alabama, Arkansas, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, and Virginia growers.	Moderate to severe yellow or purple nutsedge infestation. Moderate to severe nematode infestation. Moderate to severe pythium root, collar, crown and root rots. A need for methyl bromide for research purposes.
	(c) Florida growers	Moderate to severe yellow or purple nutsedge infestation. Moderate to severe soilborne disease infestation. Moderate to severe nematode infestation. Restrictions on alternatives due to karst topographical features and soils not supporting seepage irrigation. A need for methyl bromide for research purposes.
	(d) Georgia growers	Moderate to severe yellow or purple nutsedge infestation. Moderate to severe nematode infestation, or moderate to severe pythium root and collar rots. Moderate to severe southern blight infestation, crown or root rot. A need for methyl bromide for research purposes.
	(e) Michigan growers	Moderate to severe soilborne disease infestation. A need for methyl bromide for research purposes.

TABLE I.—APPROVED CRITICAL USES—Continued

Column A	Column B	Column C
Approved critical uses	Approved critical user and location of use	Limiting critical conditions—that either exist, or that the approved critical user reasonably expects could arise without methyl bromide fumigation:
Strawberry Fruit	(a) California growers	Moderate to severe black root rot or crown rot. Moderate to severe yellow or purple nutsedge infestation. Moderate to severe nematode infestation. Prohibition on use of 1,3-dichloropropene products because local township limits for this alternative have been reached. Time to transition to an alternative. A need for methyl bromide for research purposes.
	(b) Florida growers	Moderate to severe yellow or purple nutsedge infestation. Moderate to severe nematode infestation. Moderate to severe soilborne disease infestation. Carolina geranium or cut-leaf evening primrose infestation. Restrictions on alternatives due to karst topographical features and soils not supporting seepage irrigation a need for methyl bromide for research purposes.
	(c) Alabama, Arkansas, Georgia, Illinois, Kentucky, Louisiana, Maryland, Mississippi, Missouri, New Jersey, North Carolina, Ohio, South Carolina, Tennessee, and Virginia growers.	Moderate to severe yellow or purple nutsedge infestation. Moderate to severe nematode infestation. Moderate to severe black root and crown rot. A need for methyl bromide for research purposes.
Sweet Potato Slips	(a) California growers	Prohibition on use of 1,3-dichloropropene products because local township limits for this alternative have been reached.
Tomatoes	(a) Michigan growers	Moderate to severe soilborne disease infestation. Moderate to severe fungal pathogen infestation. A need for methyl bromide for research purposes.
	(c) Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, and Virginia growers.	Moderate to severe yellow or purple nutsedge infestation. Moderate to severe soilborne disease infestation. Moderate to severe nematodes. Restrictions on alternatives due to karst topographical features, and in Florida, soils not supporting seepage irrigation. A need for methyl bromide for research purposes.
Post-Harvest Uses:		
Food Processing	(a) Rice millers in all locations in the U.S. who are members of the USA Rice Millers Association.	Moderate to severe infestation of beetles, weevils or moths. Older structures that can not be properly sealed to use an alternative to methyl bromide. Presence of sensitive electronic equipment subject to corrosion. Time to transition to an alternative.
	(b) Pet food manufacturing facilities in the U.S. who are active members of the Pet Food Institute (For this proposed rule, ''pet food'' refers to domestic dog and cat food).	Moderate to severe infestation of beetles, moths, or cockroaches. Older structures that can not be properly sealed to use an alternative to methyl bromide. Presence of sensitive electronic equipment subject to corrosion. Time to transition to an alternative.
	(c) Bakeries in the U.S	Older structures that can not be properly sealed to use an alternative to methyl bromide. Presence of sensitive electronic equipment subject to corrosion. Time to transition to an alternative.
	(d) Members of the North American Millers' Association in the U.S.	Moderate to severe beetle infestation. Older structures that can not be properly sealed to use an alternative to methyl bromide. Presence of sensitive electronic equipment subject to corrosion. Time to transition to an alternative.

TABLE I.—APPROVED CRITICAL USES—Continued

Column A	Column B	Column C
Approved critical uses	Approved critical user and location of use	Limiting critical conditions—that either exist, or that the approved critical user reasonably expects could arise without methyl bromide fumigation:
	(e) Members of the National Pest Management Association associated with dry commodity structure fumigation (cocoa) and dry commodity fumigation (processed food, herbs and spices, dried milk and cheese processing facilities).	Moderate to severe beetle or moth infestation. Older structures that can not be properly sealed to use an alternative to methyl bromide. Presence of sensitive electronic equipment subject to corrosion. Time to transition to an alternative.
Commodities	(a) California entities storing walnuts, beans, dried plums, figs, raisins, dates (in Riverside county only), and pistachios in California.	Rapid fumigation is required to meet a critical market window, such as during the holiday season, rapid fumigation is required when a buyer provides short (2 working days or less) notification for a purchase or there is a short period after harvest in which to fumigate and there is limited silo availability for using alternatives. A need for methyl bromide for research purposes.
Dry Cured Pork Products.	(a) Members of the National Country Ham Association	Red legged ham beetle infestation. Cheese/ham skipper infestation. Dermested beetle infestation. Ham mite infestation.
	(b) Members of the American Association of Meat Processors.	Red legged ham beetle infestation. Cheese/ham skipper infestation. Dermested beetle infestation. Ham mite infestation.
	(c) Nahunta Pork Center (North Carolina)	Red legged ham beetle infestation. Cheese/ham skipper infestation. Dermested beetle infestation. Ham mite infestation.
	(d) Gwaltney and Smithfield Inc	Red legged ham beetle infestation. Cheese/ham skipper infestation. Dermested beetle infestation. Ham mite infestation.

EPA is proposing to amend the table in 40 CFR part 82, subpart A, Appendix L, as reflected above. Specifically, EPA is adding six references and deleting four references in column B. The changes are as follows: Adding Mississippi to the approved locations for cucurbit growers because that location was included in the approved Southeast Cucurbit Consortium application for 2008; removing Florida from the approved forest seedling locations because a 2008 application for that location was not submitted to EPA; removing Maryland from the approved strawberry nursery locations because a 2008 application for that location was not submitted to EPA; removing California from the approved locations for pepper growers because the United States Government did not reflect this location in its 2008 Critical Use Nomination; adding Mississippi to the approved locations for pepper growers because that location was included in the approved Southeast Pepper Consortium application for 2008; adding Mississippi and Missouri to the approved locations for strawberry fruit growers because those locations were included in the approved Southeastern Strawberry Consortium application for 2008; adding California sweet potato slip growers to reflect the authorization of that use in Decision XVIII/13; adding Mississippi to the approved locations for tomato growers because that location was included in the approved Southeastern Tomato Consortium application for 2008; removing turfgrass because that use was not agreed to by the Parties in Decision XVIII/13; adding Gwaltney and Smithfield Inc. to the approved entities for dry cured pork products because their application was approved for 2008.

The categories listed in Table I above have been designated critical uses for 2008 in Decision XVIII/13 of the Parties. The amount of methyl bromide approved for research purposes is included in the amount of methyl bromide approved by the Parties for the commodities for which ''research purposes'' is indicated as a limiting critical condition in the table above. As explained in Section V.D.5., EPA is allowing sale of 15,491 kg of methyl bromide from existing stocks for research purposes.

In accordance with the recommendations in Table 9 of the TEAP's September 2006 Final Report titled ''Evaluations of 2006 Critical Use Nominations for Methyl Bromide and Related Matters,'' available on the docket for this rulemaking, EPA is proposing that the following sectors be allowed to use critical use methyl bromide for research purposes: Commodities, cucurbits (field), eggplant (field), nursery stock (fruit, nut, flower), ornamentals, peppers (field), strawberry (field), strawberry runners, and tomatoes (field). In their applications to EPA, these sectors identified research programs that require the use of methyl bromide.

D. Proposed Critical Use Amounts

Section V.C. of this preamble explains that Table C of the annex to Decision XVIII/13 lists critical uses and amounts agreed to by the Parties to the Montreal Protocol. When added together, the authorized critical use amounts for 2008 total 5,355,946 kilograms (kg), which is equivalent to 21.0% of the U.S. 1991 methyl bromide consumption baseline of 25,528,270 kg as defined at 40 CFR 82.3. However, the maximum amount of authorized new production or import as set forth in Table D of the annex to Decision XVIII/13 is 4,595,040 kg (18.0% of baseline).

EPA is proposing to exempt limited amounts of new production and import of methyl bromide for critical uses for 2008 up to the amount of 3,101,076 kg (12.2% of baseline) as shown in Table II. EPA is also proposing to allow sale of 1,715,438 kg (6.7% of baseline) of existing inventories for critical uses in 2008. EPA is seeking comment on the proposed total levels of exempted new production and import for critical uses and the amount of material that may be sold from stocks for critical uses. The subsections below explain EPA's reasons and refined approach for proposing the above critical use amounts for 2008.

1. Background of Proposed Critical Use Amounts

The Framework Rule and subsequent CUE rules each took note of language regarding stocks of methyl bromide in relevant decisions of the Parties. In developing this proposed action, the Agency notes that paragraph six of Decision XVIII/13 contains the following language: ''That each Party which has an agreed critical use renews its commitment to ensure that the criteria in paragraph 1 of decision IX/6 are applied when licensing, permitting or authorizing critical use of methyl bromide and that such procedures take into account available stocks of banked or recycled methyl bromide, in particular, the criterion laid down in paragraph 1(b)(ii) of decision IX/6.'' Language calling on Parties to address stocks also appears in prior Decisions related to the critical use exemption.

In the Framework Rule, which established the architecture of the CUE program and set out the exempted levels of critical use for 2005, EPA interpreted paragraph 5 of Decision Ex. I/3, which is similar to Decision XVIII/13(6), ''as meaning that the U.S. should not authorize critical use exemptions without including provisions addressing drawdown from stocks for critical uses'' (69 FR 76987). Consistent with that interpretation, The Framework Rule (69 FR 52366) established provisions governing the sale of pre-phaseout inventories for critical uses, including the concept of CSAs and a prohibition on the sale of pre-phaseout inventories for critical uses in excess of the amount of CSAs held by the seller. In addition, EPA noted that stocks were further taken into account through the trading provisions that allow CUAs to be converted into CSAs. EPA is not proposing changes to these basic CSA provisions for calendar year 2008.

In the August 25, 2004 Proposed Framework Rule (69 FR 52366), EPA proposed to adjust the authorized level of new production and consumption for critical uses by the amount of ''available'' stocks. The methodology for determining the amount of ''available'' stocks considered exports, methyl bromide for feedstock uses, and the need for a buffer in case of catastrophic events. However, EPA did not adopt the proposed methodology for determining available stocks in the final Framework Rule. Instead, EPA issued CSAs in an amount equal to the difference between the total authorized CUE amount and the amount of new production or import authorized by the Parties (Total Authorized CUE Amount—Authorized New Production and Import).

In the 2006 CUE Rule, published February 6, 2006 (71 FR 5997), EPA applied the approach described in the Framework Rule by allocating as CSAs the difference between the total authorized CUE amount and the amount of new production and import authorized by the Parties (2.0% of baseline), as well as the small supplemental allocation in Decision XVII/9 (0.4% of baseline). EPA also issued CSAs allowing additional amounts of existing stocks to be sold for critical uses (roughly 3.0% of baseline). In the 2006 CUE Rule EPA issued a total of 1,136,008 CSAs, equivalent to 5.0% of baseline. Similarly, in the 2007 CUE Rule, EPA issued a number of CSAs that represented not only the difference between the total authorized CUE amount and the amount of authorized new production and import (6.2% of baseline), but also an additional amount (1.3% of baseline) for a total of 1,915,600 CSAs (7.5% of baseline). By allocating additional CSAs, EPA adjusted the portion of CUE methyl bromide to come from new production and import as compared to the proportion to come from stocks so that the total amount of methyl bromide exempted for critical uses did not exceed the total amount authorized by the Parties for that year.

EPA viewed the additional CSA amounts as an appropriate exercise of its discretion. EPA reasoned that the Agency was not required to allocate the full amount of authorized new production and consumption. The Parties agreed to ''permit'' a particular level of production and consumption; they did not—and could not—mandate that the U.S. authorize this level of production and consumption domestically. Nor does the CAA require EPA to exempt the full amount permitted by the Parties. Section 604(d)(6) of the Clean Air Act (CAA) does not require EPA to exempt any amount of production and consumption for critical uses, but instead specifies that the Agency ''may'' exempt amounts for production, importation, and consumption, thus providing EPA with substantial discretion in creating critical use exemptions.

In the July 6, 2006 Proposed 2007 CUE Rule (71 FR 38325), EPA sought comment on ''whether, in the critical use exemption context, it would be appropriate to adjust the level of new production and import with the goal of maintaining a stockpile of some specified duration * * * and on how many months of methyl bromide inventory would be appropriate, in order to maintain non-disruptive management of this chemical in the supply chain'' (71 FR 38339). In the Final 2007 CUE Rule, EPA noted that ''the Parties have not taken a decision on an appropriate amount of inventory for reserve. Nor has EPA reached any conclusion regarding what amount might be appropriate. Given this uncertainty, and the continuing decline in inventory levels, EPA is exercising caution in this year's CSA allocation. EPA will consider various approaches to this issue in the future based on the data received during this notice and comment rulemaking process and other information obtained by the Agency'' (71 FR 75399).

Data on the aggregate amount of methyl bromide held in inventory at the end of calendar years 2003, 2004, 2005, and 2006 is available in the public docket for this rulemaking. Using this aggregated inventory data, and other data gathered by EPA, the Agency estimates that on January 1, 2008 the aggregate inventory will be less than one-year's supply of critical use methyl bromide.

The benefits of pre-phaseout methyl bromide inventories for critical uses were discussed at the 18th Meeting of the Parties (MOP). The Parties did not take a decision at the 18th MOP on whether it would be appropriate to allow some specific amount of pre-phaseout stocks to remain in inventory, or what amount that might be. Instead, they left the matter for future discussion, and left open the possibility that a decision related to the issue might be taken at the 19th Meeting of the Parties in September 2007. EPA notes, however, that in another instance—namely the Essential Use Exemption process for CFC inhalers—the Parties have allowed companies to maintain working stocks up to one year's supply. As explained in the ''FDA determination letter'' available on the public docket for this rulemaking, FDA bases its determination of the amount of CFC production that is necessary for medical devices ''on an estimate of the

quantity of CFCs that would allow manufacturers to maintain as much as a 12-month stockpile.'' However, neither FDA nor EPA maintains a CFC reserve on behalf of any essential use manufacturer, or guarantees that a certain amount of CFCs will always be held in inventory.

Similarly, in this action, EPA is not proposing to maintain a reserve of methyl bromide for critical uses, or to guarantee that a certain amount of methyl bromide would always be held in inventory. EPA is, however, proposing to calculate the amount of existing methyl bromide stocks that is available for critical uses in 2008, and to consider this amount in the Agency's determination of how much sale of existing stocks and how much production and importation to allow for critical uses in 2008. Section V.D.2. describes EPA's proposed method to calculate the amount of existing stocks that is available for critical use in 2008. Section V.D.3. explains how EPA proposes to apply the calculated amount of available stocks in the Agency's critical use amount determinations.

The proposed methods for determining the critical use amounts, described in Section V.D.2. and V.D.3. of this preamble, refine the Agency's approach for determining how much critical use methyl bromide may be produced and imported and how much may be sold to critical users from existing inventories in a given year. EPA proposes to use these refinements in 2008 and, as feasible and appropriate, each year thereafter. Through data collection and experience, EPA has gained information about the CUE program that the Agency did not have when the program began. The pre-phaseout inventory has gradually declined to the point where, for the first time, EPA estimates that at the start of next year (2008) inventory will represent less than a one-year supply of critical use methyl bromide. The proposed approach for determining CUE production and import levels addresses the decline in methyl bromide inventories by considering in a more transparent manner the amount of existing stocks that is available for critical uses. As described below, the proposed approach establishes a clear and repeatable process for the Agency to make allocations that reflect a reasonable estimate of the amount of inventory available in a future control period based on data collected from earlier control periods. Thus, while EPA does not view refinements to its approach as legally required, EPA does view them as an appropriate discretionary action for the reasons given here. EPA seeks comment on the refined approach for determining critical use methyl bromide levels, which is described in detail in Sections V.D.2. and V.D.3. of this preamble, and also in a Technical Support Document available on the public docket for this rulemaking (EPA–HQ–OAR–2006–1016).

2. Calculation of Available Stocks

In this action, EPA is proposing to adjust the authorized level of new production and consumption for critical uses to account for the amount of existing stocks that is ''available'' for critical uses. This section explains how EPA proposes to calculate the amount of existing stocks that is available for critical uses in 2008. As described in more detail in Section V.D.3. of this preamble, EPA proposes to allow sale of the amount of existing inventory that the Agency has determined to be available for critical uses by issuing an equivalent number of critical stock allowances (CSAs), on a one-CSA-per-one-kilogram-of-methyl-bromide basis. EPA wants to be clear that in this action the Agency is not proposing to create a methyl bromide reserve or strategic inventory of any kind, or to guarantee that a certain amount of methyl bromide would always be held in inventory. Furthermore, in this action EPA is not proposing to add any new restrictions on sales of methyl bromide inventories.

The Parties to the Protocol recognized in their Decisions that the level of existing stocks may differ from the level of available stocks as discussed in the Proposed Framework Rule. Most recently, Decision XVIII/13(4) states, ''That a Party with a critical use exemption level in excess of permitted levels of production and consumption for critical uses is to make up any such differences between those levels by using quantities of methyl bromide from stocks that the Party has recognized to be available.'' Thus, in Decisions XVIII/13, XVII/9, Ex. II/1, XVI/2, Ex. I/3 and IX/6 the Parties recognized that not all existing stocks may be available to meet critical needs. Section 604(d)(6) of the Clean Air Act does not require that EPA adjust the amount of new production and import to reflect the availability of stocks: However, making such an adjustment is a reasonable exercise of EPA's discretion under this provision. Section 604(d)(6) provides that, ''to the extent consistent with the Montreal Protocol'' EPA ''may'' exempt production, importation, and consumption of methyl bromide for critical uses, thus providing the Agency substantial discretion to determine whether, and to what extent, production and import is appropriate for critical uses.

One commenter disagreed with EPA's interpretation in the Proposed Framework Rule that the Agency has the authority, as recognized by the Parties in Decision Ex. I/3 and similar Decisions, to ''assess how much methyl bromide is available from existing inventories'' (69 FR 52373). According to the commenter, EPA was making a ''false distinction'' between the terms ''available'' stocks and ''existing'' stocks of methyl bromide. The commenter submitted that the only difference between ''available'' and ''existing'' is the deduction to reflect developing country needs. The commenter based this argument on the language in Decision IX/6(1)(b)(ii), which states the condition that methyl bromide ''is not *available* in sufficient quality and quantity from *existing* stocks of banked or recycled methyl bromide, also bearing in mind the developing countries' need for methyl bromide.'' Thus, the commenter argued that Dec. Ex.I/3 does not create a new meaning for ''available'' that encompasses more deductions than for the developing country needs.

EPA disagrees with the commenter's broad application of the language in Decision IX/6(1)(b)(ii). EPA believes that in Dec. IX/6(1)(b)(ii) the Parties were stressing the importance of developing countries' needs, and not precluding the consideration of other factors in each individual Party's determination of available stocks of methyl bromide. Dec. IX/6(1)(b)(ii) says * * * ''*also* bearing in mind developing countries'' need,'' it does not say ''*only* bearing in mind * * *'' Furthermore, EPA underscores Dec. XVIII/13(4) and similar decisions which use the phrasing, ''quantities of methyl bromide from stocks that the Party has recognized to be available.'' EPA believes that in that Decision, and in similar language in other decisions, the Parties acknowledged that individual Parties have the discretion to determine their level of available stocks. For these reasons, EPA believes it is acting consistently with the relevant decisions. In addition, given the substantial discretion afforded by Congress under section 604(d)(6) of the Clean Air Act, EPA believes it has the authority to determine, through a notice and comment rulemaking process, what factors to include in the method for estimating the amount of existing stocks that is available.

Today's proposed approach is a logical extension of the approach used in EPA's 2006 and 2007 CUE allocation rules where EPA concluded that it was reasonable to adjust the proportion of

CUE methyl bromide to come from new production and import as compared to the proportion to come from stocks. Furthermore, it is appropriate for EPA to refine its approach in light of new information.

EPA is considering new information it has gathered about the availability of stocks for critical uses. That information is included in a Technical Support Document available in the docket for this rulemaking. EPA is proposing, and seeking comment on, the following approach to calculate the amount of existing stocks that is available for critical uses. EPA's proposed methodology for calculating the amount of available stocks can be expressed as follows: AS = ES − D − SCF, where AS = available stocks on January 1, 2008; ES = existing pre-phaseout stocks of methyl bromide held in the United States by producers, importers, and distributors on January 1, 2007; D = estimated drawdown of existing stocks during calendar year 2007; and SCF = a supply chain factor, the calculation of which is described below and in more detail in the Technical Support Document. Using the above method, EPA calculates that 1,715,438 kg (6.7% of baseline) of existing pre-phaseout stocks of methyl bromide will be ''available'' for critical uses on January 1, 2008. EPA seeks comment on the amount of the pre-phaseout stock that it estimates will be available for critical uses on January 1, 2008.

In the above formula ''existing stocks'' refers to pre-phaseout inventory—*i.e.*, methyl bromide that was produced before January 1, 2005 that is still held by domestic producers, distributors and third-party applicators. January 1, 2005 was the phaseout date for production and import of methyl bromide in the United States. ES does not include critical use methyl bromide that was produced after January 1, 2005 and carried over into subsequent years. That ''carry-over'' amount is treated separately as described in Section V.D.4. of this preamble. For the reasons discussed in Section V.D.4., EPA deducts an amount equivalent to the carry-over amount from the amount of allowable new production for the control period in question. ES also does not include methyl bromide produced under the exemption for quarantine and preshipment (QPS), methyl bromide produced with Article 5 allowances to meet the basic domestic needs of Article 5 countries, or methyl bromide produced for feedstock or transformation purposes. Such amounts have been removed from the calculation of the amount of ''available stocks'' for critical uses. Methyl bromide produced for QPS uses or for export to Article 5 countries may not be sold to domestic entities for critical uses. That methyl bromide, therefore, is separate from the CUE program.

To estimate the drawdown of existing stocks during 2007, the ''D'' term in the above method, EPA proposes to project the size of the pre-phaseout methyl bromide inventory on January 1, 2008 with a simple linear fit estimation using EPA data about the size of that inventory on January 1 of the years for which EPA has data: 2004, 2005, 2006, and 2007. Using a simple linear fit, EPA projects that the pre-phaseout methyl bromide inventory, which was 7,671,091 kg on January 1, 2007, will be drawn down by 3,224,351 kg during 2007. Therefore, EPA estimates that the size of the pre-phaseout inventory will be 4,447,740 kg on January 1, 2008. EPA's methodology for estimating the inventory drawdown is described in more detail in the Technical Support Document available on the public docket for this rulemaking.

EPA's proposed method for determining the amount of existing stocks that is available for critical uses includes a ''supply chain factor.'' The supply chain factor represents EPA's technical estimate of the amount of methyl bromide inventory that would be adequate to meet a need for critical use methyl bromide after an unforeseen domestic production failure. For 2008, EPA proposes to use a supply chain factor equal to 2,731,211 kg in the Agency's calculation of the amount of available stocks. EPA wants to be very clear that in this action the Agency is not proposing to create a ''reserve'' or ''strategic inventory'' of any kind. The supply chain factor is merely a more transparent analytical tool that will foster greater understanding of the Agency's process in determining CSA amounts.

There is one active methyl bromide production facility in the United States. EPA estimates that following an unforeseen shutdown of that facility (*e.g.*, due to an explosion, fire, hurricane), it would take 6–12 months to restart production, but only 15 weeks for significant imports of methyl bromide to reach the U.S. As discussed in the Technical Support Document, EPA estimates that after 15 weeks, U.S. demand for critical use methyl bromide could be adequately supplied with imported material. In Decision XVIII/13, the Parties authorized 5,355,946 kg for U.S. critical uses in 2008. If supply is evenly distributed across each 15-week period of 2008, then a supply disruption would cause a 15-week shortfall of 1,544,984 kg (15 weeks/52 weeks * 5,355,946 kg). However, EPA data—collected pursuant to the reporting requirements at 40 CFR 82.13—shows that a disproportionate amount of critical use methyl bromide is produced in the first 15 weeks of each year. EPA's analysis in the Technical Support Document suggests that heavy production at the beginning of each year is related to peak demand during the spring planting season. Therefore, EPA estimates that a supply disruption at or near the beginning of 2008 would cause a supply shortfall greater than 1,544,984 kg.

EPA proposes a conservative estimate of the supply chain factor that considers a supply disruption during the estimated peak 15-week period of critical use supply. As explained in more detail in the Technical Support Document, EPA estimates that since the beginning of the CUE program on January 1, 2005, critical use methyl bromide production in the first 15 weeks of each year has accounted for 51.0% of annual critical use methyl bromide production. EPA, therefore, estimates that the peak 15-week shortfall in 2008 could be 2,731,211 kg (51.0% * 5,355,946 kg). For the reasons discussed above, EPA proposes to include a supply chain factor of 2,731,211 kg in its calculation of the amount of available stocks in 2008. EPA's analysis considers many factors including foreign production capacity, shipping container capacity, shipping logistics and market dynamics. EPA seeks comment on the proposed supply chain factor in its calculation of the amount of available stocks in 2008, and on its methods and reasoning for this proposal as described in the Technical Support Document.

This estimate of a 15 week supply disruption assumes that registrants of methyl bromide products have equal access to all sources of available methyl bromide. The Agency recognizes that not all registrants are allowed to access alternative sources of methyl bromide. Therefore, registrants may need to submit applications to amend their existing registrations to legally allow alternative sources of methyl bromide to be used in formulating methyl bromide end-use products. Because such applications may require the submission of product chemistry and acute toxicology data, registrants should plan accordingly, bearing in mind the registration requirements under FIFRA and the Pesticide Registration Improvement Act (PRIA). As it is uncertain how the amendment process would affect the estimate of supply disruption, EPA will use the 15 week

figure unless other information becomes available.

There are other limitations associated with EPA's 15 week supply disruption estimate, which are discussed in the Technical Support Document. One of these limitations is that under the reporting requirements at 40 CFR 82.13, EPA collects information about the amount of pre-phaseout inventory and which entities own it, but the Agency does not collect information about the characteristics of that inventory. These unknown characteristics, such as the purity of the pre-phaseout inventory, could affect users' ability to use this inventory to meet their critical needs. For example, inventory intended for pre-plant uses may be pre-mixed with chloropicrin in compressed gas cylinders and therefore could not be used for post-harvest fumigations that require pure methyl bromide. EPA seeks information about the characteristics of the pre-phaseout inventory, because that information could help EPA refine its proposed CSA allocation amount. For example, if EPA were to obtain verifiable information that none of the pre-phaseout inventory was of the necessary composition for post-harvest uses, the Agency might decide not to allocate CSAs for post-harvest sectors and could instead allocate that amount of CSAs as post-harvest CUAs.

EPA believes there is precedent for allowing a reasonable amount of a chemical that has been phased out to remain in the supply chain to meet the needs of exempted uses. For example, in the context of the essential use exemption, as explained in the ''FDA determination letter'' available on the public docket for this rulemaking, FDA bases its determination of the amount of CFC production that is necessary for medical devices ''on an estimate of the quantity of CFCs that would allow manufacturers to maintain as much as a 12-month stockpile.'' That action is consistent with Decision XVI/12(3), which specifies that ''Parties, when preparing essential use nominations for CFCs, should give due consideration to existing stocks, whether owned or agreed to be acquired from a metered-dose inhaler manufacturer, of banked or recycled controlled substances as described in paragraph 1(b) of decision IV/25, with the objective of maintaining no more than one year's operational supply.'' As stated previously, however, neither EPA nor FDA maintains a reserve on behalf of any essential use manufacturer, or guarantees that a certain amount of CFCs will always be held in inventory. Likewise, EPA is not proposing to maintain a reserve of methyl bromide for critical uses, or to guarantee that a certain amount of methyl bromide would always be held in inventory.

Given that today's proposal is to make methyl bromide available for critical uses in 2008, the small number of methyl bromide production facilities around the world, and the continued drawdown of existing methyl bromide inventories make a major supply disruption an important issue for Agency consideration. The fact that EPA is not aware of a major methyl bromide supply disruption does not mean that such a disruption is impossible or even improbable in the future.

The Technical Support Document discusses in detail the efficacy and limitations of importing methyl bromide from abroad in the event of a domestic production plant failure. In fact, EPA estimates that in the event of a plant production failure, importing methyl bromide from abroad is likely to be the fastest and most practical short-term way to replace the lost production. Therefore, issues such as foreign excess production capacity, shipping container capacity, shipping logistics, and market dynamics are the primary focus of EPA's analysis.

As explained above, EPA is not proposing to set aside, or physically separate, stocks as an inventory reserve. By including a supply chain factor in its calculation of available stocks EPA is considering the drawdown of stocks and allocating critical use amounts that reflect the size of the existing stockpile of pre-phaseout material. Under EPA's proposed approach, stocks of methyl bromide may be used to ''fill the distribution chain'' and simultaneously provide some buffer in case of a major supply disruption.

Exports were an important consideration in EPA's inclusion of the supply chain factor. The U.S. faces different circumstances from many other Parties because it is a methyl bromide producing country as well as a user country. In fact, historically the U.S. has been the world's largest supplier of methyl bromide. Since U.S. companies supply a significant portion of the world demand for methyl bromide, a supply disruption in the U.S. would not only affect U.S. users, but would probably affect users with agreed critical uses in developed countries as well as users in developing countries that have basic domestic needs for methyl bromide. Therefore, depending on how domestic suppliers manage their inventories, the supply chain factor could indirectly reduce the risks for entities in other countries which need methyl bromide.

As explained in the Technical Support Document, EPA did not directly consider domestic demand for methyl bromide for QPS uses in its estimation of the possible shortfall of methyl bromide supplies in the event of a major supply disruption. Congress provided separate grants of authority to EPA for the quarantine and preshipment exemption and the critical use exemption in CAA sections 604(d)(5) and 604(d)(6), respectively. Therefore, methyl bromide produced for QPS uses is regulated under a completely separate exemption program from the CUE. On January 2, 2003 EPA published the QPS Rule in the **Federal Register** (68 FR 2138), which established the framework and guidelines for regulating methyl bromide produced for uses that meet the definition of QPS uses, as defined in that rule and at 40 CFR 82.3. The QPS exemption program does not restrict the amount of methyl bromide that is newly produced and imported for QPS purposes. In addition, existing regulations allow manufacturers and distributors of QPS methyl bromide to manage stockpiles of QPS methyl bromide.

EPA is acting consistently with the Montreal Protocol by not including QPS methyl bromide in calculating consumption and inventory levels related to the phase-out of methyl bromide and the CUE. Article 2H(6) of the Protocol states that the 1991 baseline level of consumption and production ''shall not include the amounts used by the Party for quarantine and pre-shipment purposes.''

Similarly, EPA did not consider domestic demand for methyl bromide for feedstock and transformation purposes in its calculation of the supply chain factor. As with the QPS exemption, methyl bromide producers are allowed to responsibly manage inventories of feedstock methyl bromide. Therefore, EPA does not find compelling reasons to account for domestic demand for feedstock methyl bromide in the supply chain factor. In this action, EPA is not proposing to change or add restrictions on methyl bromide produced for feedstock and transformation purposes.

In the past, stakeholders have raised concerns about their ability to understand exactly how EPA derives CSA amounts. One of EPA's motivations for introducing the refined methodology, described above in this section, is to provide more clarity about how proposed amounts are derived, and to make EPA's calculations more transparent. For these reasons, EPA tried to make the terms in the proposed method for calculating available stocks

proposed in this preamble as clear and definitive as possible. Since the original proposed rule, EPA has gained significant experience and information pertaining to the CUE program, and the methyl bromide industry more generally. EPA is using its added knowledge to propose a more transparent and definitive method for calculating the amount of available stocks. Further detail about the factors in the method proposed in this preamble is provided in the Technical Support Document available on the public docket for this rulemaking.

3. Proposed Approach for Determining Critical Use Amounts

EPA estimates that, as of January 1, 2008, 1,715,438 kg of pre-phaseout inventory will meet the definition of ''available stocks'' as calculated using the approach described in Section V.D.2. of this preamble. Based on these calculated figures and the allocation approach described in this Section, and after making reductions for carry-over amounts as explained in Section V.D.4. of this preamble, EPA proposes to allocate critical use allowances (CUAs) permitting 3,101,076 kg of new methyl bromide production and import for critical uses in 2008, and to allow sale of 1,715,438 kg from existing stocks for critical uses by allocating an equivalent number of critical stock allowances (CSAs). EPA's proposed allocation amounts will result in CSAs that exceed the difference between the total critical use amount and the new production amount in the Parties' decision. As discussed above, this is similar to the approach taken in EPA's rules for the previous two years. EPA seeks comment on the amount of CUAs and CSAs that the Agency is proposing to distribute in 2008. EPA also seeks comment on the more refined allocation approach that the Agency is proposing to use in 2008 and beyond, as described below in this Section.

In this action, EPA is proposing to refine its allocation approach for 2008 and beyond. EPA proposes that in 2008 and in each year thereafter, when appropriate and feasible, it will allocate CSAs in an amount equal to the number of kilograms of available stocks on January 1 of the year in question, as estimated by EPA using the method described in Section V.D.2. of this preamble. As in past years, EPA intends to allocate a total number of CUAs such that the total number of CUAs and CSAs is not greater than the total critical use amount authorized by the Parties for the year in question. To account for carry-over amounts of methyl bromide, amounts for research purposes, or for other appropriate reasons, including updated information on alternatives, EPA may allocate a total number of CUAs and CSAs that is less than the total critical use amount authorized by the Parties for the year in question. As in previous CUE rules, if EPA does allow less than the total amount authorized by the Parties, the Agency will propose and seek comment on the reasons for, and amounts of, each reduction before finalizing any such reductions. In this action EPA is not proposing to create a methyl bromide reserve or strategic inventory of any kind, or to guarantee that a certain amount of methyl bromide would always be held in inventory. Furthermore, EPA is not proposing to add any restrictions on sales of methyl bromide inventories.

EPA recognizes that in a future CUE allocation rule proposal, the Agency could estimate, using the method described in Section V.D.2., that the amount of available stocks at the beginning of a future year is less than the difference between the total critical use amount authorized by the Parties and the amount of new production and imports authorized by the Parties for the year in question. This scenario can be described with the following inequality: Available Stocks < (Total CUE Amount Authorized—New Production and Imports Authorized). Under the refined approach described above, in such a case EPA would propose to allow the maximum amount of new production and imports authorized by the Parties, minus any reductions as described below. EPA would also allow critical users to access a limited amount of existing stocks by allocating a number of CSAs equal to the difference between the total CUE amount authorized by the Parties and the amount of new production and imports authorized for the year in question (CSA = Total CUE Amount Authorized—New Production and Imports Authorized), again minus any reductions as discussed here. EPA will continue to collect inventory data and make critical use allocations on an annual basis. Similarly, unless the Parties approve multi-year critical use exemptions, EPA proposes to calculate the amount of available stocks on an annual basis and to explain those calculations in the annual CUE allocation rulemaking process. To account for carry-over amounts of methyl bromide, amounts for research purposes, or for other appropriate reasons, including updated information on alternatives, EPA could allocate a total number of CUAs and CSAs that is less than the total critical use amount authorized by the Parties for the year in question. As in previous CUE rules, if EPA does allow less than the total amount authorized by the Parties, the Agency will propose and seek comment on the reasons for, and amounts of, each reduction before finalizing any such reductions.

Finally, for completeness, EPA recognizes that as a theoretical matter it could estimate, using the method described in Section V.D.2., that the amount of available stocks at the beginning of a future year is greater than the total critical use amount authorized by the Parties for the year in question. This scenario can be described with the following inequality: Available Stocks > Total CUE Amount Authorized. In that theoretical scenario, EPA would propose to allocate a number of CSAs that is equivalent to the total CUE amount authorized by the Parties for the year in question. However, EPA could still make reductions, such as for amounts of carry-over CUE material. Therefore, in the situation described by the above inequality, EPA would not allocate any CUAs for the year in question.

4. Treatment of Carry-Over Material

As described in the December 23, 2004 Framework Rule (69 FR 76997), EPA is not permitting entities to build stocks of methyl bromide produced or imported after January 1, 2005 under the critical use exemption. Under the current regulations, quantities of methyl bromide produced, imported, exported, or sold to end-users under the critical use exemption in a calendar year must be reported to EPA the following year. These reporting requirements appear at Sections 82.13(f)(3), 82.13(g)(4), 82.13(h)(1), 82.13(bb)(2), and 82.13(cc)(2). EPA uses the reported information to calculate the amount of methyl bromide produced or imported under the critical use exemption, but not exported or sold to end-users in that year. An amount equivalent to this ''carry-over,'' whether pre-plant or post-harvest, is then deducted from the total level of allowable new production and import in the year following the year of the data report. For example, the amount of carry-over from 2005, which was reported in 2006, was deducted from the allowable amount of production or import for critical uses in 2007. As discussed in Section V.D.2., carry over material is not included in EPA's definition of existing stocks (ES) as it applies to the proposed formula for determining the amount of available stocks (AS). EPA is not including carry-over amounts as part of ES, because doing so could lead to a double-

counting of carry-over amounts, and thus a double reduction of critical use allowances (CUAs).

In 2007, 53 entities reported information to EPA under the reporting requirements at 40 CFR 82.13 about critical use methyl bromide production, imports, exports, sales and/or inventory holdings in 2006. 6,923,926 kg of critical use methyl bromide was acquired through production or import in 2006. The information reported to EPA indicates that 6,384,493 kg of critical use methyl bromide was exported or sold to end-users in 2006. EPA calculates that the carry-over amount at the end of 2006 was 539,433 kg, which is the difference between the reported amount of critical use methyl bromide acquired in 2006 and the reported amount of exports or sales of that material to end users in 2006 (6,923,926 kg − 6,384,493 kg = 539,433 kg). EPA's calculation of the amount of carry-over at the end of 2006 is consistent with the method used in the final 2007 CUE Rule, and with the method agreed to by the Parties in Decision XVI/6, which established the Accounting Framework for critical use methyl bromide, for calculating column L of the U.S. the Accounting Framework. The 2006 U.S. Accounting Framework is available in the public docket for this rulemaking. EPA seeks comment on its method for calculating the amount of carry-over critical use material at the end of each year. Commenters suggesting alternative methods for calculating the amount of carry-over material at the end of each year should be detailed and comprehensive; address what changes would be needed to the reporting requirements; and the degree of administrative burden that alternative practice might impose. EPA also seeks comment on ways to improve the completeness of data reporting by affected companies. It is important for stakeholders to recognize that the process for calculating the amount of carry-over CUE material each year relies on sales to end-user data reported to EPA by distributors and applicators. EPA specifically requests comment on whether requiring producers, importers, and distributors to report to the Agency the names of distributors and third-party applicators to whom they have sold critical-use methyl bromide would result in more complete reporting of sales to end-user data, and whether this would justify the additional burden of such requirements.

In previous CUE rules, EPA has used the approach described in the Framework Rule for implementing carry-over reductions. Consistent with that approach, EPA is proposing to reduce the total level of new production and import for critical uses by 539,432 kg to reflect the total level of carry-over material available at the end of 2006. After applying this reduction to the total volumes of allowable new production or import, EPA pro-rated CUAs to each company based on their 1991 baseline market share.

Chemtura Corporation has submitted a petition available on the public docket for this rulemaking that recommends alternative methods for apportioning carry-over reductions among CUA holders. Some of Chemtura's proposals would require increases to existing reporting requirements for producers, distributors or third-party applicators. EPA encourages interested parties to consult Chemtura's petition. EPA seeks comment on the recommendations in that petition, as well as any additional suggestions regarding the apportionment of carry-over among companies. Comments suggesting alternative methods for implementing carry-over reductions should be detailed and comprehensive; address what changes, if any, would be needed to the reporting requirements; and the degree of burden the alternative practice might impose.

5. Amounts for Research Purposes

Decision XVII/9(7) ''request[ed] Parties to endeavor to use stocks, where available, to meet any demand for methyl bromide for the purposes of research and development.'' Consistent with that Decision, in the 2007 CUE Rule, EPA reduced the amount of new production and import by 21,702 kilograms, which was the amount needed for research. Consistent with Decision XVII/9, EPA continued to encourage methyl bromide suppliers to sell inventory to researchers and encouraged researchers to purchase inventory.

Decision XVIII/15(1) authorizes ''the production and consumption of [methyl bromide] necessary to satisfy laboratory and analytical critical uses.'' Paragraph 2 of that decision states that methyl bromide produced under the exemption for laboratory and analytical uses may be used as a reference or standard; in laboratory toxicology studies; to compare the efficacy of methyl bromide and its alternatives inside a laboratory; and as a laboratory agent which is destroyed in a chemical reaction in the manner of feedstock. In a separate notice-and-comment rulemaking titled the ''Global Essential Laboratory and Analytical Use Exemption,'' EPA is proposing to implement the exemption authorized in Decision XVIII/15. More information about that rulemaking process is available on the docket for that rule (EPA–HQ–OAR–2007–0384).

There continues to be a need for methyl bromide for research purposes that do not meet the criteria for laboratory and analytical uses, as defined in Decision XVIII/15. A common example is an outdoor field experiment that requires methyl bromide as a standard control treatment with which to compare the trial alternatives' results. The critical use sectors that were approved by the Parties to use methyl bromide for research purposes in 2008 are listed in Section V.C. and have ''research purposes'' listed in their limiting critical conditions in Table I of this preamble.

In this action, EPA is proposing to allow sale of 15,491 kg of existing stocks for research purposes in 2008 to account for the amount authorized for those purposes. EPA proposes to allow methyl bromide sale from stocks for exempted research purposes by expending CSAs. An explanation of what amounts of methyl bromide and of what sectors qualify for research purposes can be found in Section V.C. of this preamble. If EPA adopts this proposal it will continue to encourage methyl bromide suppliers to sell inventory to researchers and to encourage researchers to purchase inventory for research purposes. EPA seeks comment on its proposal to issue CSAs for sale of methyl bromide stocks for exempted research purposes.

6. Methyl Bromide Alternatives

In the 2006 CUE Rule (71 FR 5985) EPA allocated less methyl bromide for critical uses than was authorized by the Parties in order to account for the recent registration of sulfuryl fluoride. The allocation reductions in that rule reflected transition rates that were included for the first time in the 2007 U.S. Critical Use Nomination (CUN). In the 2007 CUE Rule, EPA explained why a similar reduction was made in that rule: ''The report of the Methyl Bromide Technical Options Committee (MBTOC) indicated that the MBTOC did not make any reductions in these [post-harvest] use categories for the uptake of sulfuryl fluoride in 2007 because the United States Government indicated that it would do so in its domestic allocation procedures. Therefore, EPA is reducing the total volume of critical use methyl bromide by 53,703 kilograms to reflect the continuing transition to sulfuryl fluoride'' (75 FR 75390).

The United States continues to make progress transitioning to alternatives to methyl bromide fumigation. Preliminary results of a study (forthcoming) indicate

that the cost of post-harvest cocoa fumigation with sulfuryl fluoride is not substantially greater than the cost of using methyl bromide for that fumigation. As a result the National Pest Management Association (NPMA) decided to withdraw its nomination request for critical use methyl bromide for cocoa for calendar year 2009 and not to seek critical use methyl bromide for cocoa at all in calendar year 2010.

NPMA, however, has expressed the need for some critical use methyl bromide for cocoa in 2008 as the sector transitions to sulfuryl fluoride. NPMA explained to EPA that some larger companies have already begun integrating sulfuryl fluoride into their operations. However, there are other companies that have not begun that transition. NPMA believes that those companies would be unprepared if EPA does not allow a portion of the 50,188 kg of critical use methyl bromide for cocoa approved by the Parties for 2008. Given the circumstances discussed above, EPA seeks comment on how much of the 50,188 kg of critical use methyl bromide approved by the Parties for cocoa for 2008 should be allowed by the Agency. Commenters on this topic should recommend specific amounts of critical use methyl bromide for cocoa in 2008, and provide detailed justifications for their recommendations.

Besides the issues regarding post-harvest cocoa fumigation discussed above, EPA is not proposing to make any other reductions in post-harvest or pre-plant critical use allowances to account for the uptake of sulfuryl fluoride, or any other pre-plant or post-harvest alternatives. In the 2008 CUN the Agency applied transition rates for all critical use sectors. The MBTOC report of September 2006 included reductions in its recommendations for critical use categories based on the transition rates in the 2008 CUN. MBTOC's recommendations were then considered in the Parties' 2008 authorization amounts, as listed in Decision XVIII/13. Therefore, transition rates, which account for the uptake of alternatives, have already been applied for authorized 2008 critical use amounts. Furthermore, the 2009 CUN, which represents the most recent analysis and the best available data for methyl bromide alternatives, does not conclude that transition rates should be increased for 2008.

As the 2009 CUN reflects, besides the post-harvest cocoa issue discussed above in this section, the United States Government has not found new information that supports changing the 2008 transition rates included in the 2008 CUN and applied by MBTOC. EPA continues to gather information about methyl bromide alternatives through the CUE application process, and by other means. For example, in August 2006, under the authority of Section 114 of the Clean Air Act, EPA collected information from a group of millers and fumigators about their experiences with sulfuryl fluoride and methyl bromide.

EPA seeks comment on its proposal not to make further reductions in 2008 to account for the uptake of methyl bromide alternatives, because the Agency has already accounted for alternatives' transition rates. EPA continues to support research and adoption of methyl bromide alternatives, and to request information about the economic and technical feasibility of all existing and potential alternatives.

E. The Criteria in Decisions IX/6 and Ex. I/4

Paragraphs 2 and 6 of Decision XVIII/13 request parties to ensure that the conditions or criteria listed in Decisions Ex. I/4 and IX/6, paragraph 1, are applied to exempted critical uses for the 2008 control period. A discussion of the Agency's application of the criteria in paragraph 1 of Decision IX/6 appears in sections V.A., V.C., V.D., and V.H. of this preamble. In section V.C. the Agency is soliciting comments from the public on the technical and economic basis for determining that the uses listed in this proposed rule meet the criteria of the critical use exemption (CUE). The critical use nominations (CUNs) detail how each proposed critical use meets the criteria listed in paragraph 1 of Decision IX/6, apart from the criterion located at (b)(ii), as well as the criteria in paragraphs 5 and 6 of Decision Ex. I/4.

The criterion in Decision IX/6(1)(b)(ii), which refers to the use of available stocks of methyl bromide, is addressed in sections V.D., V.G., and V.H. of this preamble. The Agency has previously provided its interpretation of the criterion in Decision IX/6(1)(a)(i) regarding the presence of significant market disruption in the absence of an exemption, and EPA refers readers to the 2006 CUE final rule (71 FR 5989) as well as to the memo on the docket titled ''*Development of 2003 Nomination for a Critical Use Exemption for Methyl Bromide for the United States of America*'' for further elaboration.

The remaining considerations, including the lack of available technically and economically feasible alternatives under the circumstance of the nomination; efforts to minimize use and emissions of methyl bromide where technically and economically feasible; the development of research and transition plans; and the requests in Decision Ex. I/4(5) that Parties consider and implement MBTOC recommendations, where feasible, on reductions in the critical use of methyl bromide and in paragraph 6 for Parties that submit critical use nominations to include information on the methodology they use to determine economic feasibility, are all addressed in the nomination documents.

Some of these criteria are evaluated in other documents as well. For example, the U.S. has further considered matters regarding the adoption of alternatives and research into methyl bromide alternatives, criterion (1)(b)(iii) in Decision IX/6, in the development of the National Management Strategy (NMS) submitted to the Ozone Secretariat in December 2005 and in on-going consultations with industry. The NMS addresses all of the aims specified in Decision Ex.I/4(3) to the extent feasible and is available in the docket for this rulemaking.

F. Emissions Minimization

EPA notes for the regulated community the reference to emission minimization techniques in paragraph 8 of Decision XVIII/13, which states that Parties shall request critical users to employ ''emission minimization techniques such as virtually impermeable films, barrier film technologies, deep shank injection and/or other techniques that promote environmental protection, whenever technically and economically feasible.'' In addition, EPA understands that research is being conducted on the potential to reduce rates and emissions using newly available high-barrier films and that these studies show promising results. Users of methyl bromide should make every effort to minimize overall emissions of methyl bromide by implementing measures such as the ones listed above, to the extent consistent with state and local laws and regulations. The Agency encourages researchers and users who are successfully utilizing such techniques to inform EPA of their experiences as part of their comments on this proposed rule and to provide such information with their critical use applications. In addition, the Agency welcomes comments on the implementation of emission minimization techniques and whether and how further emission minimization could be achieved.

F. Critical Use Allowance Allocations

EPA is proposing to allow limited amounts of new production or import of methyl bromide for critical uses for

2008 up to the amount of 3,101,076 kg (12.2% of baseline) as shown in Table II below. EPA is seeking comment on the total levels of exempted new production or import for pre-plant and post-harvest critical uses in 2008. Each critical use allowance (CUA) is equivalent to 1 kg of critical use methyl bromide. These allowances expire at the end of the control period and, as explained in the Framework Rule, are not bankable from one year to the next. This proposal for allocating the following number of pre-plant and post-harvest CUAs to the entities listed below is subject to the trading provisions at 40 CFR 82.12, which are discussed in section V.G. of the preamble to the Framework Rule (69 FR 76982).

TABLE II.—PROPOSED ALLOCATION OF CRITICAL USE ALLOWANCES

Company	2008 Critical use allowances for pre-plant uses * (kilograms)	2008 Critical use allowances for post-harvest uses * (kilograms)
Great Lakes Chemical Corp.—A Chemtura Company	1,691,276	193,248
Albemarle Corp	695,491	79,468
Ameribrom, Inc	384,343	43,916
TriCal, Inc	11,967	1,367
Total	** 2,783,078	** 317,998

* For production or import of class I, Group VI controlled substance exclusively for the Pre-Plant or Post-Harvest uses specified in Appendix L to 40 CFR part 82.
** Due to rounding, numbers do not add exactly.

Paragraph five of Decision XVIII/13 states ''that Parties shall endeavor to license, permit, authorize, or allocate quantities of critical use methyl bromide as listed in tables A and C of the annex to the present decision.'' This is similar to language in Decisions Ex. I/3(4), Ex. II/1(4) and VII/9(4) regarding 2005, 2006 and 2007 critical uses, respectively. The language from these Decisions calls on Parties to endeavor to allocate critical use methyl bromide on a sector basis.

In establishing the critical use exemption program, the Agency endeavored to allocate directly on a sector-by-sector basis by analyzing and proposing this option among others in the August 2004 Framework Rule notice (69 FR 52366). EPA solicited comment on both universal and sector-based allocation of critical use allowances. The Agency evaluated the various options based on their economic, environmental, and practical effects. After receiving comments, EPA determined in the final Framework Rule (69 FR 76989) that a lump-sum, or universal, allocation, modified to include distinct caps for pre-plant and post-harvest uses, was the most efficient and least burdensome approach that would achieve the desired environmental results, and that a sector-specific approach would pose significant administrative and practical difficulties. Although the approach adopted in the Framework Rule does not directly allocate allowances to each category of use, the Agency anticipates that reliance on market mechanisms will achieve similar results indirectly. The TEAP recommendations are based on data submitted by the U.S. which in turn are based on recent historic use data in the current methyl bromide market. In other words, the TEAP recommendations agreed to by the Parties are based on current use and the current use patterns take place in a market where all pre-plant and post-harvest methyl bromide uses compete for a lump sum supply of critical use material. Therefore, the Agency believes that under a system of universal allocations, divided into pre-plant and post-harvest sectors, the actual critical use will closely follow the sector breakout listed by the TEAP. These issues were addressed in the previous rule and EPA is not aware of any factors that would alter the analysis performed during the development of the Framework Rule. A summary of the options analysis conducted by EPA is available in the docket for this rulemaking.

EPA is not proposing to change the approach adopted in the Framework Rule for the allocation of CUAs but, in an endeavor to address Decision XVIII/13(5), EPA will consider additional comment on the Agency's allocation of CUAs in the two groupings (pre-plant and post-harvest) that the Agency has employed in the past.

H. Critical Stock Allowance Allocations and Total Volumes of Critical Use Methyl Bromide

For the reasons described in Section V.D., EPA is proposing to allocate critical stock allowances (CSAs) to the entities listed below in Table III for the 2008 control period in the amount of 1,715,438 kilograms (kg) (6.7% of U.S. 1991 baseline). This proposed amount of CSA allowances is consistent with the proposed approach described in Section V.D.4. and in a Technical Support Document available on the public docket for this rulemaking (Docket ID#: EPA–HQ–OAR–2006–1016).

In 2006 the United States District Court for the District of Columbia upheld EPA's treatment of company-specific methyl bromide inventory information as confidential. *NRDC* v. *Leavitt,* 2006 WL 667327 (D.D.C. March 14, 2006). EPA's allocation of CSAs is based on each company's proportionate share of the aggregate inventory. Therefore, the documentation regarding company-specific allocation of CSAs is in the confidential portion of the rulemaking docket and the individual CSA allocations are not listed in the table below. EPA will inform the listed companies of their CSA allocations in a letter following publication of the final rule.

TABLE III.—ALLOCATION OF CRITICAL STOCK ALLOWANCES

Company
Albemarle
Ameribrom, Inc.
Bill Clark Pest Control, Inc.
Blair Soil Fumigation
Burnside Services, Inc.
Cardinal Professional Products
Carolina Eastern, Inc.
Degesch America, Inc.
Dodson Bros.
Great Lakes Chemical Corp.
Harvey Fertilizer & Gas
Helena Chemical Co.
Hendrix & Dail
Hy Yield Bromine

TABLE III.—ALLOCATION OF CRITICAL STOCK ALLOWANCES—Continued

Company
Industrial Fumigation Company
J.C. Ehrlich Co.
Pacific Ag
Pest Fog Sales Corp.
Prosource One
Reddick Fumigants
Royster-Clark, Inc.
Southern State Cooperative, Inc.
Trical Inc.
Trident Agricultural Products
UAP Southeast (NC)
UAP Southeast (SC)
Univar
Vanguard Fumigation Co.
Western Fumigation
Total—1,715,438 kilograms.

Several companies that receive very small amounts of CSAs from EPA have contacted the Agency and requested that they be permitted to permanently retire their allowances. Some companies receive as few as 3 allowances which allow the holder to sell up to 3 kilograms of methyl bromide to critical uses. Due to the small allocation and because they typically do not sell critical use methyl bromide, they find the allocation of CSAs, and associated record-keeping and reporting requirements, to be unduly burdensome. In response to this concern, in the Proposed 2007 CUE rule EPA proposed to allow CSA holders, on a voluntary basis, to permanently relinquish their allowances through written notification to the Agency. EPA received no adverse comments. However, no CSA holders contacted EPA to take advantage of that voluntary opportunity.

For purposes of the 2008 CUE rule and beyond, EPA is again allowing CSA holders, on a voluntary basis, to permanently relinquish their allowances through written notification to the person indicated in the ''addresses'' section of this preamble during the comment period for this rulemaking. Such companies would not receive CSA allocations and would be excluded from future allocations. All allowances forfeited by companies through the written notification process will be reallocated to the remaining companies on a pro-rata basis. EPA strongly encourages CSA holders to take advantage of this voluntary opportunity to retire their CSA allocations in order to reduce their administrative burden.

I. Stocks of Methyl Bromide

As discussed above and in the December 23, 2004 Framework Rule, an approved critical user may obtain access to exempted production and import of methyl bromide and to limited inventories of pre-phaseout methyl bromide, the combination of which constitute the supply of ''critical use methyl bromide'' intended to meet the needs of agreed critical uses. The Framework Rule established provisions governing the sale of pre-phaseout inventories for critical uses, including the concept of CSAs and a prohibition on the sale of pre-phaseout inventories for critical uses in excess of the amount of CSAs held by the seller. In the Framework Rule EPA also established trading provisions that allow critical use allowances (CUAs) to be converted into CSAs. Under this proposed action, no significant changes would be made to those provisions.

EPA believes that the refined approach proposed in Section V.D. of this preamble includes important measures that could reduce the risks of methyl bromide shortages for critical uses. For example, this transparent approach allows improved stakeholder comment regarding the amount of available stocks and resulting adjustments to the CUA amounts. However, as in prior years, the Agency will continue to closely monitor CUA and CSA data. Further, as stated in the final 2006 CUE rule, safety valves continue to exist. If an inventory shortage occurs, EPA may consider various options including, but not limited to, promulgating a final version of the petition process proposed on October 27, 2005 (70 FR 62030), taking into account comments received on that proposal; proposing a different administrative mechanism to serve the same purpose; or authorizing conversion of a limited number of CSAs to CUAs through a rulemaking, bearing in mind the upper limit on U.S. production/import for critical uses. In sections V.D. and V.G. of this preamble, EPA seeks comment on the amount of critical use methyl bromide to come from stocks compared to new production and import.

With regard to information about stocks of methyl bromide, EPA has requested such information since late 2003. On December 11, 2003, EPA initially requested information on the amount of methyl bromide held in inventory from a group of five methyl bromide producers, importers, and distributors. The information submitted in response to that Section 114 request was subsequently requested under the Freedom of Information Act (''FOIA''). On August 26, 2004, EPA issued a final determination concerning the confidentiality of that information. In the determination, EPA found that aggregated data on the amount of methyl bromide that had been stockpiled and maintained in inventory in 2002 and 2003 by the group of five businesses (''5-business aggregate'') could not be withheld pursuant to any FOIA exemption. Part of the basis for EPA's determination was that entities' individual information could not be deduced from aggregate stockpile data, and therefore, the 5-business aggregate was not confidential.

Subsequent to the August 26, 2004 determination, two of the businesses whose information was included in the five-business aggregate filed suit to prevent EPA from releasing this information. *Ameribrom* v. *Leavitt et al.*, 2:04–cv–04393 (D.N.J.), was filed September 9, 2004 and *Hendrix and Dail* v. *Leavitt, et al.*, 04–CV–134 (E.D.N.C.), was filed September 14, 2004. However, both companies subsequently filed for voluntary dismissal.

In addition to 2002 and 2003 methyl bromide inventory data for the group of five entities, EPA has collected similar information for a broader group of entities for the years 2003, 2004, 2005 and now 2006. 2003 stockpile data for all entities that held stocks of methyl bromide for sale or for transfer was collected in accordance with a notice published on August 25, 2004 (69 FR 52403) titled ''Request for Information on Existing and Available Stocks of Methyl Bromide.'' 2004 stockpile data for all methyl bromide producers, importers, exporters, distributors, and applicators was collected pursuant to a Section 114 request dated April 15, 2005. 2005 and 2006 stockpile data for all methyl bromide producers, importers, distributors, and applicators was collected pursuant to a rule published on December 13, 2005 (70 FR 73604) that amended methyl bromide reporting requirements at 40 CFR 82.13 in a manner that enables EPA to calculate the aggregate stockpile for each calendar year. On September 7, 2006 the Agency released data on the aggregate amount of methyl bromide held in inventory at the end of calendar years 2003, 2004 and 2005.

On April 23, 2007 EPA sent letters to all entities which had reported holding methyl bromide inventory at the end of 2003, 2004, 2005, or 2006. The letters confirmed EPA's intention to treat the aggregate of the methyl bromide stockpile information reported to the Agency for calendar year 2006 in the same manner as similar aggregates calculated from information for the years 2003, 2004, and 2005. The letters explained that under EPA regulations at 40 CFR 2.204(d)(2), the aggregate of the methyl bromide stockpile information

for calendar year 2006 reported to the Agency under the requirements at 40 CFR 82.13 is clearly not eligible for confidential treatment. This determination was based in part on the great difficulty (due to the number of submitters) of ascertaining the size of any individual entity's methyl bromide stockpile from the information submitted under the reporting requirements at 40 CFR 82.13, as aggregated by the Agency. EPA did not receive any objections to releasing the aggregate information for 2006 and proceeded to release that information on May 14, 2007. The aggregate information for 2003, 2004, 2005, and 2006 is available in the docket for this rulemaking.

In this action, EPA is proposing to release the aggregate of methyl bromide stockpile information reported to the Agency under the reporting requirements at 40 CFR 82.13 for the end of 2007, and each year thereafter. For the reasons given in the April 23, 2007 letters, which are available in the docket, this aggregate information is clearly not entitled to confidential treatment. EPA proposes to release the aggregate of this stockpile data in future years without first notifying entities by letter, as EPA has done in the past two years. EPA seeks comment on this proposal. If the Agency does not receive any comments opposing this proposal, the aggregate of methyl bromide stockpile data collected under the reporting requirements at 40 CFR 82.13 will not be treated as confidential information and may be released in future without further notice.

VI. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order (EO) 12866 (58 FR 51735, October 4, 1993), this action proposes a ''significant regulatory action.'' This action is likely to result in a rule that may raise novel legal or policy issues. Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under EO 12866 and any changes made in response to OMB recommendations have been documented in the docket for this action.

B. Paperwork Reduction Act

This proposed action does not impose any new information collection burden. The Office of Management and Budget (OMB) has previously approved the information collection requirements contained in the existing regulations at 40 CFR Part 82 under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* and has assigned OMB control number 2060–0564, and EPA ICR number 2179.03. A copy of the OMB approved Information Collection Request (ICR) may be obtained from Susan Auby, Collection Strategies Division; U.S. Environmental Protection Agency (2822T); 1200 Pennsylvania Ave., NW., Washington, DC 20460 or by calling (202) 566–1672.

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.

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 in 40 CFR are listed in 40 CFR part 9.

C. Regulatory Flexibility Act

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice-and-comment rulemaking requirements under the Administrative Procedure Act or any other statute 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 organizations, and small governmental jurisdictions. For purposes of assessing the impacts of this proposed rule on small entities, small entity is defined as: (1) A small business that is identified by the North American Industry Classification System (NAICS) Code in the Table below; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less that 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

Category	NAICS code	SIC code	NAICS Small business size standard (in number of employees or millions of dollars)
Agricultural production	1112—Vegetable and Melon farming, 1113—Fruit and Nut Tree Farming, 1114—Greenhouse, Nursery, and Floriculture Production.	0171—Berry Crops, 0172—Grapes, 0173—Tree Nuts, 0175—Deciduous Tree Fruits (except apple orchards and farms), 0179—Fruit and Tree Nuts, NEC, 0181—Ornamental Floriculture and Nursery Products, 0831—Forest Nurseries and Gathering of Forest Products.	$0.75 million.
Storage Uses	115114—Postharvest Crop activities (except Cotton Ginning), 311211—Flour Milling, 311212—Rice Milling, 493110—General Warehousing and Storage, 493130—Farm Product Warehousing and Storage.	2041—Flour and Other Grain Mill Products, 2044—Rice Milling, 4221—Farm Product Warehousing and Storage, 4225—General Warehousing and Storage.	$6.5 million. 500 employees. $23.5 million.

Category	NAICS code	SIC code	NAICS Small business size standard (in number of employees or millions of dollars)
Distributors and Applicators	115112—Soil Preparation, Planting and Cultivating.	0721—Crop Planting, Cultivation, and Protection.	$6.5 million.
Producers and Importers	325320—Pesticide and Other Agricultural Chemical Manufacturing.	2879—Pesticides and Agricultural Chemicals, NEC.	500 employees.

Agricultural producers of minor crops and entities that store agricultural commodities are categories of affected entities that contain small entities. This proposed rule will only affect entities that applied to EPA for a de-regulatory exemption. In most cases, EPA received aggregated requests for exemptions from industry consortia. On the exemption application, EPA asked consortia to describe the number and size distribution of entities their application covered. EPA estimated that 3,218 entities petitioned EPA for an exemption for the 2005 control period. EPA received requests from a comparable number of entities for the 2006 and 2007 control periods. Since many applicants did not provide information on the distribution of sizes of entities covered in their applications, EPA estimated that, based on the above definition, between one-fourth and one-third of the entities may be small businesses. In addition, other categories of affected entities do not contain small businesses based on the above description.

After considering the economic impacts of this proposed rule on small entities, EPA certifies that this action will not have a significant economic impact on a substantial number of small entities. In determining whether a rule has a significant economic impact on a substantial number of small entities, the impact of concern is any significant *adverse* economic impact on small entities, since the primary purpose of the regulatory flexibility analyses is to identify and address regulatory alternatives ''which minimize any significant economic impact of the proposed rule on small entities.'' (5 U.S.C. 603–604). Thus, an Agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves a regulatory burden, or otherwise has a positive economic effect on all of the small entities subject to the rule. Since this rule exempts methyl bromide for approved critical uses after the phaseout date of January 1, 2005, this is a de-regulatory action which will confer a benefit to users of methyl bromide. EPA believes the estimated de-regulatory value for users of methyl bromide is between $20 million and $30 million annually. We have therefore concluded that this proposed rule will relieve regulatory burden for all small entities.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

This proposed rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local, or tribal governments or the private sector. This action is deregulatory and does not impose any new requirements on any entities. Thus, this proposed rule is not subject to the requirements of sections 202 and 205 of the UMRA. Further, EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' The phrase ''policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

This proposed rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. This proposed rule is expected to primarily affect producers, suppliers, importers and exporters and users of methyl bromide. Thus, Executive Order 13132 does not apply to this proposed rule.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure ''meaningful and timely input by

tribal officials in the development of regulatory policies that have tribal implications.'' This proposed rule does not have tribal implications, as specified in Executive Order 13175. This proposed rule does not significantly or uniquely affect the communities of Indian tribal governments. The proposed rule does not impose any enforceable duties on communities of Indian tribal governments. Thus, Executive Order 13175 does not apply to this proposed rule.

G. Executive Order No. 13045: Protection of Children From Environmental Health and Safety Risks

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 Executive Order 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.

EPA interprets Executive Order 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 proposed rule is not subject to Executive Order 13045 because it does not establish an environmental standard intended to mitigate health or safety risks.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This proposed rule is not a ''significant energy action'' as defined in Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001)) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This proposed rule does not pertain to any segment of the energy production economy nor does it regulate any manner of energy use. Therefore, we have concluded that this proposed rule is not likely to have any adverse energy effects.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA''), Public Law No. 104–113, Section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. This rulemaking does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order (EO) 12898 (59 FR 7629 (Feb. 16, 1994)) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this proposed rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations, because it effects the level of environmental protection equally for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population. Any ozone depletion that results from this proposed rule will impact all affected populations equally because ozone depletion is a global environmental problem with environmental and human effects that are, in general, equally distributed across geographical regions.

List of Subjects in 40 CFR Part 82

Environmental protection, Ozone depletion, Chemicals, Exports, Imports.

Dated: August 17, 2007.

Stephen L. Johnson,

Administrator.

For the reasons stated in the preamble, 40 CFR part 82 is proposed to be amended as follows:

PART 82—PROTECTION OF STRATOSPHERIC OZONE

1. The authority citation for part 82 continues to read as follows:

Authority: 42 U.S.C. 7414, 7601, 7671–7671q.

2. Section 82.8 is amended by revising the table in paragraph (c)(1) and paragraph (c)(2) to read as follows:

§ 82.8 Grant of essential use allowances and critical use allowances.

* * * * *

(c) * * *

(1) * * *

Company	2008 Critical use allowances for pre-plant uses* (kilograms)	2008 Critical use allowances for post-harvest uses* (kilograms)
Great Lakes Chemical Corp.—A Chemtura Company	1,691,276	193,248
Albemarle Corp	695,491	79,468
Ameribrom, Inc	384,343	43,916
TriCal, Inc	11,967	1,367
Total	2,783,078	317,998

*For production or import of class I, Group VI controlled substance exclusively for the Pre-Plant or Post-Harvest uses specified in appendix L to this subpart.

(2) Allocated critical stock allowances granted for specified control period. The following companies are allocated critical stock allowances for 2008 on a pro-rata basis in relation to the inventory held by each.

Company
Albemarle
Ameribrom, Inc.
Bill Clark Pest Control, Inc.
Blair Soil Fumigation
Burnside Services, Inc.
Cardinal Professional Products
Carolina Eastern, Inc.
Degesch America, Inc.
Dodson Bros.
Great Lakes Chemical Corp.
Harvey Fertilizer & Gas
Helena Chemical Co.
Hendrix & Dail
Hy Yield Bromine
Industrial Fumigation Company
J.C. Ehrlich Co.
Pacific Ag
Pest Fog Sales Corp.
Prosource One
Reddick Fumigants
Royster-Clark, Inc.
Southern State Cooperative, Inc.
TriCal, Inc.
Trident Agricultural Products
UAP Southeast (NC)
UAP Southeast (SC)
Univar
Vanguard Fumigation Co.
Western Fumigation
Total—1,715,438 kilograms.

3. Appendix L to Subpart A is revised to read as follows:

Appendix L to Subpart A of Part 82—Approved Critical Uses and Limiting Critical Conditions for Those Uses for the 2008 Control Period

Column A	Column B	Column C
Approved critical uses	Approved critical user and location of use	Limiting critical conditions—that either exist, or that the approved critical user reasonably expects could arise without methyl bromide fumigation:
Pre-Plant Uses:		
Cucurbits	(a) Michigan growers	Moderate to severe soilborne disease infestation. A need for methyl bromide for research purposes.
	(b) Southeastern U.S. limited to growing locations in Alabama, Arkansas, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, and Virginia.	Moderate to severe yellow or purple nutsedge infestation. Moderate to severe soilborne disease infestation. Moderate to severe root knot nematode infestation. A need for methyl bromide for research purposes.
	(c) Georgia growers	Moderate to severe yellow or purple nutsedge infestation. Moderate to severe soilborne disease infestation. Moderate to severe root knot nematode infestation. A need for methyl bromide for research purposes.
Eggplant	(a) Florida growers	Moderate to severe yellow or purple nutsedge infestation. Moderate to severe soilborne disease infestation. Restrictions on alternatives due to karst topographical features and soils not supporting seepage irrigation. A need for methyl bromide for research purposes.
	(b) Georgia growers	Moderate to severe yellow or purple nutsedge infestation. Moderate to severe nematode infestation. Moderate to severe pythium collar, crown and root rot. Moderate to severe southern blight infestation. Restrictions on alternatives due to karst topographical features. A need for methyl bromide for research purposes.
	(c) Michigan growers	Moderate to severe soilborne disease infestation. A need for methyl bromide for research purposes.
Forest Nursery Seedlings.	(a) Growers in Alabama, Arkansas, Georgia, Louisiana, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, and Virginia.	Moderate to severe yellow or purple nutsedge infestation. Moderate to severe soilborne disease infestation. Moderate to severe nematode infestation.
	(b) International Paper and its subsidiaries limited to growing locations in Alabama, Arkansas, Georgia, South Carolina, and Texas.	Moderate to severe yellow or purple nutsedge infestation. Moderate to severe soilborne disease infestation.
	(c) Public (government-owned) seedling nurseries in Illinois, Indiana, Kentucky, Maryland, Missouri, New Jersey, Ohio, Pennsylvania, West Virginia, and Wisconsin.	Moderate to severe weed infestation including purple and yellow nutsedge infestation. Moderate to severe Canada thistle infestation. Moderate to severe nematode infestation. Moderate to severe soilborne disease infestation.
	(d) Weyerhaeuser Company and its subsidiaries limited to growing locations in Alabama, Arkansas, North Carolina, and South Carolina.	Moderate to severe yellow or purple nutsedge infestation. Moderate to severe soilborne disease infestation. Moderate to severe nematode or worm infestation.
	(e) Weyerhaeuser Company and its subsidiaries limited to growing locations in Oregon and Washington.	Moderate to severe yellow nutsedge infestation. Moderate to severe soilborne disease infestation.
	(f) Michigan growers	Moderate to severe soilborne disease infestation. Moderate to severe Canada thistle infestation. Moderate to severe nutsedge infestation. Moderate to severe nematode infestation.

Column A	Column B	Column C
Approved critical uses	Approved critical user and location of use	Limiting critical conditions—that either exist, or that the approved critical user reasonably expects could arise without methyl bromide fumigation:
	(g) Michigan herbaceous perennials growers	Moderate to severe nematode infestation. Moderate to severe soilborne disease infestation. Moderate to severe yellow nutsedge and other weed infestation.
Orchard Nursery Seedlings.	(a) Members of the Western Raspberry Nursery Consortium limited to growing locations in California and Washington.	Moderate to severe nematode infestation. Presence of medium to heavy clay soils. Prohibition on use of 1,3-dichloropropene products because local township limits on use of this alternative have been reached. A need for methyl bromide for research purposes.
	(b) Members of the California Association of Nursery and Garden Centers representing Deciduous Tree Fruit Growers.	Moderate to severe nematode infestation. Presence of medium to heavy clay soils. Prohibition on use of 1,3-dichloropropene products because local township limits on use of this alternative have been reached. A need for methyl bromide for research purposes.
	(c) California rose nurseries	Moderate to severe nematode infestation. Prohibition on use of 1,3-dichloropropene products because local township limits on use of this alternative have been reached. A need for methyl bromide for research purposes.
Strawberry Nurseries	(a) California growers	Moderate to severe soilborne disease infestation. Moderate to severe yellow or purple nutsedge infestation. Moderate to severe nematode infestation. A need for methyl bromide for research purposes.
	(b) North Carolina and Tennessee growers	Moderate to severe black root rot. Moderate to severe root-knot nematode infestation. Moderate to severe yellow and purple nutsedge infestation. A need for methyl bromide for research purposes.
Orchard Replant	(a) California stone fruit growers	Moderate to severe nematode infestation. Moderate to severe soilborne disease infestation. Replanted (non-virgin) orchard soils to prevent orchard replant disease. Presence of medium to heavy soils. Prohibition on use of 1,3-dichloropropene products because local township limits on use of this alternative have been reached.
	(b) California table and raisin grape growers	Moderate to severe nematode infestation. Moderate to severe soilborne disease infestation. Replanted (non-virgin) orchard soils to prevent orchard replant disease. Medium to heavy soils. Prohibition on use of 1,3-dichloropropene products because local township limits for this alternative have been reached.
	(c) California wine grape growers	Moderate to severe nematode infestation. Moderate to severe soilborne disease infestation. Replanted (non-virgin) orchard soils to prevent orchard replant disease. Medium to heavy soils. Prohibition on use of 1,3-dichloropropene products because local township limits for this alternative have been reached.
	(d) California walnut growers	Moderate to severe nematode infestation. Moderate to severe soilborne disease infestation. Replanted (non-virgin) orchard soils to prevent orchard replant disease. Medium to heavy soils. Prohibition on use of 1,3-dichloropropene products because local township limits for this alternative have been reached.

Column A	Column B	Column C
Approved critical uses	Approved critical user and location of use	Limiting critical conditions—that either exist, or that the approved critical user reasonably expects could arise without methyl bromide fumigation:
	(e) California almond growers	Moderate to severe nematode infestation. Moderate to severe soilborne disease infestation. Replanted (non-virgin) orchard soils to prevent orchard replant disease. Medium to heavy soils. Prohibition on use of 1,3-dichloropropene products because local township limits for this alternative have been reached.
Ornamentals	(a) California growers	Moderate to severe soilborne disease infestation. Moderate to severe nematode infestation. Prohibition on use of 1,3-dichloropropene products because local township limits for this alternative have been reached. A need for methyl bromide for research purposes.
	(b) Florida growers	Moderate to severe weed infestation. Moderate to severe soilborne disease infestation. Moderate to severe nematode infestation. Restrictions on alternatives due to karst topographical features and soils not supporting seepage irrigation. A need for methyl bromide for research purposes.
Peppers	(b) Alabama, Arkansas, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, and Virginia growers.	Moderate to severe yellow or purple nutsedge infestation. Moderate to severe nematode infestation. Moderate to severe pythium root, collar, crown and root rots. A need for methyl bromide for research purposes.
	(c) Florida growers	Moderate to severe yellow or purple nutsedge infestation. Moderate to severe soilborne disease infestation. Moderate to severe nematode infestation. Restrictions on alternatives due to karst topographical features and soils not supporting seepage irrigation. A need for methyl bromide for research purposes.
	(d) Georgia growers	Moderate to severe yellow or purple nutsedge infestation. Moderate to severe nematode infestation, or moderate to severe pythium root and collar rots. Moderate to severe southern blight infestation, crown or root rot. A need for methyl bromide for research purposes.
	(e) Michigan growers	Moderate to severe soilborne disease infestation. A need for methyl bromide for research purposes.
Strawberry Fruit	(a) California growers	Moderate to severe black root rot or crown rot. Moderate to severe yellow or purple nutsedge infestation. Moderate to severe nematode infestation. Prohibition on use of 1,3-dichloropropene products because local township limits for this alternative have been reached. Time to transition to an alternative. A need for methyl bromide for research purposes.
	(b) Florida growers	Moderate to severe yellow or purple nutsedge infestation. Moderate to severe nematode infestation. Moderate to severe soilborne disease infestation. Carolina geranium or cut-leaf evening primrose infestation. Restrictions on alternatives due to karst topographical features and soils not supporting seepage irrigation a need for methyl bromide for research purposes.
	(c) Alabama, Arkansas, Georgia, Illinois, Kentucky, Louisiana, Maryland, Mississippi, Missouri, New Jersey, North Carolina, Ohio, South Carolina, Tennessee, and Virginia growers.	Moderate to severe yellow or purple nutsedge infestation. Moderate to severe nematode infestation. Moderate to severe black root and crown rot. A need for methyl bromide for research purposes.
Sweet Potato Slips	(a) California growers	Prohibition on use of 1,3-dichloropropene products because local township limits for this alternative have been reached.

Column A	Column B	Column C
Approved critical uses	Approved critical user and location of use	Limiting critical conditions—that either exist, or that the approved critical user reasonably expects could arise without methyl bromide fumigation:
Tomatoes	(a) Michigan growers	Moderate to severe soilborne disease infestation. Moderate to severe fungal pathogen infestation. A need for methyl bromide for research purposes.
	(c) Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, and Virginia growers.	Moderate to severe yellow or purple nutsedge infestation. Moderate to severe soilborne disease infestation. Moderate to severe nematodes. Restrictions on alternatives due to karst topographical features, and in Florida, soils not supporting seepage irrigation. A need for methyl bromide for research purposes.
Post-Harvest Uses:		
Food Processing	(a) Rice millers in all locations in the U.S. who are members of the USA Rice Millers Association.	Moderate to severe infestation of beetles, weevils or moths. Older structures that can not be properly sealed to use an alternative to methyl bromide. Presence of sensitive electronic equipment subject to corrosion. Time to transition to an alternative.
	(b) Pet food manufacturing facilities in the U.S. who are active members of the Pet Food Institute (For this proposed rule, ''pet food'' refers to domestic dog and cat food).	Moderate to severe infestation of beetles, moths, or cockroaches. Older structures that can not be properly sealed to use an alternative to methyl bromide. Presence of sensitive electronic equipment subject to corrosion. Time to transition to an alternative.
	(c) Bakeries in the U.S	Older structures that can not be properly sealed to use an alternative to methyl bromide. Presence of sensitive electronic equipment subject to corrosion. Time to transition to an alternative.
	(d) Members of the North American Millers' Association in the U.S.	Moderate to severe beetle infestation. Older structures that can not be properly sealed to use an alternative to methyl bromide. Presence of sensitive electronic equipment subject to corrosion. Time to transition to an alternative.
	(e) Members of the National Pest Management Association associated with dry commodity structure fumigation (cocoa) and dry commodity fumigation (processed food, herbs and spices, dried milk and cheese processing facilities).	Moderate to severe beetle or moth infestation. Older structures that can not be properly sealed to use an alternative to methyl bromide. Presence of sensitive electronic equipment subject to corrosion. Time to transition to an alternative.
Commodities	(a) California entities storing walnuts, beans, dried plums, figs, raisins, dates (in Riverside county only), and pistachios in California.	Rapid fumigation is required to meet a critical market window, such as during the holiday season, rapid fumigation is required when a buyer provides short (2 working days or less) notification for a purchase or there is a short period after harvest in which to fumigate and there is limited silo availability for using alternatives. A need for methyl bromide for research purposes.
Dry Cured Pork Products.	(a) Members of the National Country Ham Association	Red legged ham beetle infestation. Cheese/ham skipper infestation. Dermested beetle infestation. Ham mite infestation.
	(b) Members of the American Association of Meat Processors.	Red legged ham beetle infestation. Cheese/ham skipper infestation. Dermested beetle infestation. Ham mite infestation.
	(c) Nahunta Pork Center (North Carolina)	Red legged ham beetle infestation. Cheese/ham skipper infestation. Dermested beetle infestation. Ham mite infestation.
	(d) Gwaltney and Smithfield Inc	Red legged ham beetle infestation. Cheese/ham skipper infestation. Dermested beetle infestation. Ham mite infestation.

[FR Doc. E7–16896 Filed 8–24–07; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–R04–SFUND–2007–0720; FRL–8458–8]

National Oil and Hazardous Substance Pollution Contingency Plan National Priorities List

AGENCY: Environmental Protection Agency.

ACTION: Notice of intent to delete the Standard Auto Bumper Superfund Site from the National Priorities List.

SUMMARY: The Environmental Protection Agency (EPA) Region 4 is issuing a notice of intent to delete the Standard Auto Bumper Superfund Site (Site) located in Hialeah, Florida, from the National Priorities List (NPL) and requests public comments on this notice of intent. The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is found at Appendix B of 40 CFR part 300 which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). The EPA and the State of Florida, through the Florida Department of Environmental Protection (FDEP), have determined that all appropriate response actions under CERCLA, other than operation and maintenance and five-year reviews, have been completed. However, this deletion does not preclude future actions under Superfund.

In the ''Rules and Regulations'' section of today's **Federal Register**, we are publishing a direct final notice of deletion of the Standard Auto Bumper Superfund Site without prior notice of intent to delete because we view this as a noncontroversial revision and anticipate no adverse comment. We have explained our reasons for this deletion in the preamble to the direct final deletion. If we receive no adverse comment(s) on this notice of intent to delete or the direct final notice of deletion, we will not take further action on this notice of intent to delete. If we receive adverse comment(s), we will withdraw the direct final notice of deletion and it will not take effect. We will, as appropriate, address all public comments in a subsequent final deletion notice based on this notice of intent to delete. We will not institute a second comment period on this notice of intent to delete. Any parties interested in commenting must do so at this time. For additional information, see the direct final notice of deletion which is located in the Rules section of this **Federal Register**.

DATES: Comments concerning this Site must be received by September 26, 2007.

ADDRESSES: Submit your comments, identified by EPA–R04–SFUND–2007–0720, by one of the following methods:

1. *www.regulations.gov:* Follow the on-line instructions for submitting comments.

2. *E-mail: taylor.michael@epa.gov.*

3. *Fax:* (404) 562–8896.

4. *Mail:* EPA–R04–SFUND–2007–0720, Superfund Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960.

5. *Hand Delivery or Courier:* Michael Taylor, Remedial Project Manager, Superfund Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Michael Taylor, Remedial Project Manager, Superfund Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960, Phone: (404) 562–8762, Electronic Mail: *taylor.michael@epa.gov.*

SUPPLEMENTARY INFORMATION: For additional information, see the Direct Final Notice of Deletion which is located in the Rules section of this **Federal Register**.

Information Repositories: Repositories have been established to provide detailed information concerning this decision at the following addresses:

1. John F. Kennedy Memorial Library, Hialeah Public Library, 190 West 49th Street, Hialeah, Florida 33012, Hours: Monday through Thursday–10 a.m. until 8:45 p.m., and Friday–Saturday–9:30 a.m. until 4:45 p.m.

2. U.S. EPA Record Center, Attn: Ms. Debbie Jourdan, Atlanta Federal Center, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960, Phone: (404) 562–8862, Hours 8 a.m. to 4 p.m., Monday through Friday by appointment only.

Dated: August 13, 2007.

J.I. Palmer, Jr.,

Regional Administrator, Region 4.

[FR Doc. E7–16684 Filed 8–24–07; 8:45 am]
BILLING CODE 6560–50–P

Notices

Federal Register
Vol. 72, No. 165
Monday, August 27, 2007

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

Submission for OMB Review; Comment Request

August 22, 2007.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (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 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 should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8681.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Rural Business Service

Title: 7 CFR 4284–G, Rural Business Opportunity Grants.

OMB Control Number: 0570–0024.

Summary of Collection: The Rural Business Opportunity Grant (RBOG) program was authorized by section 741 of the Federal Agriculture Improvement and Reform Act of 1996, Public Law 104–127. 7 CFR 4284–G provides the detailed program regulations, as well as, including application procedures and reporting requirements for grant recipients. The objective of the RBOG program is to promote sustainable economic development in rural areas. This purpose is achieved through grants made by the Rural Business Cooperative Service (RBS) to public and private non-profit organizations and cooperatives to pay costs of economic development planning and technical assistance for rural businesses.

Need and Use of the Information: The information collected is from grant applicants and grant recipients. Grantees should keep complete and accurate accounting records as evidence that the grant funds were used properly. The information is necessary for RBS to process applications in a responsible manner, make prudent program decisions, and effectively monitor the grantees' activities to ensure that funds obtained from the Government are used appropriately.

Description of Respondents: Not for-profit institutions; State, Local or Tribal Government.

Number of Respondents: 248.

Frequency of Responses: Recordkeeping: Reporting: On occasion; Quarterly; Monthly.

Total Burden Hours: 17,054.

Charlene Parker,

Departmental Information Collection Clearance Officer.

[FR Doc. E7–16915 Filed 8–24–07; 8:45 am]

BILLING CODE 3410–XT–P

DEPARTMENT OF AGRICULTURE

Forest Service

Off-Highway Vehicle Travel Management Plan

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The Mt. Hood National Forest (Forest) will prepare an Environmental Impact Statement (EIS) to document and disclose the potential environmental effects of establishing and designating a system of roads, trails and areas for off-highway vehicles (OHV). The Proposed Action will change OHV access through much of the Forest in order to meet the intent of the *Travel Management; Designated Routes and Areas for Motor Vehicle Use; Final Rule* that was published on November 9, 2005 (70 FR 216). The Proposed Action focuses on travel management within six proposed OHV areas and motorized access to dispersed (undeveloped) camping. Within each area, specific OHV routes are proposed by motor vehicle class, and new trails are proposed for construction where they would create trail loop opportunities. A Forest Plan Amendment would be required to achieve the purpose and need, and implement the Proposed Action.

DATES: Comments concerning the scope of this analysis must be received no later than October 1, 2007 to ensure they are fully incorporated into the Draft EIS. Two public meetings are scheduled as follows.

1. September 11, 2007 from 6 p.m. to 7:30 p.m. in Portland, OR.

2. September 12, 2007 from 6 p.m. to 7:30 p.m. in Hood River, OR.

ADDRESSES: Submit written comments to Jennie O'Connor, Off-Highway Vehicle Travel Management Plan Leader, Mt. Hood National Forest, 6780 Highway 35, Parkdale, Oregon 97041. Electronic comments can be submitted to *comments-pacificnorthswest-mthood@fs.fed.us.* The meeting locations are:

1. University Place Hotel and Conference Center in the Willamette Falls Room (310 SW Lincoln Street, Portland, OR 97201).

2. Best Western Hood River Inn in the Riverview Room (1108 East Marina Way, Hood River, OR 97031).

FOR FURTHER INFORMATION CONTACT: Jennie O'Connor, Natural Resource Planner, Mt. Hood National Forest, 6780 Highway 35, Parkdale, Oregon 97041 or by e-mailing *jmoconnor@fs.fed.us* or by calling (541) 352–6002 x634.

SUPPLEMENTARY INFORMATION:

Need for the Proposal

One purpose of this project is to designate routes for off-highway vehicle (OHV) use by class of vehicle (excluding over-snow vehicles) and time of year. Another purpose of this project is to determine where licensed motor vehicles will continue to be allowed to drive off roads to access dispersed (undeveloped) camping. By meeting these purposes, the Mt. Hood National Forest will comply with 36 CFR parts 212, 251, 261, and 295—*Travel Management; Designated Routes and Areas for Motor Vehicle Use; Final Rule* [**Federal Register**, Vol. 70, No. 215 (2005)] for off-highway vehicle (OHV) use. The final rule states that we ''must strike an appropriate balance in managing all types of recreational activities. To this end, a designated system of roads, trails, and areas for motor vehicle use established with public involvement will enhance public enjoyment of National Forests while maintaining other important values and uses of NFS [National Forest Systems] lands'' (page 28265). This National Environmental Policy Act (NEPA) process will only address OHV use and motorized access to dispersed camping; subsequent NEPA processes may address access and travel management issues.

In order to comply with the OHV and motorized access to dispersed camping portions of the Final Travel Management Rule, there is the underlying need for:

- Designating and/or constructing OHV routes and areas (as appropriate) within the identified six areas to provide recreation opportunities;
- Changing the current management direction in the Mt. Hood Land and Resource Management Plan to comply with the Final Travel Management Rule;
- Balancing recreation opportunities for OHV use with other recreational uses of the National Forest and resource sustainability; and
- Designating areas where licensed vehicles will continue to be allowed to drive off roads for the purpose of accessing dispersed camping.

Proposed Action

The Proposed Action will change OHV access through much of the Forest in order to meet the intent of the Final Travel Management Rule. The Proposed Action focuses on travel management within six proposed OHV areas and motorized access to dispersed camping. All National Forest System lands were considered by the Forest Service and members of the public during a two-year long dialogue with the public. The six areas resulted from this dialogue provide a balance between providing recreational opportunities and protecting natural resources as required by the Final Travel Management Rule.

Within each area, specific OHV routes are proposed by motor vehicles class, and new trails are proposed for construction where they would create trail loop opportunities. Through the NEPA planning process, the Forest Service will consider alternative OHV routes within each of the six designated OHV areas. OHV use would be allowed only on these designated routes.

The six areas proposed for OHV use are listed below.

- McCubbins Gulch, Barlow Ranger District.
- Rock Creek, Barlow Ranger District.
- Gibson Prairie, Hood River Ranger District.
- Bear Creek, Hood River Ranger District.
- Peavine, Clackamas Ranger District.
- LaDee Flats, Clackamas Ranger District.

The Forest Service's Proposed Action includes the following features.

- Some roads identified in the Roads Analysis—Mt. Hood National Forest (2003) as decision roads (not needed for management purposes) would be converted to OHV trails and removed from the road system in order to improve the safety of all users.
- New OHV trails would be constructed within these six areas to connect existing roads and trails and to provide loop routes.
- Some decisions roads would be proposed to be closed, if designating nearby routes would cause these roads to become a law enforcement or natural resource problem. Approximately 12 miles of roads are proposed to be closed.
- Mixed-use routes would be proposed in each area. Mixed-use routes allow OHV and licensed motor vehicles to use the same routes.
- Classes of motor vehicles allowed would be designated for all routes.
- An area within the Rock Creek OHV area would have some restrictions on camp fires and overnight dispersed camping.
- A staging area would be identified within each OHV area. The staging area would be a day-use area that serves as a trailhead for motorized recreation. McCubbins Gulch Campground would continue to be the staging area for this OHV area.

In addition to OHV use, motorized access to dispersed camping will be designated for the Forest. Licensed motor vehicles would be allowed to leave the designated road system up to 150-feet from a proposed designated route to access dispersed camping. Some routes are not proposed in order to protect natural resources (e.g., sensitive species) or to comply with existing management direction (e.g., no motorized use in wilderness or some wild and scenic rivers).

A Forest Plan amendment would be required to achieve the purpose and need, and implement the Proposed Action. The Amendment would close all areas and roads to OHV use, unless designated open; and would discontinue all motorized use cross-country use, except allowing licensed motorized access to dispersed camping in designated area.

Interactive electronic maps and route data and other information about the project are available on the Internet at: *http://www.fs.fed.us/r6/mthood/projects/.* Also, maps of the proposed areas and additional information on the proposal are available by contacting Jennie O'Connor, Mt. Hood National Forest (see above).

Proposed Scoping

As directed by the National Environmental Policy Act (1969), the Forest Service is now seeking comments from individuals, organizations, local and state governments, and other federal agencies that may be interested in or affected by the proposed action. Comments may pertain to the nature and scope of the environmental, social, and economic issues, and possible alternatives to the proposed action. Comments will help the Forest Service assess the proposed action, develop alternatives and prepare a draft environmental impact statement.

The Forest Service will host two open houses to present and answer questions about the proposed action. The meetings are scheduled for September 11, 2007 in Portland from 6 p.m. to 7:30 p.m. and for September 12, 2007 in Hood River from 6 p.m. to 7:30 p.m. Since there will be no formal presentations at the open houses, please feel free to come at any time during the meetings.

Preliminary Issues Identified to Date

The potential for impacts/effects as a result of designating and constructing OHV routes as well as motorized access to dispersed camping are important considerations that need to be addressed in the analysis. The following issues were identified during the preliminary effects analysis and public input in designating the OHV routes, both conducted in 2005.

- *Soils:* Sedimentation input from the disturbance next to streams. Impacts to

cryptobiotic crust, which do not recover quickly.

• *Fisheries:* Presence of threatened, endangered and sensitive aquatic species. Potential stream crossings by OHVs. Trails located within riparian reserves.

• *Botany:* Impacts to sensitive plant, fungi, lichen and moss habitat, if users venture off designated routes. Increased potential to spread non-native invasive plants.

• *Law enforcement:* Capacity to enforce designated OHV routes and ability to keep users to the designated routes.

• *Fire and fuels:* Increased potential for fire starts, especially at staging areas.

• *Recreation:* Conflicts between user groups, particularly non-motorized and motorized trail use.

• *Social:* Increased accidents, noise and crime due to increased OHV use. Potential sanitation problems associated with the more people. Conflicts with local residents.

Alternatives Considered

The No Action alternative will serve as a baseline for comparison of alternatives. This alternative will offer no treatment of affected sites. It will be fully developed and analyzed. The proposed action, as described above will be considered as an alternative. Additional alternatives may be developed around the proposed action to address key issues identified in the scoping and public involvement process.

Estimated Dates for Draft and Final EIS

The draft EIS is expected to be filed with the Environmental Protection Agency (EPA) and to be available for public comment by April 2007. The comment period on the draft EIS will be 45 days from the date the EPA publishes the notice of availability in the **Federal Register.**

The Forest Service believes, at this early state, it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, reviewers of the draft EIS must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions. *Vermont Yankee Nuclear Power Corp.* v. *NRDC.* 435 U.S. 519.553 (1978). Also, environmental objectives that could be raised at the draft EIS stage but that are not raised until after the completion of the final EIS may be waived or dismissed by the courts. *City of Angoon* v. *Hodel,* 803 F. 2d 1016, 1022 (9th Cir. 1986) and *Wisconsin Heritage, Inc.* v. *Harris,* 490 F. Supp. 1334 (E.D. Wis. 1980). Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the 45-day comment period; so that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to them in the final EIS.

To assist the Forest Service in identifying and considering issues and concerns on the proposed action, comments on the draft EIS should be as specific as possible. It is also helpful if the comments refer to specific pages or chapters of the draft statement. Comments may also address the adequacy of the draft EIS or the merits of the alternatives formulated and discussed in the statement. Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act (40 CFR 1503.3).

Comments received in response to this solicitation, including names and addresses of those who comment, will be considered part of the public record on this proposed action and will be available for public inspection. Comments submitted anonymously will be accepted and considered; however, those who submit anonymous comments may not have standing to appeal the subsequent decision under 36 CFR part 215. Additionally, pursuant to 7 CFR 1.27(d), any person may request the agency to withhold a submission from the public record by showing how the Freedom of Information Act (FOIA) permits such confidentiality. Persons requesting such confidentiality should be aware that, under the FOIA, confidentiality may be granted in only very limited circumstances, such as to protect trade secrets. The Forest Service will inform the requester of the agency's decision regarding the request for confidentiality, and where the request is denied, the agency will return the submission and notify the requester that the comments may be resubmitted with or without name and address within a specified number of days.

Comments on the draft EIS will be analyzed, considered, and responded to by the Forest Service in preparing the final EIS. The final EIS is scheduled to be completed in June 2008. The Responsible Official will be Gary Larsen, Forest Supervisor of the Mt. Hood National Forest. He will consider comments, responses, environmental consequences discussed in the final EIS, and applicable laws, regulations, and policies in making a decision regarding this proposed action. The responsible official will document the decision and rationale for the decision in the Record of Decision. It will be subject to Forest Service Appeal Regulations (36 CFR part 215).

Dated: August 17, 2007.

Gary L. Larsen,

Forest Supervisor, Mt. Hood National Forest.

[FR Doc. 07–4164 Filed 8–24–07; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

National Agricultural Library

Notice of Intent To Seek Approval To Collect Information

AGENCY: USDA, Agricultural Research Service, National Agricultural Library.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13) and Office of Management and Budget (OMB) regulations at 5 CFR part 1320 (60 FR 44978, August 29, 1995), this notice announces the National Agricultural Library's intent to request approval for renewal information collection relating to existing nutrition education and training materials targeting low-income persons. This voluntary form gives Food Stamp nutrition education providers the opportunity to share resources that they have developed or used.

DATES: Comments on this notice must be received by 65 days after date of publication in the **Federal Register** to be assured of consideration.

ADDRESSES: Address all comments concerning this notice to Gina Hundley, Technical Information Specialist, Food and Nutrition Information Center, National Agricultural Library, 10301 Baltimore Avenue, Beltsville, MD 20705–2351, telephone (301) 504–5368 or fax (301) 504–6409.

Submit electronic comments to *ghundley@nal.usda.gov*

SUPPLEMENTARY INFORMATION:

Title: Food Stamp Nutrition Connection Resource Sharing Form.

OMB Number: 0518–0031.

Expiration Date: Three years from date of approval.

Type of Request: Renewal of existing data collection from Food Stamp nutrition education providers.

Abstract: This voluntary ''Sharing Form'' gives Food Stamp nutrition education providers the opportunity to share information about resources that they have developed or used. Data

collected using this form helps the Food and Nutrition Information Center (FNIC) identify existing nutrition education and training resources for review and inclusion in an online database. Educators can search this database via the Food Stamp Nutrition Connection Web site *http://foodstamp.nal.usda.gov.* In 2001, the United States Department of Agriculture's (USDA) Food and Nutrition Service established the Food Stamp Nutrition Connection to improve access to Food Stamp Program nutrition resources. Educators nationwide can use this site to identify curricula, lesson plans, research, training tools and participant materials. Developed and maintained at the National Agricultural Library's FNIC, this resource system helps educators find the tools and information they need to provide quality nutrition education for low-income audiences.

The Sharing Form is available for completion online at the Food Stamp Nutrition Connection Web site. Individuals may also print the form and return it via fax or mail. The form consists of four parts. These various sections include: Part 1 consisting of three questions about the responder; Part 2 with nine questions about the resource; Part 3 with five questions about the resource development; and Part 4 with six questions about ordering/obtaining the resource. Responders are asked to complete only relevant sections of the form. Instructions about which sections to complete, based on one's relationship to the resource, are provided in Part 1. For instance, those that use the resource but are neither its developer or distributor would only complete Parts 1 and 2.

This form enables FNIC to inform nutrition educators of existing nutrition education and training materials targeting low-income Americans. This identification of existing materials will help educators spend their monies wisely in the development of needed educational resources.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 0.7 minutes per response.

Respondents: Food Stamp nutrition education providers.

Estimated Number of Respondents: 50 per year.

Estimated Total Annual Burden on Respondents: 16.

Comments

Comments are invited on (a) whether the proposed collection of information is necessary for the proper performance for the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and the assumptions used; (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 those who respond, including the use of appropriate automated, electronic, mechanical, or other technology. Comments should be sent to the address in the preamble. All responses to this notice will be summarized and included in the request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record.

Antoinette Betschart,

Associate Administrator, ARS.

[FR Doc. E7–16847 Filed 8–24–07; 8:45 am]

BILLING CODE 3410–03–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Deemed Export Advisory Committee; Notice of Partially Closed Meeting

The Deemed Export Advisory Committee (DEAC) will meet in an open session on Monday, September 10, 2007 from 9 a.m.–11 a.m. in the main auditorium of the Herbert C. Hoover building, 14th Street & Pennsylvania Avenue, Washington, DC 20230. Registration will begin at 8:30 a.m. The HCHB is easily accessible from the Federal Triangle metro stop. Public parking is available for a fee in the Ronald Reagan International Trade Center across 14th street.

The DEAC is a Federal Advisory Committee established in accordance with the requirements of the Federal Advisory Committee Act, as amended, 5 U.S.C. app. 2. It advises the Secretary of Commerce on deemed export licensing policy. A tentative agenda of topics for discussion is listed below. While these topics will likely be discussed, this list is not exhaustive and there may be discussion of other related items during the public session.

September 10, 2007

Public Session

1. Introductory Remarks.
2. Current Deemed Export Control Policy Issues.
3. Technology Transfer Issues.
4. U.S. Industry Competitiveness.
5. U.S. Academic and Government Research Communities.
6. Industry, Academia and other Stakeholder Comments.

A limited number of seats will be available for the public session. Reservations will not be accepted. To the extent time permits, members of the general public may present oral statements to the DEAC. The general public may submit written statements at any time before or after the meeting. However, to facilitate distribution to DEAC members, BIS suggests that general public presentation materials or comments be forwarded before the meeting to Ms. Yvette Springer at *Yspringer@bis.doc.gov.*

September 10, 2007

Closed Session

The DEAC will also meet in a closed session on Monday, September 10, 2007, from approximately 11 a.m.–4:30 p.m. During the closed session, there will be discussion of matters determined to be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 sections 10(a)(1) and 10(a)(3). The Assistant Secretary for Administration formally determined on September 20, 2007 pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. app. 2 section (10(d)), that the portion of the meeting concerning trade secrets and commercial or financial information deemed privileged or confidential as described in 5 U.S.C. 552b(c)(4), the portion of the meeting concerning matters the premature disclosure of which would be likely to significantly frustrate implementation of an agency action as described in 5 U.S.C. 552b(c)(9)(B), and the portion of the meeting dealing with matters that are (A) specifically authorized under criteria established by an Executive Order to be kept secret in the interests of national defense or foreign policy and (B) in fact properly classified pursuant to such Executive Order (5 U.S.C. 552b(c)(1)(A) and (10(B)), shall be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 sections 10(a)(1) and 10(a)(3). All other portions of the DEAC meeting will be open to the public.

For more information, please call Yvette Springer at (202) 482–2813.

Dated: August 22, 2007.

Yvette Springer,

Committee Liaison Officer.

[FR Doc. 07–4185 Filed 8–24–07; 8:45 am]

BILLING CODE 3510–JT–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN: 0648–XB99

South Atlantic Fishery Management Council; Public Meetings (Addendum)

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

ACTION: Addendum to Earlier Notice - South Atlantic Fishery Management Council to meet September 17–21, 2007 meeting in N. Myrtle Beach SC.

SUMMARY: In addition to the items noted in the earlier Notice for the September 17–21, 2007 meeting of the South Atlantic Fishery Management Council (Council), the full Council will also consider a control date for the commercial dolphin/wahoo sector and the Council will take action as appropriate.

DATES: The meeting will be held in September 2007. See **SUPPLEMENTARY INFORMATION** for specific dates and times.

ADDRESSES: The meeting will be held at the Avista Resort, 300 North Ocean Boulevard, N. Myrtle Beach, SC, 29582; Telephone: (1–800) 968–8986 or 843/249–2521. Copies of documents are available from Kim Iverson, Public Information Officer, South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer; telephone: (843) 571–4366 or toll free at (866) SAFMC–10; fax: (843) 769–4520; email: *kim.iverson@safmc.net*.

SUPPLEMENTARY INFORMATION: The original notice published on August 14, 2007 (72 FR 45419).

Meeting Date

Council Session: September 21, 2007, 10:45 a.m. - 12 noon

Documents regarding these issues are available from the Council office (see **ADDRESSES**).

Although non-emergency issues not contained in this agenda may come before this Council for discussion, those issues may not be the subjects of formal Council action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305 (c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Except for advertised (scheduled) public hearings and public comment, the times and sequences specified on this agenda are subject to change.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Council office (see **ADDRESSES**) 2 days prior to the beginning of the meeting.

Dated: August 21, 2007.

Emily Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. E7–16877 Filed 8–24–07; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF DEFENSE

Office of the Secretary

[No. DoD–2006–OS–0215]

Submission for OMB Review; Comment Request

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

DATES: Consideration will be given to all comments received by September 26, 2007.

Title, Form, and OMB Number: Involuntary Allotment Application; DD Form 2653; OMB Control Number 0704–0367.

Type of Request: Revision.

Number of Respondents: 7,883.

Responses Per Respondent: 1.

Annual Responses: 7,883.

Average Burden Per Response: 30 minutes.

Annual Burden Hours: 3,942.

Needs and Uses: This information collection requirement is necessary to initiate an involuntary allotment from the pay of a member of the Uniformed Services for indebtedness owed a third party under 5 U.S.C. 5520a. 5 U.S.C. 5520a authorizes involuntary allotments if there is a final court judgment acknowledging the debt and it is determined by competent military or executive authority to be in compliance with the procedural requirements of the Servicemembers Civil Relief Act. In order to satisfy these statutory requirements, the DD Form 2653, requires the respondent to provide identifying information on the member of the Uniformed Services; provide a certified copy of the judgment, and certify, if applicable, that the judgment complies with the Servicemembers Civil Relief Act.

Affected Public: Business or other for-profit, individuals or households.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: Ms. Hillary Jaffe.

Written comments and recommendations on the proposed information collection should be sent to Ms. Jaffe at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503.

You may also submit comments, identified by docket number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DoD Clearance Officer: Ms. Patricia Toppings.

Written requests for copies of the information collection proposal should be sent to Ms. Toppings at WHS/ESD/Information Management Division, 1777 North Kent Street, RPN, Suite 11000, Arlington, VA 22209–2133.

Dated: August 21, 2007.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 07–4172 Filed 8–24–07; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Office of the Secretary

[No. DoD–2007–OS–0016]

Submission for OMB Review; Comment Request

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the

Paperwork Reduction Act (44 U.S.C. Chapter 35).

DATES: Consideration will be given to all comments received by September 26, 2007.

Title, Form and OMB Number: Department of Defense Public and Community Service (PACS) Program; DD Forms 2581 and 2581–1; OMB Control Number 0704–0324.

Type of Request: Extension.

Number of Respondents: 414

Responses Per Respondent: 1.

Annual Responses: 414.

Average Burden Per Response: 14 minutes.

Annual Burden Hours: 97.

Needs and Uses: In accordance with 10 U.S.C. 1143a(c), the Public and Community Service (PACS) Registry provides registered PACS organizations with information regarding the availability of individuals with interest in working a PACS organization. The 800 phone resume request line associated with this information collection, as well as the DD Form 2581, ''Operation Transition Employer Registration'' and DD Form 2581–1, ''Public and Community Service Organization Validation,'' are used in support of the Department of Defense program for public service employment assistance.

Affected Public: Business or other for-profit, not-for-profit institutions, Federal government, state, local or tribal government.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: Ms. Hillary Jaffe.

Written comments and recommendations on the proposed information collection should be sent to Ms. Jaffe at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503.

You may also submit comments, identified by docket number and title, by the following method:

• *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Patricia Toppings.

Written requests for copies of the information collection proposal should be sent to Ms. Toppings at WHS/ESD/Information Management Division, 1777 North Kent Street, RPN, Suite 11000, Arlington, VA 22209–2133.

Dated: August 21, 2007.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 07–4173 Filed 8–24–07; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Office of the Secretary

[No. DoD–2007–OS–0017]

Submission for OMB Review; Comment Request

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

DATES: Consideration will be given to all comments received by September 26, 2007.

Title, Form, and OMB Number: National Security Education Program (NSEP) Service Agreement for Scholarship and Fellowship Awards, DD Form 2752; and National Security Education Program (NSEP) Service Agreement Report (SAR), DD Form 2753; OMB Control Number 0704–0368.

Type of Request: Revision.

Number of Respondents: 1,650.

Responses per Respondent: 1.

Annual Responses: 1,650.

Average Burden per Response: 10 minutes.

Annual Burden Hours: 275.

Needs and Uses: This information collection requirement is necessary to obtain verification that applicable scholarship and fellowship recipients are fulfilling service obligation mandated by the National Security Education Program Act of 1991, Title VIII of Pub. L. 102–183, as amended.

Affected Public: Individuals or households; Federal government.

Frequency: Annually.

Respondent's Obligation: Mandatory.

OMB Desk Officer: Ms. Hillary Jaffe.

Written comments and recommendations on the proposed information collection should be sent to Ms. Jaffe at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503.

You may also submit comments, identified by docket number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DoD Clearance Officer: Ms. Patricia Toppings.

Written requests for copies of the information collection proposal should be sent to Ms. Toppings at WHS/ESD/Information Management Division, 1777 North Kent Street, RPN, Suite 11000, Arlington, VA 22209–2133.

Dated: August 21, 2007.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 07–4174 Filed 8–24–07; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Office of the Secretary

[No. DoD–2007–OS–0093]

Proposed Collection: Comment Request

AGENCY: Department of Defense, Defense Security Service.

ACTION: Notice.

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Defense Security Service (DSS) announces the proposed extension of a public information collection affecting cleared DoD contractors and seeks public comments on the provision thereof. Comments are invited on: (a) Whether the proposed collection shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the information to be collected; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by October 26, 2007.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

• *Mail:* Federal Docket Management System Office, 1160 Defense Pentagon, Washington, DC 20301–1160.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed data collection or obtain a copy of the proposal and associated collection instrument, please write to the Defense Security Service, Program Integration Branch, 1340 Braddock Place, Alexandria, VA 22314–1650, or call Defense Security Service, (703) 325–5327.

Title, Associated Form, and OMB Number: ''Department of Defense Security Agreement'', ''Appendage to Department of Defense Security Agreement'' ''Certificate Pertaining to Foreign Interests''; DD Forms 441, 441–1 and SF 328; OMB Control Number 0704–0194.

Needs and Uses: Executive Order (EO) 12829, ''National Industrial Security Program (NISP)'' stipulates that the Secretary of Defense shall serve as the Executive Agent for inspecting and monitoring the contractors, licensees, and grantees who require or will require access to or who store or will store classified information; and for determining the eligibility for access to classified information of contractors, licensees, and grantees and their respective employees. The specific requirements necessary to protect classified information released to private industry are set forth in DoD 5200.22–M. ''National Industrial Security Program Operating Manual (NISPOM).'' Respondents must execute DD Form 441, ''Department of Defense Security Agreement,'' which is the initial contract between industry and the government. This legally binding document details the responsibility of both parties and obligates the contractor to fulfill requirements outlined in DoD 5220.22–M. The DD Form 441–1, ''Appendage to Department of Defense Security Agreement,'' is used to extend the agreement to branch offices of the contractor. SF Form 328, ''Certificate Pertaining to Foreign Interests'' must be submitted to provide certification regarding elements of Foreign Ownership, Control or Influence (FOCI) as stipulated in paragraph 2–302b of the DoD 5220.22–M.

Affected Public: Business or other for-profit and not-for-profit institutions.

Total Annual Burden Hours: 9,108.

Number of Respondents: 3,070.

Responses Per Respondent: 2.

Average Burden Per Respondent: 1.5 hours.

Frequency: One time and/or on occasion (e.g., initial facility clearance processing, when the respondent changes: name, organizational structure, moves; or upon request, etc.)

SUPPLEMENTARY INFORMATION:

Summary of Information Collection

The execution of the DD Form 441, 441–1 and SF 328 is a factor in making a determination as to whether a contractor is eligible to have a facility security clearance. It is also a legal basis for imposing NISP security requirements on eligible contractors. These requirements are necessary in order to preserve and maintain the security of the United States through establishing standards to prevent the improper disclosure of classified information.

Dated: August 21, 2007.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 07–4175 Filed 8–24–07; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Office of the Secretary

[No. DoD–2007–OS–0092]

Proposed Collection; Comment Request

AGENCY: Defense Security Service, DoD.

ACTION: Notice.

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Defense Security Service announces the proposed extension of a public information collection and seeks public comments on the provision thereof. 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 information collection, (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by October 26, 2007.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

• *Mail:* Federal Docket Management System Office, 1160 Defense Pentagon, Washington, DC 20301–1160.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instrument, please write to the Defense Industrial Security Clearance Office (DISCO), 2780 Airport Drive, Suite 400, Columbus, OH 43219–2268, or call DISCO at (614) 827–1530/1528.

Title, Associated Form and OMB Number: Personnel Security Clearance Change Notification; NISCO Form 562; OMB Control Number 0704–0418.

Needs and Uses: DISCO Form 562 is used by contractors participating in the National Industrial Security Program to report various changes in employee personnel clearance status or identification information, e.g., reinstatements, conversions, terminations, changes in name or other previously submitted information.

Affected Public: Business or other for-profit; not-for-profit institutions.

Annual Burden Hours: 45,816.

Number of Respondents: 11,454.

Responses Per Respondent: 20.

Average Burden Per Response: 12 minutes.

Frequency: On occasion.

SUPPLEMENTARY INFORMATION:

Summary of Information Collection

The execution of the DISCO FORM 562 is a factor in making a

determination as to whether a contractor employee is eligible to have a security clearance. These requirements are necessary in order to preserve and maintain the security of the United States through establishing standards to prevent the improper disclosure of classified information.

Dated: August 21, 2007.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 07–4176 Filed 8–24–07; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Office of the Secretary

[No. DoD–2007–OS–0091]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense (Personnel and Readiness), DoD.

ACTION: Notice.

In compliance with section 3506(c)(2)(A) of the *Paperwork Reduction Act of 1995,* the Office of the Under Secretary of Defense (Personnel and Readiness) announces the following proposed new public information collection and seeks public comment on the provisions thereof. 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 burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by October 26, 2007.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

• *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

• *Mail:* Federal Docket Management System Office, 1160 Defense Pentagon, Washington, DC 20301–1160.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Office of the Under Secretary of Defense (Personnel and Readiness), ATTN: Lieutenant Colonel Ronald S. Hunter, 4000 Defense Pentagon, Washington, DC 20301–4000, or call at (703) 695–3176.

Title, Associated Form, and OMB Control Number: Survivor Benefit Plan (SBP)/Reserve Component (RC) SBP Request for Deemed Election; DD Form 2656–10, OMB Control Number 0704–TBD.

Needs and Uses: This information collection requirement is necessary to properly identify the former spouse who is eligible to request a deemed SBP election on behalf of the member. Since a Uniformed Services member may have more than one former spouse, the requested information will serve to identify the correct former spouse.

Affected Public: Individuals or households.

Annual Burden Hours: 400.

Number of Respondents: 1,200.

Responses Per Respondent: 1.

Average Burden Per Response: 20 minutes.

Frequency: On occasion.

SUPPLEMENTARY INFORMATION:

Summary of Information Collection

A former spouse who has been awarded coverage under the Survivor Benefit Plan either by court order or written agreement, may, within one year of such court order or written agreement submit a request to have an election for such coverage deemed or behalf of the member. Such request will be made by submitting the proposed form and a copy of the court order, regular on its face, which requires such election or incorporates, ratifies, or approves the written agreement of such person; or a statement from the clerk of the court (or other appropriate official) that such agreement has been filed with the court in accordance with applicable state law.

A former spouse is not required to submit a request for a deemed election. However, if a request for deemed election is not submitted within one year period described in the previous paragraph and the members fail to elect former spouse SBP coverage, no former spouse coverage will be provided.

The proposed form, DD form 2656–10, ''Survivor Benefit Plan (SBP)/Reserve Component (RC) SBP Request for Deemed Election,'' will become the prescribed form required for submitting such request.

Dated: August 21, 2007.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 07–4180 Filed 8–24–07; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Office of the Secretary

[No. DoD–2007–OS–0090]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense (Personnel and Readiness), DoD.

ACTION: Notice.

In compliance with section 3506(c)(2)(A) of the *Paperwork Reduction Act of 1995*, the Office of the Under Secretary of Defense (Personnel and Readiness) announces the following proposed extension of a public information collection and seeks public comment on the provisions thereof. 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 burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by October 26, 2007.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

• *Mail:* Federal Docket Management System Office, 1160 Defense Pentagon, Washington, DC 20301–1160.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public

viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Office of the Under Secretary of Defense (Personnel and Readiness) (Military Personnel Policy)/Accession Policy, ATTN: Major Eric Martinez, 4000 Defense Pentagon, Washington, DC 20301–4000, or call at (703) 695–5527.

Title, Associated Form, and OMB Control Number: Request for Verification of Birth, DD Form 372, OMB Control Number 0704–0006.

Needs and Uses: Title 10, U.S.C. 505, 532, 3253, and 8253, require applicants meet minimum and maximum age and citizenship requirements for enlistment into the Armed Forces (including the Coast Guard). If an applicant is unable to provide a birth certificate, the recruiter will forward a DD Form 372, ''Request for Verification of Birth,'' to a state or local agency requesting verification of the applicant's birth date. This verification of the birth date ensures that the applicant does not fall outside the age limitations, and the applicants place of birth supports the citizenship status claimed by the applicant.

Affected Public: State, local or tribal Government.

Annual Burden Hours: 8,300 hours.

Number of Respondents: 100,000.

Responses Per Respondent: 1.

Frequency: On occasion.

SUPPLEMENTARY INFORMATION:

Summary of Information Collection

This information provides the Armed Services with the exact birth date of an applicant. The DD Form 372 is the method of collecting and verifying birth date on applicants who are unable to provide a birth certificate from their city, county, or state. The DoD Form 372 is considered the official request for obtaining the birth date on applicants.

Dated: August 21, 2007.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 07–4181 Filed 8–24–07; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Office of the Secretary

[No. DoD–2007–OS–0094]

Proposed Collection; Comment Request

AGENCY: Defense Contract Management Agency, DoD.

ACTION: Notice.

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Defense Contract Management Agency announces the proposed extension of a public information collection and seeks public comment on the provisions thereof. 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 information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by October 26, 2007.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Federal Docket Management System Office, 1160 Defense Pentagon, Washington, DC 20301–1160.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Director, Defense Contract Management Agency, Attn: Gary Moorman, 6350 Walker Lane, Suite 300 Alexandria, VA 22310, or call Mr. Gary Moorman at 703–254–2134.

Title; Associated Form; and OMB Number: Request for Government Approval for Aircrew Qualifications and Training, DD Form 2627 and Request for Approval of Contractor Flight Crewmember, DD Form 2628; OMB Control Number 0704–0347.

Needs and Uses: The information collection requirement is necessary to request qualification training for contractor crewmembers. The DD Form 2628 requests approval for contractor personnel to function as a flight crewmember.

Affected Public: Individuals; business or other for profit; not-for-profit institutions; state, local or tribal government.

Annual Burden Hours: 7.

Number of Respondents: 42.

Responses Per Respondent: 2.

Average Burden Per Response: 5 minutes.

Frequency: On occasion.

SUPPLEMENTARY INFORMATION:

Summary of Information Collection

The requirement to have government approval of contract flight crewmembers is in Defense Contract Management Agency Directive 1, Chapter 8, Contractor's Flight and Ground Operations. The contractor provides a personal history and requests the government approve training in a particular type government aircraft (DD Form 2627). The contractor certifies the crewmember has passed a flight evaluation and, with the DD Form 2628, requests approval for the personnel to operate and fly government aircraft. Without the approvals, the contractor cannot use their personnel as requested.

Dated: August 21, 2007.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 07–4183 Filed 8–24–07; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal Nos. 07–57]

36(b)(1) Arms Sales Notification

AGENCY: Department of Defense, Defense Security Cooperation Agency.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated 21 July 1996.

FOR FURTHER INFORMATION CONTACT: Ms. B. English, DSCA/DBO/CFM, (703) 601–3740.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 07–57 with attached transmittal, and policy justification.

Dated: August 20, 2007.

C.R. Choate,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–M

DEFENSE SECURITY COOPERATION AGENCY

WASHINGTON, DC 20301-2800

In reply refer to:
I-07/010729-CFM

The Honorable Nancy Pelosi
Speaker of the House of Representatives
Washington, DC 20515-6501

Dear Madam Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 07-57, concerning the Department of the Army's proposed Letter(s) of Offer and Acceptance to Iraq for defense articles and services estimated to cost $150 million. After this letter is delivered to your office, we plan to issue a press statement to notify the public of this proposed sale.

Sincerely,

Richard J. Millies
Deputy Director

Enclosures:
1. Transmittal
2. **Policy Justification**

Same ltr to:

House	**Senate**
Committee on Foreign Affairs	**Committee on Foreign Relations**
Committee on Armed Services	**Committee on Armed Services**
Committee on Appropriations	**Committee on Appropriations**

Transmittal No. 07-57

Notice of Proposed Issuance of Letter of Offer
Pursuant to Section 36(b)(1)
of the Arms Export Control Act, as amended

(i) Prospective Purchaser: Iraq

(ii) Total Estimated Value:

Major Defense Equipment*	$ 0 million
Other	$150 million
TOTAL	$150 million

(iii) Description and Quantity or Quantities of Articles or Services under Consideration for Purchase: upgrade of 16 UH-I HUEY helicopters to the UH-II configuration, spare and repair parts, support equipment, publications and technical data, communications equipment, maintenance, personnel training and training equipment, Quality Assurance Team support services, U.S. Government and contractor engineering and logistics support services, preparation of aircraft for shipment, and other related elements of logistics support

(iv) Military Department: Army (UAI)

(v) Prior Related Cases, if any: none

(vi) Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid: none

(vii) Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold: none

(viii) Date Report Delivered to Congress:

* as defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Iraq - Upgrade of UH-I to UH-II HUEY Helicopters

The Government of Iraq has requested a possible sale to upgrade 16 UH-I HUEY helicopters to the UH-II configuration, spare and repair parts, support equipment, publications and technical data, communications equipment, maintenance, personnel training and training equipment, Quality Assurance Team support services, U.S. Government and contractor engineering and logistics support services, preparation of aircraft for shipment, and other related elements of logistics support. The estimated cost is $150 million.

This proposed sale will contribute to the foreign policy and national security of the United States by helping to improve the security of a friendly country.

The sale of the these helicopters and support will enhance the ability of the Iraqi forces to sustain themselves in their efforts to bring stability to the country and prevent overflow of unrest into neighboring countries.

The proposed sale of this equipment and support will not affect the basic military balance in the region.

The contractor is ARINC Corporation in Annapolis, Maryland. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this sale will require the assignment of up to four U.S. Government Quality Assurance representatives to Iraq for three weeks following delivery of the helicopters.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

[FR Doc. 07–4188 Filed 8–24–07; 8:45 am]
BILLING CODE 5001–06–C

DEPARTMENT OF DEFENSE

Department of the Air Force

[No. USAF–2007–0021]

Submission for OMB Review; Comment Request

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

DATES: Consideration will be given to all comments received by September 26, 2007.

Title, Form, and OMB Number: Air Force ROTC College Scholarship On-line Application; OMB Control Number 0701–0101.

Type of Request: Extension.

Number of Respondents: 17,000.

Responses Per Respondent: 1.

Annual Responses: 17,000.

Average Burden Per Response: 30 minutes.

Annual Burden Hours: 8,500.

Needs and Uses: The AFROTC scholarship application is required for completion by high school seniors and recent graduates for the purpose of competing for an AFROTC 4 year scholarship. Respondents must complete and submit their application via the AFROTC.com Web site. Submitted data will be evaluated by AFROTC scholarship selections boards to determine eligibility and to select individuals for the award of a college scholarship.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: Ms. Hillary Jaffe.

Written comments and recommendations on the proposed information collection should be sent to Ms. Jaffe at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503.

You may also submit comments, identified by docket number and title, by the following method:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions

from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Patricia Toppings.

Written requests for copies of the information collection proposal should be sent to Ms. Toppings at WHS/ESD/Information Management Division, 1777 North Kent Street, RPN, Suite 11000, Arlington, VA 22209–2133.

Dated: August 21, 2007.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 07–4167 Filed 8–24–07; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Department of the Air Force

[No. USAF–2007–0022]

Submission for OMB Review; Comment Request

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

DATES: Consideration will be given to all comments received by September 26, 2007.

Title, Form, and OMB Number: Application for Air Force ROTC Membership; AFROTC Form 20; OMB Control Number 0701–0105.

Type of Request: Extension.

Number of Respondents: 12,000.

Responses Per Respondent: 1.

Annual Responses: 12,000.

Average Burden Per Response: 20 minutes.

Annual Burden Hours: 4,000.

Needs and Uses: Air Force ROTC uses the AFROTC Form 20 to collect data from applicants to the Air Force ROTC program. This collected data is used to determine whether or not an applicant is eligible to join the Air Force ROTC program and, if accepted, the enrollment status of the applicant within the program. Upon acceptance into the program, the collected information is used to establish personal records for Air Force ROTC cadets. Eligibility for membership cannot be determined if this information is not collected.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: Ms. Hillary Jaffe.

Written comments and recommendations on the proposed information collection should be sent to Ms. Jaffe at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503.

You may also submit comments, identified by docket number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Patricia Toppings.

Written requests for copies of the information collection proposal should be sent to Ms. Toppings at WHS/ESD/Information Management Division, 1777 North Kent Street, RPN, Suite 11000, Arlington, VA 22209–2133.

Dated: August 21, 2007.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 07–4168 Filed 8–24–07; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Department of the Air Force

[No. USAF–2007–0023]

Submission for OMB Review; Comment Request

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

DATES: Consideration will be given to all comments received by September 26, 2007.

Title, Form and OMB Number: Application for establishment of Air Force junior ROTC Unit; AFJROTC 59; OMB Control Number 0701–0114.

Type of Request: Extension.

Number of Respondents: 40.

Responses Per Respondent: 1.

Annual Responses: 40.

Average Burden Per Response: 30 minutes.

Annual Burden Hours: 20.

Needs and Uses: HQ AF Officer Accession and Training Schools, AF Junior ROTC (HQ AFOATS/JR) is responsible for the activation of AF Junior ROTC units at host schools. The information collection requirement is necessary to obtain information about schools that would like to host an Air Force Junior ROTC unit. Respondents are high school officials who provide information about their school. The completed application is used to determine the eligibility of the school to host an Air Force JROTC unit. Failure to submit the application renders the school ineligible for consideration to host an Air Force Junior ROTC unit.

Affected Public: Not-for-profit institutions.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: Ms. Hillary Jaffee.

Written comments and recommendations on the proposed information collection should be sent to Ms. Jaffe at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503.

You may also submit comments, identified by docket number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DoD Clearance Officer: Ms. Patricia Toppings.

Written requests for copies of the information collection proposal should be sent to Ms. Toppings at WHS/ESD/Information Management Division, 1777 North Kent Street, RPN, Suite 11000, Arlington, VA 22209–2133.

Dated: August 21, 2007.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 07–4169 Filed 8–24–07; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Department of the Air Force

[No. USAF–2007–0005]

Submission for OMB Review; Comment Request

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

DATES: Consideration will be given to all comments received by September 26, 2007.

Title, Form, and OMB Number: Request for Approval of Foreign Government Employment of Air Force Members; OMB Control Number 0701–0134.

Type of Request: Extension.

Number of Respondents: 10.

Responses Per Respondent: 1.

Annual Responses: 10.

Average Burden Per Response: 1 hour.

Annual Burden Hours: 10.

Needs and Uses: The information collection requirement is to obtain the information needed by the Secretary of the Air Force and Secretary of State on which to base a decision to approve/disapprove a request to work for a foreign government. This approval is specified by Title 37, United States Code, Section 908. This statute delegates such approval authority of Congress to the respective service secretaries and to the Secretary of State.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: Ms. Hillary Jaffe.

Written comments and recommendations on the proposed information collection should be sent to Ms. Jaffe at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503.

You may also submit comments, identified by docket number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DoD Clearance Officer: Ms. Patricia Toppings.

Written requests for copies of the information collection proposal should be sent to Ms. Toppings at WHS/ESD/Information Management Division, 1777 North Kent Street, RPN, Suite 11000, Arlington, VA 22209–2133.

Dated: August 21, 2007.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 07–4170 Filed 8–24–07; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Department of the Air Force

[No. USAF–2007–0024]

Submission for OMB Review; Comment Request

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

DATES: Consideration will be given to all comments received by September 26, 2007.

Title, Form and OMB Number: United States Air Force Academy School Official's Evaluation of Candidate; United States Air Force Form 145; OMB Control Number 0701–0152.

Type of Request: Extension.

Number of Respondents: 4,100.

Responses Per Respondent: 1.

Annual Responses: 4,100.

Average Burden Per Response: 45 minutes.

Annual Burden Hours: 3,075.

Needs and Uses: The information collection requirement is necessary to obtain data on candidate's background and aptitude in determining eligibility and selection to the Air Force Academy.

Affected Public: Individuals or households.

Frequency: On Occasion.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: Ms. Hillary Jaffe.

Written comments and recommendations on the proposed information collection should be sent to Ms. Jaffe at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503.

You may also submit comments, identified by docket number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DoD Clearance Officer: Ms. Patricia Toppings.

Written requests for copies of the information collection proposal should be sent to Ms. Toppings at WHS/ESD/Information Management Division, 1777 North Kent Street, RPN, Suite 11000, Arlington, VA 22209–2133.

Dated: August 21, 2007.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 07–4171 Filed 8–24–07; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Department of the Air Force

[No. USAF–2007–0026]

Proposed Collection; Comment Request

AGENCY: Department of the Air Force, DoD.

ACTION: Notice.

In compliance with Section 3506(c)(2)(A) of the *Paperwork Reduction Act of 1995,* the Secretary of the Air Force, Office of Communication, Research and Assessment Division (SAF/CMA) announces a proposed new public information collection and seeks public comment on the provisions thereof. 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 information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by October 26, 2007.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.

• *Mail:* Federal Docket Management System Office, 1160 Defense Pentagon, Washington, DC 20301–1160.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Lt Col Robert Pope, Deputy Chief, Research and Assessment Division, SAF/CMA, Room 5C279, 1690 Air Force Pentagon, Washington, DC 20330-1690, or telephone at (703) 697–1046.

Title; Associated Form; and OMB Number: Presentation Comment card and Air Force Week Event Comment Card; OMB Number 0701–TBD.

Needs and Uses: The information collection requirement is necessary to obtain audience feedback data in order to improve future Air Force presentations and future Air Force Week on-base public events. The data that is collected will be used to improve these communication products. The respondents will be attendees at these events and participation will be anonymous and voluntary.

Affected Public: Individuals or households.

Annual Burden Hours: 200.

Number of Respondents: 2,000.

Responses Per Respondent: 1.

Average Burden Per Response: 6 minutes.

Frequency: On occasion.

SUPPLEMENTARY INFORMATION:

Summary of Information Collection

The information will be aggregated and used by the Secretary of the Air Force, Office of Communication, Research and Assessment Division (SAF/CMA) to provide substantive feedback to the organizers of presentations and events so that changes can be made according to attendee opinions.

Dated: August 21, 2007.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 07–4177 Filed 8–24–07; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Department of the Army

[USA–2007–0022]

Proposed Collection; Comment Request

AGENCY: Department of the Army, DoD.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Department of the Army announces the proposed extension to a public information collection and seeks public comments on the provision thereof. 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 information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by October 26, 2007.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.

• *Mail:* Federal Docket Management System Office, 1160 Defense Pentagon, Washington, DC 20301–1160.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Department of the Army, U.S. Army Corps of Engineers, Institute for Water Resources, Corps of Engineers, Waterborne Commerce Statistics Center, ATTN: CEWRC–NDC–C, P.O. Box 61280, New Orleans, LA 70161–1280, or call Department of the Army Reports Clearance Officer at 703–428–6440.

Title, Form and OMB Number: Record of Arrivals and Departures of Vessels at Marine Terminals, ENG Form 3926, OMB Control Number 0710–0005.

Needs and Uses: The Corps of Engineers uses ENG Form 3926 in conjunction with ENG Form 3925, 3925B, and 3925P as the basic source of input to conduct the Waterborne Commerce Statistics data collection program. The annual publications ''Waterborne Commerce of the United States, Parts 1–5'' are the results of this program.

Affected Public: Business or Other For-Profit.

Annual Burden Hours: 2,700.

Number of Respondents: 400.

Responses Per Respondent: 13.5.

Average Burden Per Response: 30 minutes.

Frequency: Monthly.

SUPPLEMENTARY INFORMATION:

Summary of Information Collection

The Corps of Engineers uses ENG Form 3926 as a quality control instrument by comparing the data collected on the Corps Vessel Operation Report with that collected on ENG Form 3926. The information is voluntarily submitted by the respondents to assist the Waterborne Commerce Statistics Center in the identification of vessel operators who fail to report significant vessel moves and tonnage. This information is invaluable in documenting the movement of petroleum products out of Valdez, Alaska. Without the information furnished on the ENG Form 3926 at least 50,000,000 tons of petroleum products would go unreported each year.

Dated: August 21, 2007.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 07–4178 Filed 8–24–07; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Department of the Army

[No. USA–2007–0021]

Proposed Collection; Comment Request

AGENCY: Department of the Army, DoD.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the *Paperwork Reduction Act of 1995,* the Department of the Army announces a proposed extension of a public information collection and seeks public comment on the provisions thereof. 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 information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by October 26, 2007.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

• *Mail:* Federal Docket Management System Office, 1160 Defense Pentagon, Washington, DC 20301–1160.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to U.S. Army ROTC Cadet Command, ATTN: ATCC–O1, 55 Patch Road, Building 56, Fort Monroe, VA 23651–1052, or call Department of the Army Reports Clearance Officer at 703–428–6440.

Title, Associated Form and OMB Number: Army ROTC Referral Information, ROTC Form 155–R, OMB Control Number 0702–0111.

Needs and Uses: The Army ROTC Program produces approximately 75 percent of the newly commissioned officers for the U.S. Army. The Army ROTC must have the ability to attract quality men and women who will pursue college degrees. Currently, there are 13 recruiting teams (Goldminers) located in various places across the United States aiding in this cause. Their mission is to refer quality high school students to colleges and universities offering Army ROTC. Goldminers, two officer personnel, will collect ROTC Referral information at a high school campus and document it on ROTC Cadet Command Form 155–R.

Affected Public: Individuals or households.

Annual Burden Hours: 4,075.

Number of Respondents: 16,300.

Responses Per Respondent: 1.

Average Burden Per Response: 15 minutes.

Frequency: On occasion.

SUPPLEMENTARY INFORMATION:

Summary of Information Collection

The purpose of the information is to provide prospect referral data to a Professor of Military Science to contact individuals who have expressed an interest in Army ROTC. If Goldminers did not collect referral information, we would suffer a negative impact on the recruiting effort and subsequent commissioning of new officers for the U.S. Army.

Dated: August 21, 2007.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 07–4179 Filed 8–24–07; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Department of the Army

Notice of Availability of a Record of Decision (ROD) for Base Realignment and Closure (BRAC) Actions at Fort Belvoir, VA; Correction

AGENCY: Department of the Army, DoD.

ACTION: Notice; correction.

SUMMARY: The Department of the Army published a Notice of Availability in the **Federal Register** of August 10, 2007, concerning the Record of Decision for Base Realignment and Closure (BRAC) actions at Fort Belvoir, Virginia. The Notice of Availability contained incorrect information.

FOR FURTHER INFORMATION CONTACT: Mr. Don Carr, Fort Belvoir Public Affairs Office, at (703) 805–2583 during normal business hours Monday through Friday.

Correction

In the **Federal Register** of August 10, 2007, in FR Doc. 07–3911, on page 45021, the second column, line 5, correct this line to read: ''places a net of 4,284 personnel on Fort Belvoir's Main Post and defers a decision on 6,200 personnel.''

Dated: August 22, 2007.

Addison D. Davis, IV,

Deputy Assistant Secretary of the Army (Environment, Safety and Occupational Health).

[FR Doc. 07–4192 Filed 8–24–07; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF DEFENSE

Department of the Army

Notice of Availability of a Record of Decision (ROD) for Base Realignment and Closure Actions at Aberdeen Proving Ground, MD

AGENCY: Department of the Army, DoD.

ACTION: Record of Decision (ROD).

SUMMARY: The Department of the Army announces the availability of a ROD which summarizes the decision for implementing realignment actions as directed by the Base Realignment and Closure (BRAC) Commission at Aberdeen Providing Ground (APG), Maryland.

ADDRESSES: To obtain copies of the ROD, contact Mr. Buddy Keesee at: Department of the Army, Directorate of Safety, Health, and Environment, Attention: IMNE–APG–SHE–R, Building 5650, Aberdeen Proving Ground, MD 21005–5001; e-mail *Buddy.Keesee@us.army.mil.*

FOR FURTHER INFORMATION CONTACT: Mr. Buddy Keesee at (410) 278–6755 during normal business hours.

SUPPLEMENTARY INFORMATION: The Army has decided to proceed with implementing the Preferred Alternative consistent with the analysis in the Environmental Impact Statement (EIS) dated July 2007, supporting studies, and comments provided during normal

comment and review periods. The Proposed Action includes construction, renovation, and operation of proposed facilities to accommodate incoming military missions at APG. To implement the BRAC recommendations, APG will be receiving personnel, equipment, and missions from various closure and realignment actions within the Department of Defense. To implement the BRAC Commission recommendations, the Army will provide the necessary facilities, buildings, and infrastructure to support incoming military missions and a net gain of about 4,400 people as mandated by the 2005 BRAC Commission's recommendations at APG. The No Action Alternative would not meet the Army's purpose and need for the Proposed Action as the BRAC realignment is required by Congress and needed for Army transformation to be effective.

Special consideration was given to the effect of the Preferred Alternative on natural resources, cultural resources, and traffic. All practicable means to avoid or minimize environmental harm from the Preferred Alternative have been adopted. The Army will minimize effects on all environmental and socioeconomic resources by implementing best management practices as described in the EIS. Mitigation measures, as described in the ROD, will be implemented, subject to the availability of funding, to minimize, avoid, or compensate for the adverse effects identified in the EIS at APG for biological resources and cultural resources. The EIS also identifies transportation projects that could eliminate adverse impacts from implementing the Preferred Alternative. The ROD describes the disposition of these projects and the approach the Army will take to mitigate traffic concerns.

The ROD states that implementing the Preferred Alternative reflects a proper balance between initiatives for protection of the environment, appropriate mitigation, and actions to achieve the Army's requirements.

An electronic version of the ROD is available for download at: *http://www.hqda.army.mil/acsim/brac/nepa_eis_docs.htm*.

Dated: August 20, 2007.

Addison D. Davis, IV,

Deputy Assistant Secretary of the Army (Environment, Safety and Occupational Health).

[FR Doc. 07–4191 Filed 8–24–07; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF DEFENSE

Office of the Secretary

[No. DoD–2007–OS–0089]

Proposed Collection; Comment Request

AGENCY: Defense Logistics Agency, DoD.

ACTION: Notice.

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, *the Defense Logistics Agency* announces a proposed extension of a public information collection and seeks public comment on the provisions thereof. 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 information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by October 26, 2007.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

• *Mail:* Federal Docket Management System Office, 1160 Defense Pentagon, Washington, DC 20301–1160.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Defense Logistics Agency, ATTN: Ms. Fran Mutschler, DDC J–3/J–4 TOT, 2001 Mission Drive, New Cumberland, PA 17070–5000, or call DDC at (717) 770–5040.

Title and OMB Number: Defense Logistics Agency Survey of Supply Vendors; OMB Control Number 0704–0429.

Needs and Uses: The Defense Logisitics Agency (DLA) is transforming its distribution business practices. It is developing an automated system that will give it visibility on the location and movement of material originating at Government and contractor locations alike, and the ability to use that information for Corporate-wide planning and management. DLA needs to understand corresponding business practices of segments of the contractor community. The survey information will be used by DLA to help determine the extent to which shipments from contractor locations can be integrated into DLA's distribution practices.

Affected Public: Business or other for-profit.

Annual Burden Hours: 200.

Number of Respondents: 200.

Responses Per Respondent: 1.

Average Burden Per Response: 1 hour.

Frequency: On occasion.

SUPPLEMENTARY INFORMATION:

Summary of Information Collection

Respondents are businesses who supply material to the Defense Logistics Agency in direct support of customer requirements or to be placed into stock for future requirements. The survey will seek information concerning each contractor's demographics, order management practices, shipping practices, costs and pricing, and utilization of technology. Participation in the survey will be voluntary.

Dated: August 21, 2007.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 07–4182 Filed 8–24–07; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF EDUCATION

Submission for OMB Review; Comment Request

AGENCY: Department of Education.

SUMMARY: The IC Clearance Official, Regulatory Information Management Services, Office of Management invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before September 26, 2007.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Education Desk Officer, Office of Management and Budget, 725

17th Street, NW., Room 10222, Washington, DC 20503. Commenters are encouraged to submit responses electronically by e-mail to *oira_submission@omb.eop.gov* or via fax to (202) 395–6974. Commenters should include the following subject line in their response ''Comment: [insert OMB number], [insert abbreviated collection name, e.g., ''Upward Bound Evaluation'']. Persons submitting comments electronically should not submit paper copies.

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 IC Clearance Official, Regulatory Information Management Services, Office of Management, 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.

Dated: August 21, 2007.

Angela C. Arrington,

IC Clearance Official, Regulatory Information Management Services, Office of Management.

Institute of Education Sciences

Type of Review: New.

Title: The Effectiveness of a Program to Accelerate Vocabulary Development in Kindergarten.

Frequency: Semi-Annually.

Affected Public: Individuals or household; State, Local, or Tribal Gov't, SEAs or LEAs.

Reporting and Recordkeeping Hour Burden:

Responses: 4,294.

Burden Hours: 1,208.

Abstract: The proposed project is a multi-year data collection effort to evaluate the effectiveness of PAVEd for Success (PAVE), an intervention designed to improve teachers' vocabulary instructional practices and thereby promote vocabulary development among kindergarteners in the Delta region of Mississippi. The children in this region are well behind national averages in vocabulary skills, and vocabulary knowledge is an essential component of literacy development that has generally been difficult to improve. The PAVE program is one vocabulary program that has shown promise, but more rigorous testing is required to establish evidence of its effectiveness. The study sample will include 120–160 teachers, and 1,200–1,600 kindergarten students in a randomized control trial in 60–80 schools. Student's literacy skills and teacher's literacy instruction practices will be assessed to determine the impact of PAVE on students and teachers.

Requests for copies of the information collection submission for OMB review may be accessed from *http://edicsweb.ed.gov,* by selecting the ''Browse Pending Collections'' link and by clicking on link number 3388. When you access the information collection, click on ''Download Attachments'' to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., Potomac Center, 9th Floor, Washington, DC 20202–4700. Requests may also be electronically mailed to *ICDocketMgr@ed.gov* or faxed to 202–245–6623. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be electronically mailed to *ICDocketMgr@ed.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. E7–16869 Filed 8–24–07; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Submission for OMB Review; Comment Request

AGENCY: Department of Education.

SUMMARY: The IC Clearance Official, Regulatory Information Management Services, Office of Management invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before September 26, 2007.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Education Desk Officer, Office of Management and Budget, 725 17th Street, NW., Room 10222, Washington, DC 20503. Commenters are encouraged to submit responses electronically by e-mail to *oira_submission@omb.eop.gov* or via fax to (202) 395–6974. Commenters should include the following subject line in their response ''Comment: [insert OMB number], [insert abbreviated collection name, e.g., ''Upward Bound Evaluation'']. Persons submitting comments electronically should not submit paper copies.

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 IC Clearance Official, Regulatory Information Management Services, Office of Management, 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.

Dated: August 21, 2007.

Angela C. Arrington,

IC Clearance Official, Regulatory Information Management Services, Office of Management.

Office of Special Education and Rehabilitative Services

Type of Review: Revision.

Title: Special Education—Institutional Reporting on Regulatory Compliance Related to the Personnel Preparation Program Service Obligation.

Frequency: On Occasion; Annually.

Affected Public: Individuals or household.

Reporting and Recordkeeping Hour Burden:

Responses: 7,875.

Burden Hours: 16,250.

Abstract: The data collection under this request are governed by Section 304.1–304.32 of the December 9, 1999 regulations that implement section 673(h) of the IDEA amendments of 1997 which requires that individuals who receive a scholarship through the Personnel Preparation Program funded under the Act subsequently provide special education and related services to children with disabilities for a period of two years for every year for which assistance was received. Scholarship recipients who do not satisfy the requirements of the regulations must repay all or part of the cost of assistance in accordance with regulations issued by the Secretary. These regulations implement requirements governing among other things, the service obligation for scholars, oversight by grantees, and repayment of scholarship. In order for the Federal government to ensure the goals of the program are achieved, certain data collection, record keeping, and documentation are necessary.

Requests for copies of the information collection submission for OMB review may be accessed from *http://edicsweb.ed.gov,* by selecting the ''Browse Pending Collections'' link and by clicking on link number 3380. When you access the information collection, click on ''Download Attachments'' to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., Potomac Center, 9th Floor, Washington, DC 20202–4700. Requests may also be electronically mailed to *ICDocketMgr@ed.gov* or faxed to 202–245–6623. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be electronically mailed to *ICDocketMgr@ed.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. E7–16870 Filed 8–24–07; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[CFDA No.84.938H]

Fund for the Improvement of Postsecondary Education; New Hurricane Education Recovery Awards

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Notice reopening the New Hurricane Education Recovery Awards fiscal year (FY) 2007 competition.

SUMMARY: On July 16, 2007, we published in the **Federal Register** (72 FR 38827) a notice inviting applications for the New Hurricane Education Recovery Awards for FY 2007 competition. That notice established an August 17, 2007 deadline date for eligible applicants to apply for this funding. Only applicants who timely submitted a pre-application and received an e-mail from the Department with the applicant's calculated allotment for an award were eligible to submit a full application by the August 17, 2007 deadline.

In order to afford as many eligible applicants who timely submitted pre-applications as possible an opportunity to receive funding, we are reopening the New Hurricane Education Recovery Awards FY 2007 competition to eligible applicants who timely submitted a pre-application and received an e-mail from the Department with the applicant's calculated allotment for an award. Accordingly, the **DATES** section is updated as follows.

DATES: *Applications Available:* August 27, 2007. *Deadline for Transmittal of Applications:* August 28, 2007.

Note: Applications for grants under the Hurricane Education Recovery Awards must be submitted electronically using the Governmentwide Grants.gov Apply site at *http://www.grants.gov.* For information about how to submit your application electronically, please refer to *Electronic Submission of Applications* in the July 16, 2007 notice (72 FR 38829–38830). We encourage eligible applicants to submit their applications as soon as possible to avoid any problems with filing electronic applications on the deadline date.

FOR FURTHER INFORMATION CONTACT: Ms. Rosemary Wolfe, Fund for the Improvement of Postsecondary Education, U.S. Department of Education, 1990 K Street, NW., 6th Floor, Washington, DC 20006–8544. Telephone: (202) 502–7516 or via Internet: *HERA2@ed.gov* or *Rosemary.Wolfe@ed.gov.*

If you use a telecommunications device for the deaf (TDD), you may call the Federal Relay Service (FRS) at 1–800–877–8339. Individuals with disabilities may obtain this notice in an alternative format (e.g., Braille, large print, audiotape, or computer diskette) on request to the contact person listed in this section.

Electronic Access to This Document: You may view this document, as well as other Department of Education documents published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *http://www.ed.gov/news/fedregister.*

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC, area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.gpoaccess.gov/nara/index.html.*

Program Authority: 20 U.S.C. 1138–1138d.

Dated: August 23, 2007.

Diane Auer Jones,

Assistant Secretary for Postsecondary Education.

[FR Doc. E7–17019 Filed 8–24–07; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Office of Special Education and Rehabilitative Services; Overview Information; National Institute on Disability and Rehabilitation Research (NIDRR)—Disability and Rehabilitation Research Projects and Centers Program—Advanced Rehabilitation Research Training (ARRT) Projects; Notice Inviting Applications for New Awards for Fiscal Year (FY) 2008

Catalog of Federal Domestic Assistance (CFDA) Number: 84.133P–1.

Dates: Applications Available: August 27, 2007.

Deadline for Transmittal of Applications: October 26, 2007.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purpose of this program is to provide research training and experience at an advanced level to individuals with doctorates or similar advanced degrees who have clinical or other relevant experience. ARRT projects train rehabilitation researchers, including individuals with disabilities, with particular attention to research areas that support the implementation and objectives of the Rehabilitation Act of 1973, as amended (Act), and that improve the effectiveness of services authorized under the Act.

Priority: In accordance with 34 CFR 75.105(b)(2)(ii), this priority is from the regulations for this program (34 CFR 350.12 and 350.64 through 350.65).

Absolute Priority: For FY 2008, this priority is an absolute priority. Under 34 CFR 75.105(c)(3), we consider only applications that meet this priority.

This priority is: *Advanced Rehabilitation Research Training Projects*

ARRT projects must—(1) Recruit and select candidates for advanced research training; (2) provide a training program that includes didactic and classroom instruction, is multidisciplinary, emphasizes scientific research methodology, and may involve collaboration among institutions; (3) provide research experience, laboratory experience, or its equivalent in a community-based research setting, and a practicum experience that involves each trainee in clinical research and in practical activities with organizations representing individuals with disabilities; (4) provide academic mentorship or guidance, and opportunities for scientific collaboration with qualified researchers at the host university and other appropriate institutions; and (5) provide opportunities for participation in the development of professional presentations and publications, and for attendance at professional conferences and meetings, as appropriate for the individual's field of study and level of experience.

It is expected that applicants will articulate goals, objectives, and expected outcomes for the research training activity. Applicants should describe expected public benefits of this training activity, especially benefits for individuals with disabilities, and propose projects that optimally are designed to demonstrate outcomes that are consistent with the proposed goals. Applicants are encouraged to include information describing how they will measure outcomes, including the indicators that will represent the end-result. Submission of this measurement information is voluntary, except where required by the selection criteria listed in the application package.

A grantee for an ARRT project must provide training to individuals for at least one academic year, unless a longer training period is necessary to ensure that each trainee is qualified to conduct independent research upon completion of the course of training.

Trainees under an ARRT project must devote at least eighty percent of their time to the activities of the training program during the training period.

Note: This program is in concert with President George W. Bush's New Freedom Initiative (NFI) and NIDRR's Final Long-Range Plan for FY 2005–2009 (Plan).

The NFI can be accessed on the Internet at the following site: *http://www.whitehouse.gov/infocus/newfreedom.* The Plan is comprehensive and integrates many issues relating to disability and rehabilitation research topics. The Plan, which was published in the **Federal Register** on February 15, 2006 (71 FR 8165), can be accessed on the Internet at the following site: *http://www.ed.gov/about/offices/list/osers/nidrr/policy.html.*

Through the implementation of the Plan, NIDRR seeks to—(1) Improve the quality and utility of disability and rehabilitation research; (2) foster an exchange of expertise, information, and training to facilitate the advancement of knowledge and understanding of the unique needs of traditionally underserved populations; (3) determine best strategies and programs to improve rehabilitation outcomes for underserved populations; (4) identify research gaps; (5) identify mechanisms of integrating research and practice; and (6) disseminate findings.

Program Authority: 29 U.S.C. 762(k).

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 80, 81, 82, 84, 85, 86, and 97. (b) The regulations for this program in 34 CFR part 350.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: The Administration has requested $106,705,470 for awards for NIDRR for FY 2008, of which we intend to use an estimated $600,000 for the ARRT competition. The actual level of funding, if any, depends on final congressional action. However, we are inviting applications to allow enough time to complete the grant process if Congress appropriates funds for this program.

Estimated Range of Awards: $147,000 to $150,000.

Estimated Average Size of Awards: $150,000.

Maximum Award: We will reject any application that proposes a budget exceeding $150,000 for a single budget period of 12 months. The Assistant Secretary for Special Education and Rehabilitative Services may change the maximum amount through a notice published in the **Federal Register**.

Note: Indirect cost reimbursement on a training grant is limited to eight percent of a modified total direct cost base, defined as total direct costs less stipends, tuition and related fees, and capital expenditures of $5,000 or more.

Estimated Number of Awards: 4.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 60 months.

III. Eligibility Information

1. *Eligible Applicants:* Institutions of higher education.

2. *Cost Sharing or Matching:* This competition does not require cost sharing or matching.

IV. Application and Submission Information

1. *Address to Request Application Package:* You can obtain an application package via the Internet or from the Education Publications Center (ED Pubs). To obtain a copy via the Internet, use the following address: *http://www.ed.gov/fund/grant/apply/grantapps/index.html.*

To obtain a copy from ED Pubs, write, fax, or call the following: Education Publications Center, P.O. Box 1398, Jessup, MD 20794–1398. Telephone, toll free: 1–877–433–7827. FAX: (301) 470–1244. If you use a telecommunications device for the deaf (TDD), call, toll free: 1–877–576–7734.

You can contact ED Pubs at its Web site, also: *http://www.ed.gov/pubs/edpubs.html* or at its e-mail address: *edpubs@inet.ed.gov.*

If you request an application from ED Pubs, be sure to identify this competition as follows: CFDA Number 84.133P–1.

Individuals with disabilities can obtain a copy of the application package in an alternative format (e.g., Braille, large print, audiotape, or computer diskette) by contacting the program contact person listed under *Alternative Format* in section VIII of this notice.

2. *Content and Form of Application Submission:* Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this competition.

Page Limit: The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you limit Part III to the equivalent of no more than 75 pages, using the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative. Single spacing may be used for titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.

• Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).

The suggested page limit does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the one-page abstract, the resumes, the bibliography, or the letters of support. However, the page limit does apply to all of the application narrative section (Part III).

The application package will provide instructions for completing all components to be included in the application. Each application must include a cover sheet (Standard Form 424); budget requirements (ED Form 524) and budget narrative justification; other required forms; an abstract, Human Subjects narrative, Part III narrative; resumes of staff; and other related materials, if applicable.

3. *Submission Dates and Times:*

Applications Available: August 27, 2007.

Deadline for Transmittal of Applications: October 26, 2007.

Applications for grants under this competition may be submitted electronically using the Grants.gov Apply site (Grants.gov), or in paper format by mail or hand delivery. For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery, please refer to section IV. 6. *Other Submission Requirements* in this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII in this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

4. *Intergovernmental Review:* This program is not subject to Executive Order 12372 and the regulations in 34 CFR part 79.

5. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

6. *Other Submission Requirements:* Applications for grants under this competition may be submitted electronically or in paper format by mail or hand delivery.

a. *Electronic Submission of Applications.*

To comply with the President's Management Agenda, we are participating as a partner in the Governmentwide Grants.gov Apply site. Advanced Rehabilitation Research Training Projects, CFDA Number 84.133P–1 is included in this project. We request your participation in Grants.gov.

If you choose to submit your application electronically, you must use the Governmentwide Grants.gov Apply site at *http://www.Grants.gov*. Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not e-mail an electronic copy of a grant application to us.

You may access the electronic grant application for Advanced Rehabilitation Research Training Projects at *http://www.Grants.gov*. You must search for the downloadable application package for this competition by the CFDA number. Do not include the CFDA number's alpha suffix in your search (e.g., search for 84.133, not 84.133P).

Please note the following:

• Your participation in Grants.gov is voluntary.

• When you enter the Grants.gov site, you will find information about submitting an application electronically through the site, as well as the hours of operation.

• Applications received by Grants.gov are date and time stamped. Your application must be fully uploaded and submitted and must be date and time stamped by the Grants.gov system no later than 4:30 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not consider your application if it is date and time stamped by the Grants.gov system later than 4:30 p.m., Washington, DC time, on the application deadline date. When we retrieve your application from Grants.gov, we will notify you if we are rejecting your application because it was date and time stamped by the Grants.gov system after 4:30 p.m., Washington, DC time, on the application deadline date.

• The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through Grants.gov.

• You should review and follow the Education Submission Procedures for submitting an application through Grants.gov that are included in the application package for this competition to ensure that you submit your application in a timely manner to the Grants.gov system. You can also find the Education Submission Procedures pertaining to Grants.gov at *http://e-Grants.ed.gov/help/GrantsgovSubmissionProcedures.pdf*.

• To submit your application via Grants.gov, you must complete all steps in the Grants.gov registration process (see *http://www.grants.gov/applicants/get_registered.jsp*). These steps include (1) Registering your organization, a multi-part process that includes registration with the Central Contractor Registry (CCR); (2) registering yourself as an Authorized Organization Representative (AOR); and (3) getting authorized as an AOR by your organization. Details on these steps are outlined in the Grants.gov 3–Step Registration Guide (see *http://www.grants.gov/section910/Grants.govRegistrationBrochure.pdf)*. You also must provide on your application the same D–U–N–S Number used with this registration. Please note that the registration process may take five or more business days to complete, and you must have completed all registration steps to allow you to submit successfully an application via Grants.gov. In addition you will need to update your CCR registration on an annual basis. This may take three or more business days to complete.

• You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you submit your application in paper format.

• If you submit your application electronically, you must submit all documents electronically, including all information you typically provide on the following forms: Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications. Please note that two of these forms—the SF 424 and the Department of Education Supplemental Information for SF 424—have replaced the ED 424 (Application for Federal Education Assistance).

• If you submit your application electronically, you must attach any narrative sections of your application as files in a .DOC (document), .RTF (rich text), or .PDF (Portable Document) format. If you upload a file type other than the three file types specified in this

paragraph or submit a password-protected file, we will not review that material.

• Your electronic application must comply with any page-limit requirements described in this notice.

• After you electronically submit your application, you will receive from Grants.gov an automatic notification of receipt that contains a Grants.gov tracking number. (This notification indicates receipt by Grants.gov only, not receipt by the Department.) The Department then will retrieve your application from Grants.gov and send a second notification to you by e-mail. This second notification indicates that the Department has received your application and has assigned your application a PR/Award number (an ED–specified identifying number unique to your application).

• We may request that you provide us original signatures on forms at a later date.

Application Deadline Date Extension in Case of Technical Issues with the Grants.gov System: If you are experiencing problems submitting your application through Grants.gov, please contact the Grants.gov Support Desk, toll free, at 1–800–518–4726. You must obtain a Grants.gov Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the Grants.gov system, we will grant you an extension until 4:30 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30 p.m., Washington, DC time, on the application deadline date, please contact the person listed under *For Further Information Contact* in section VII in this notice and provide an explanation of the technical problem you experienced with Grants.gov, along with the Grants.gov Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the Grants.gov system and that that problem affected your ability to submit your application by 4:30 p.m., Washington, DC time, on the application deadline date. The Department will contact you after a determination is made on whether your application will be accepted.

Note: The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the Grants.gov system. We will not grant you an extension if you failed to fully register to submit your application to Grants.gov before the application deadline date and time or if the technical problem you experienced is unrelated to the Grants.gov system.

b. *Submission of Paper Applications by Mail.*

If you submit your application in paper format by mail (through the U.S. Postal Service or a commercial carrier), you must mail the original and two copies of your application, on or before the application deadline date, to the Department at the applicable following address:

By mail through the U.S. Postal Service: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.133P–1), 400 Maryland Avenue, SW., Washington, DC 20202–4260; or

By mail through a commercial carrier: U.S. Department of Education, Application Control Center, Stop 4260, Attention: (CFDA Number 84.133P–1), 7100 Old Landover Road, Landover, MD 20785–1506.

Regardless of which address you use, you must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

If your application is postmarked after the application deadline date, we will not consider your application.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

c. *Submission of Paper Applications by Hand Delivery.*

If you submit your application in paper format by hand delivery, you (or a courier service) must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.133P–1), 550 12th Street, SW., Room 7041, Potomac Center Plaza, Washington, DC 20202–4260. The Application Control Center accepts hand deliveries daily between 8 a.m. and 4:30 p.m., Washington, DC time, except Saturdays, Sundays, and Federal holidays.

Note for Mail or Hand Delivery of Paper Applications: If you mail or hand deliver your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the competition under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245–6288.

V. Application Review Information

Selection Criteria: The selection criteria for this competition are from 34 CFR 350.54 and are listed in the application package.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN). We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section in this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multi-year award, you must submit an annual performance report that provides the most current performance and financial expenditure information as specified by the Secretary in 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific

requirements on reporting, please go to *http://www.ed.gov/fund/grant/apply/appforms/appforms.html.*

4. *Performance Measures:* To evaluate the overall success of its research program, NIDRR assesses the quality of its funded projects through review of grantee performance and products. Each year, NIDRR examines, through expert review, a portion of its grantees to determine:

- Percentage of NIDRR-supported fellows, post-doctoral trainees, and doctoral students who publish results of NDRR-sponsored research in refereed journals.
- Average number of publications per award based on NIDRR-funded research and development activities in refereed journals.
- The percentage of grantee research and development that has appropriate study design, meets rigorous standards of scientific and/or engineering methods, and builds on and contributes to knowledge in the field.
- The average number of publications per award based on NIDRR-funded research and development activities in refereed journals.
- The percentage of new grants that include studies funded by NIDRR that assess the effectiveness of interventions, programs, and devices using rigorous and appropriate methods.
- The percentage of NIDRR-supported fellows, post-doctoral trainee, and doctoral students who publish results of NIDRR-sponsored research in refereed journals.

NIDRR uses information submitted by grantees as part of their Annual Performance Reports (APRs) for these reviews. NIDRR also determines, using information submitted as part of the APR, the number of publications in refereed journals that are based on NIDRR-funded research and development activities.

Department of Education program performance reports, which include information on NIDRR programs, are available on the Department's Web site: *http://www.ed.gov/about/offices/list/opepd/sas/index.html.*

Updates on the Government Performance and Results Act of 1993 (GPRA) indicators, revisions and methods appear on the NIDRR Program Review Web site: *http://www.neweditions.net/pr/commonfiles/pmconcepts.htm.*

Grantees should consult these sites, on a regular basis, to obtain details and explanations on how NIDRR programs contribute to the advancement of the Department's long-term and annual performance goals.

VII. Agency Contact

For Further Information Contact: Marlene Spencer, U.S. Department of Education, 400 Maryland Avenue, SW., room 6026, PCP, Washington, DC 20202. Telephone: (202) 245–7532 or by e-mail: *marlene.spencer@ed.gov.*

If you use a TDD, call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

VIII. Other Information

Alternative Format: Individuals with disabilities can obtain this document and a copy of the application package in an alternative format (e.g., Braille, large print, audiotape, or computer diskette) by contacting the Grants and Contracts Services Team, U.S. Department of Education, 400 Maryland Avenue, SW., room 5075, PCP, Washington, DC 20202–2550. Telephone: (202) 245–7363. If you use a TDD, call the FRS, toll free, at 1–800–877–8339.

Electronic Access to This Document: You can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *http://www.ed.gov/news/fedregister.*

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC, area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.gpoaccess.gov/nara/index.html.*

Dated: August 22, 2007.

William W. Knudsen,

Acting Deputy Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. E7–16899 Filed 8–24–07; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Energy Information Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Energy Information Administration (EIA), Department of Energy (DOE).

ACTION: Agency Information Collection Activities: Submission for OMB Review; Comment Request.

SUMMARY: The EIA has submitted the energy information collection Form EIA–871A/J, ''Commercial Buildings Energy Consumption Survey,'' to the Office of Management and Budget (OMB) for reinstatement under section 3507(h)(1) of the Paperwork Reduction Act of 1995 (Pub. L. 104–13) (44 U.S.C. 3501 et seq).

DATES: Comments must be filed by September 26, 2007. If you anticipate that you will be submitting comments but find it difficult to do so within that period, you should contact the OMB Desk Officer for DOE listed below as soon as possible.

ADDRESSES: Send comments to the OMB Desk Officer for DOE, Office of Information and Regulatory Affairs, Office of Management and Budget. To ensure receipt of the comments by the due date, submit by FAX (202–395–7285). The mailing address is 726 Jackson Place, NW., Washington, DC 20503. The OMB DOE Desk Officer may be telephoned at (202) 395–4650. (A copy of your comments should also be provided to EIA's Statistics and Methods Group at the address below.)

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Grace Sutherland. To ensure receipt of the comments by the due date, submission by FAX (202–586–5271) or e-mail (*grace.sutherland@eia.doe.gov*) is recommended. The mailing address is Statistics and Methods Group (EI–70), Forrestal Building, U.S. Department of Energy, Washington, DC 20585–0670. Ms. Sutherland may be contacted by telephone at (202) 586–6264.

SUPPLEMENTARY INFORMATION: This section contains the following information about the energy information collection submitted to OMB for review: (1) The collection numbers and title; (2) the sponsor (i.e., the Department of Energy component); (3) the current OMB docket number (if applicable); (4) the type of request (i.e., new, revision, extension, or reinstatement); (5) response obligation (i.e., mandatory, voluntary, or required to obtain or retain benefits); (6) a description of the need for and proposed use of the information; (7) a categorical description of the likely respondents; and (8) an estimate of the total annual reporting burden (i.e., the estimated number of likely respondents times the proposed frequency of response per year times the average hours per response).

1. EIA–871 A/J, ''Commercial Buildings Energy Consumption Survey''.

2. Energy Information Administration.

3. OMB Number 1905–0145.

4. Reinstatement, with change, of a previously approved collection for which approval was discontinued.

5. Voluntary (buildings) Mandatory (energy suppliers).

6. The EIA–871 A/J is used to collect data on energy consumption by commercial buildings and the characteristics of these buildings. The surveys fulfill planning, analyses and decision-making needs of DOE, other Federal agencies, State governments, and the private sector. Respondents are owners/managers of selected commercial buildings and their energy suppliers.

7. Business or other for-profit.

8. 2,511 hours.

Statutory Authority: Section 3507(h)(1) of the Paperwork Reduction Act of 1995 (Pub. L. No. 104–13) (44 U.S.C. 3501 *et seq.*).

Issued in Washington, DC, August 17, 2007.

Jay H. Casselberry,

Agency Clearance Officer, Energy Information Administration.

[FR Doc. E7–16895 Filed 8–24–07; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–RCRA–2007–0232; FRL–8461–1]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; Land Disposal Restrictions (Renewal), EPA ICR Number 1442.19, OMB Control Number 2050–0085

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA)(44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. The ICR, which is abstracted below, describes the nature of the information collection and its estimated burden and cost.

DATES: Additional comments may be submitted on or before September 26, 2007.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–RCRA–2007–0232, to (1) EPA, either online using *www.regulations.gov* (our preferred method), or by e-mail to *rcra-docket@epa.gov,* or by mail to: RCRA Docket (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; and (2) OMB, by mail to: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Peggy Vyas, Office of Solid Waste, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone: 703–308–5477; fax: 703–308–8433; e-mail: *vyas.peggy@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On April 17, 2007 (72 FR 19195), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments. Any additional comments on this ICR should be submitted to EPA and OMB within 30 days of this notice.

EPA has established a public docket for this ICR under Docket ID No. EPA–HQ–RCRA–2007–0232, which is available for online viewing at *www.regulations.gov,* or in person viewing at the Resource Conservation and Recovery Act (RCRA) Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room is open from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the RCRA Docket is (202) 566–0270.

Use EPA's electronic docket and comment system at *www.regulations.gov,* to submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the docket that are available electronically. Once in the system, select ''docket search,'' then key in the docket ID number identified above. Please note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing at *www.regulations.gov* as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose public disclosure is restricted by statute. For further information about the electronic docket, go to *www.regulations.gov.*

Title: Land Disposal Restrictions (Renewal).

ICR numbers: EPA ICR No. 1442.19, OMB Control No. 2050–0085.

ICR Status: This ICR is scheduled to expire on August 31, 2007. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB. 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 in title 40 of the CFR, after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9, are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: Section 3004 of the Resource Conservation and Recovery Act (RCRA), as amended, requires that EPA develop standards for hazardous waste treatment, storage, and disposal as may be necessary to protect human health and the environment. Subsections 3004(d), (e), and (g) require EPA to promulgate regulations that prohibit the land disposal of hazardous waste unless it meets specified treatment standards described in subsection 3004(m).

The regulations implementing these requirements are codified in the Code of Federal Regulations (CFR) Title 40, Part 268. EPA requires that facilities maintain the data outlined in this ICR so that the Agency can ensure that land disposed waste meets the treatment standards. EPA strongly believes that the recordkeeping requirements are necessary for the agency to fulfill its congressional mandate to protect human health and the environment.

Burden Statement: The annual reporting burden for this ICR is roughly 85.3 hours per response. The annual recordkeeping burden for this ICR is roughly 5.96 hours per 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 which have subsequently changed; 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.

Respondents/Affected Entities: Private sector and State, Local, or Tribal governments.

Estimated Number of Respondents: 195,710.

Frequency of Response: On occasion.

Estimated Total Annual Hour Burden: 1,166,337.

Estimated Total Annual Cost: $131,913,786, which includes $50,946 annualized capital and $88,731,016 O&M costs.

Changes in the Estimates: There is an increase of 343,343 hours in the total estimated burden currently identified in the OMB Inventory of Approved ICR Burdens. This increase is due to the increase in the number of respondents, from 129,584 to 195,710. Particularly, the number of small quantity generators increased because a better method for counting them was used this time. The number of land disposal facilities also increased from 131, which came from the 2001 BRS estimate, to 464, which came from the 2005 BRS estimate from RCRAInfo.

Dated: August 20, 2007.

Joseph A. Sierra,

Acting Director, Collection Strategies Division.

[FR Doc. E7–16913 Filed 8–24–07; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2006–0752; FRL–8460–9]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; NESHAP for Petroleum Refineries, Catalytic Cracking, Reforming and Sulfur Units (Renewal); EPA ICR Number 1844.03, OMB Control Number 2060–0554

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. The ICR which is abstracted below describes the nature of the collection and the estimated burden and cost.

DATES: Additional comments may be submitted on or before September 26, 2007.

ADDRESSES: Submit your comments, referencing docket ID number EPA–HQ–OECA–2006–0752, to (1) EPA online using *www.regulations.gov* (our preferred method), or by e-mail to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center (EPA/DC), Environmental Protection Agency, Enforcement and Compliance Docket and Information Center, mail code 2201T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460, and (2) OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: María Malavé, Compliance Assessment and Media Programs Division (Mail Code 2223A), Office of Compliance, Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; telephone number: (202) 564–7027; fax number: (202) 564–0050; e-mail address: *malave.maria@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On October 6, 2006 (71 *FR* 58853), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments. Any additional comments on this ICR should be submitted to EPA and OMB within 30 days of this notice.

EPA has established a public docket for this ICR under docket ID number EPA–HQ–OECA–2006–0752, which is available for public viewing online at *http://www.regulations.gov,* or in person viewing at the Enforcement and Compliance Docket and Information Center in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Avenue, NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the Enforcement and Compliance Docket and Information Center is (202) 566–1752.

Use EPA's electronic docket and comment system at *http://www.regulations.gov,* to submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the docket that are available electronically. Once in the system, select ''docket search,'' then key in the docket ID number identified above. Please note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing at *http://www.regulations.gov,* as EPA receives them and without change, unless the comment contains copyrighted material, Confidential Business Information (CBI), or other information whose public disclosure is restricted by statute. For further information about the electronic docket, go to *www.regulations.gov*.

Title: NESHAP for Petroleum Refineries, Catalytic Cracking, Reforming and Sulfur Units (Renewal).

ICR Numbers: EPA ICR Number 1844.03, OMB Control Number 2060–0554.

ICR Status: This ICR is scheduled to expire on August 31, 2007. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB. 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 in title 40 of the CFR, after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9, and displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: The National Emission Standards for Hazardous Air Pollutants (NESHAP), for the regulations published at 40 CFR part 63, subpart UUU, were proposed on September 11, 1998, promulgated on April 11, 2002, and amended on February 9, 2005.

In general, all NESHAP standards require initial notifications, performance tests, and periodic reports. Owners or operators are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining compliance, and are required of all sources subject to NESHAP. Specifically, data is being collected on performance of the continuous monitoring systems for gasoline vapor and related hazardous air pollutants (HAPs), any excess emissions, and any operating parameter exceedances.

Any owner or operator subject to the provisions of this part shall maintain a file of these measurements, and retain

the file for at least five years following the date of such measurements, maintenance reports, and records. All reports are sent to the delegated state or local authority. In the event that there is no such delegated authority, the reports are sent directly to the United States Environmental Protection Agency (EPA) regional office.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 42 (rounded) hours per 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 which have subsequently changed; 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.

Respondents/Affected Entities: Owners or operators of major source petroleum refineries.

Estimated Number of Respondents: 132.

Frequency of Response: Initially and semiannually.

Estimated Total Annual Hour Burden: 11,040 hours.

Estimated Total Annual Cost: $7,833,941, which includes $0 annualized Capital Startup costs, $6,850,602 annualized Operating and Maintenance (O&M) costs, and $983,339 annualized Labor costs.

Changes in the Estimates: There is a decrease of 1,627 hours in the total estimated burden currently identified in the OMB Inventory of Approved ICR Burdens. The decrease in labor burden from the most recently approved ICR is due to an adjustment. The decrease in the total estimated labor burden as currently identified in the OMB Inventory of Approved Burden is not due to any program changes. The change in the burden and cost estimates occurred because the standard has been in effect for more than three years and the requirements are different during initial compliance (new facilities) as compared to on-going compliance (existing facilities). The previous ICR reflected those burdens and costs associated with the initial activities for subject facilities. This includes purchasing monitoring equipment, conducting performance tests and establishing recordkeeping systems. This ICR reflects the on-going burden and costs for existing facilities since we have assumed that there are no new sources. However, it is estimated that three affected emission source units had qualified for a compliance date extension and would be complying with the initial compliance requirements during the period of this ICR (one per year) and one affected facility (0.33 per year) will conduct a performance test due to a process/operating change. Activities for existing sources include continuous monitoring of pollutants and the submission of semiannual reports. The overall result is a decrease in labor burden hours. However, the annual costs increased due to the inclusion of operation and maintenance costs for monitoring systems which are assumed to be operating after the compliance date of the rule.

Dated: August 20, 2007.

Joseph A. Sierra,

Acting Director, Collection Strategies Division.

[FR Doc. E7–16922 Filed 8–24–07; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2006–0777; FRL–8460–8]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; NESHAP for Stationary Reciprocating Internal Combustion Engines (Renewal); EPA ICR Number 1975.04, OMB Control Number 2060–0548

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. The ICR which is abstracted below describes the nature of the collection and the estimated burden and cost.

DATES: Additional comments may be submitted on or before September 26, 2007.

ADDRESSES: Submit your comments, referencing docket ID number EPA–HQ–OECA–2006–0777, to (1) EPA online using *www.regulations.gov* (our preferred method), or by e-mail to *docket.oeca@epa.gov*, or by mail to: EPA Docket Center (EPA/DC), Environmental Protection Agency, Enforcement and Compliance Docket and Information Center, Mail Code 2201T , 1200 Pennsylvania Avenue, NW., Washington, DC 20460, and (2) OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Learia Williams, Compliance Assessment and Media Programs Division, Office of Compliance, Mail Code 2223A, Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; telephone number: (202) 564–4113; fax number: (202) 564–0050; e-mail address: *williams.learia@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On October 5, 2006 (71 FR 58853), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments. Any additional comments on this ICR should be submitted to EPA and OMB within 30 days of this notice.

EPA has established a public docket for this ICR under docket ID number EPA–HQ–OECA–2006–0777, which is available for public viewing online at *http://www.regulations.gov*, or in person viewing at the Enforcement and Compliance Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Avenue, NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the Enforcement and Compliance Docket is (202) 566–1752.

Use EPA's electronic docket and comment system at *http://www.regulations.gov*, to submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the docket that are available electronically. Once in the system, select ''docket search,'' then key in the docket ID number identified above. Please note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing at *http://www.regulations.gov*, as EPA receives them and without

change, unless the comment contains copyrighted material, confidential business information (CBI), or other information whose public disclosure is restricted by statute. For further information about the electronic docket, go to *www.regulations.gov.*

Title: NESHAP for Stationary Reciprocating Internal Combustion Engines (Renewal).

ICR Numbers: EPA ICR Number 1975.04, OMB Control Number 2060–0548.

ICR Status: This ICR is scheduled to expire on August 31, 2007. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB. 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 in title 40 of the CFR, after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9, and displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: The respondents to the information collection are owners or operators of new, reconstructed, and existing stationary reciprocating internal combustion engine (RICE) with a site-rating of more than 250 brake horsepower (hp) located at a major source of hazardous air pollutant (HAP) emissions that emits or has the potential to emit any single HAP at a rate of 10 tons (9.07 megagrams) or more per year or any combination of HAP at a rate of 25 tons (22.68 megagrams) or more per year. The information is requested by the agency to determine compliance with the rule. This information will then be used by enforcement agencies to verify that sources subject to the standard are meeting the emission reductions mandated by the Clean Air Act.

Owners/operators of stationary reciprocating internal combustion engines facilities are required to submit initial notification, performance tests, and periodic reports. Respondents are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. Semiannual reports are also required. These notifications, reports, and records are essential in determining compliance; and are required, in general, of all sources subject to NESHAP.

Any owner or operator subject to the provisions of this part shall maintain a file of these measurements, and retain the file for at least five years following the date of such measurements, maintain reports and records. All reports are sent to the delegated state or local authority. In the event that there is no such delegated authority, the reports are sent directly to the EPA regional office. This information is being collected to assure compliance with 40 CFR part 63, subpart ZZZZ as authorized in section 112 and 114(a) of the Clean Air Act. The required information consists of emissions data and other information that have been determined to be private.

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 Number for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15, and are identified on the form and/or instrument, if applicable.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 22 hours per 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 which have subsequently changed; 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.

Respondents/Affected Entities: Stationary reciprocating internal combustion engines.

Estimated Number of Respondents: 4,104.

Frequency of Response: Initially, monthly, quarterly, semiannually and annually.

Estimated Total Annual Hour Burden: 421,613.

Estimated Total Annual Cost: $160,095,898 which includes $1,867,340 annualized Capital Startup costs, $5,720,142 Operating and Maintenance (O&M) costs, $52,508,416 annualized labor costs.

Changes in the Estimates: There is an overall increase in the total estimated burden as currently identified in the OMB Inventory of Approved Burdens due to two considerations. First, this ICR is a combination of two approved ICRs which cover the original promulgated standard and the revised standard that expanded applicability to stationary reciprocation internal combustion engines (RICE) 250 hp or greater. Secondly, there are a substantial number of new RICE added to the inventory each year. The overall result is an increase in burden hours and cost.

The above rationalizations also apples to the capital/startup and operation and maintenance (O&M) cost of this ICR.

Dated: August 21, 2007.

Joseph A. Sierra,

Acting Director, Collection Strategies Division.

[FR Doc. E7–16924 Filed 8–24–07; 8:45 am]

BILLING CODE 6560–50–P

EXPORT-IMPORT BANK OF THE UNITED STATES

Notice of Open Special Meeting of the Advisory Committee of the Export-Import Bank of the United States (Ex-Im Bank)

SUMMARY: The Advisory Committee was established by Public Law 98–181, November 30, 1983, to advise the Export-Import Bank on its programs and to provide comments for inclusion in the reports of the Export-Import Bank on its programs and to provide comments for inclusion in the reports of the Export-Import Bank of the United States to Congress.

Time and Place: Wednesday, September 19, 2007 from 9 a.m. to 12 p.m. The meeting will be held at Ex-Im Bank in the Main Conference Room 1143, 811 Vermont Avenue, NW., Washington, DC 20571.

Agenda: Agenda items include a short summary of the Bank's recent activities, plus presentations from the Finance & Government Team and the Labor & Agriculture Team of the 2007 Advisory Committee members.

Public Participation: The meeting will be open to public participation, and the last 10 minutes will be set aside for oral questions or comments. Members of the public may also file written statement(s) before or after the meeting. If you plan to attend, a photo ID must be presented at the guard's desk as part of the clearance process into the building, and you may contact Teri Stumpf to be

placed on an attendee list. If any person wishes auxiliary aids (such as a sign language interpreter) or other special accommodations, please contact, prior to September 5, 2007, Teri Stumpf, Room 1209, 811 Vermont Avenue, NW., Washington, DC 20571, Voice: (202) 565–3502 or TDD (202) 565–3377.

Further Information: For further information, contact Teri Stumpf, Room 1209, 811 Vermont Ave., NW., Washington, DC 20571, (202) 565–3502.

Howard A. Schweitzer,

General Counsel.

[FR Doc. 07–4154 Filed 8–24–07; 8:45 am]

BILLING CODE 6690–01–M

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Agency Meeting

Pursuant to the provisions of the ''Government in the Sunshine Act'' (5 U.S.C. 552b), notice is hereby given that at 4 p.m. on Tuesday, August 21, 2007, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider matters relating to the Corporation's supervisory activities.

In calling the meeting, the Board determined, on motion of Vice Chairman Martin J. Gruenberg, seconded by Mr. Scott Polakoff, acting in the place and stead of Director John C. Reich (Director, Office of Thrift Supervision), concurred in by Director Thomas J. Curry (Appointive), Director John C. Dugan (Director, Comptroller of the Currency), and Chairman Shelia C. Bair, that Corporation business required its consideration of the matters on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(4), (c)(6), (c)(8), and (c)(9)(A)(ii) of the ''Government in the Sunshine Act'' (5 U.S.C. 552b(c)(4), (c)(6), (c)(8), and (c)(9)(A)(ii)).

The meeting was held in the Board Room of the FDIC Building located at 550 17th Street, NW., Washington, DC.

Dated: August 22, 2007.

Federal Deposit Insurance Corporation.

Valerie J. Best,

Assistant Executive Secretary.

[FR Doc. E7–16968 Filed 8–24–07; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at *www.ffiec.gov/nic/*.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than September 21, 2007.

A. Federal Reserve Bank of Richmond (A. Linwood Gill, III, Vice President) 701 East Byrd Street, Richmond, Virginia 23261-4528:

1. Virginia Community Capital, Inc., Christiansburg, Virginia, which is currently operating as a Community Development Financial Institution; to become a bank holding company.

In connection with this application, Applicant also has applied to, by acquiring Community Capital Bank of Virginia, Christiansburg, Virginia, continue to engage in lending and community development activities, pursuant to sections 225.28(b)(1), (b)(12)(i), and (b)(12)(ii) of Regulation Y.

B. Federal Reserve Bank of Chicago (Burl Thornton, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690-1414:

1. Marshall & Ilsley Corporation, Milwaukee, Wisconsin, and FIC Acquisition Corporation, Indianpolis, Indiana; to acquire 100 percent of the voting shares of First Indiana Corporation, and thereby indirectly acquire voting shares of First Indiana Bank, N.A., both of Indianapolis, Indiana.

In connection with this application, FIC Acquisition Corporation; has applied to become a bank holding company by acquiring 100 percent of the voting shares of First Indiana Corporation, and First Indiana Bank, N.A., all of Indianapolis, Indiana.

Board of Governors of the Federal Reserve System, August 22, 2007.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E7–16882 Filed 8–24–07; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60 Day–07–0260]

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 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–5960 and send comments to Maryam I. Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov*.

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 or other forms of information technology. Written comments should

be received within 60 days of this notice.

Proposed Project

Health Hazard Evaluation and Technical Assistance—Requests and Emerging Problems—Extension (OMB No. 0920–0260)—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In accordance with its mandates under the Occupational Safety and Health Act of 1970 and the Federal Mine Safety and Health Act of 1977, the National Institute for Occupational Safety and Health (NIOSH) responds to requests for health hazard evaluations (HHE) to identify chemical, biological or physical hazards in workplaces throughout the United States. Each year, NIOSH receives approximately 400 such requests. Most HHE requests come from the following types of companies: Service, manufacturing companies, health and social services, transportation, construction, agriculture/ mining, skilled trade and construction.

A printed Health Hazard Evaluation request form is available in English and in Spanish. The form is also available on the Internet and differs from the printed version only in format and in the fact that it uses an Internet address to submit the form to NIOSH. Both the printed and Internet versions of the form provide the mechanism for employees, employers, and other authorized representatives to supply the information required by the regulations governing the NIOSH Health Hazard Evaluation program (42 CFR 85.3–1). In general, if employees are submitting the form it must contain the signatures of three or more current employees. However, regulations allow a single signature if the requestor: Is one of three (3) or fewer employees in the process, operation, or job of concern; or is any officer of a labor union representing the employees for collective bargaining purposes. An individual management official may request an evaluation on behalf of the employer. The information provided is used by NIOSH to determine whether there is reasonable cause to justify conducting an investigation and provides a mechanism to respond to the requestor.

In the case of 25% to 50% of the health hazard evaluation requests received, NIOSH determines an on-site evaluation is needed. The primary purpose of an on-site evaluation is to help employers and employees identify and eliminate occupational health hazards. In most on-site evaluations employees are interviewed to help further define concerns, and in approximately 50% these evaluations (presently estimated to be about 100 facilities), questionnaires are distributed to the employees (averaging about 40 employees per site for this last subgroup). The interview and survey questions are specific to each workplace and its suspected diseases and hazards, however, items are derived from standard medical and epidemiologic techniques. The request forms take an estimated 12 minutes to complete. The interview forms take 30 minutes to complete.

NIOSH distributes interim and final reports of health hazard evaluations, excluding personal identifiers, to: Requesters, employers, employee representatives; the Department of Labor (Occupational Safety and Health Administration or Mine Safety and Health Administration, as appropriate); and, as needed, other state and federal agencies.

NIOSH administers a follow-back program to assess the effectiveness of its health hazard evaluation program in reducing workplace hazards. This program entails the mailing of follow-back questionnaires to employer and employee representatives at all the workplaces where NIOSH conducted site visits. In a small number of instances, a follow-back on-site evaluation may be conducted. The initial follow-back questionnaire is administrated immediately following the site visits and takes about 15 minutes. Another follow-back questionnaire is sent a year later and requires about 15 minutes to complete. At 24 months, a final follow-back questionnaire regarding the completed evaluation is sent which takes about 15 minutes to complete.

For requests where NIOSH does not conduct an onsite evaluation, the requester receives a follow-back questionnaire 12 months after our response and a second one 24 months after our response. The first questionnaire takes about 10 minutes to complete and the second questionnaire takes about 15 minutes to complete.

Because of the large number of investigations conducted each year, the need to respond quickly to requests for assistance, the diverse and unpredictable nature of these investigations, and its follow-back program to assess evaluation effectiveness; NIOSH requests an umbrella clearance for data collections performed within the domain of its health hazard evaluation program. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	No. of respondents	No. of responses/ respondent	Average burden/response (in hours)	Total burden (in hours)
Employees & Representatives (request form)	275	1	12/60	55
Employers (request form)	107	1	12/60	21
Employees (interview)	3800	1	15/60	950
Employees (questionnaire)	4040	1	30/60	2020
Employees and Employers immediately after onsite evaluation (follow-back)	760	1	15/60	190
Employees and Employers 12 months after onsite evaluation (follow-back)	760	1	15/60	190
Employees and Employers 24 months after onsite evaluation (follow-back)	760	1	15/60	190
Primary Requester without onsite evaluation 12 months (follow-back)	50	1	10/60	8
Primary Requester without onsite evaluation 24 months (follow-back)	50	1	15/60	13
Total				3637

Dated: August 20, 2007.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E7–16920 Filed 8–24–07; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for Health Statistics (NCHS), Classifications and Public Health Data Standards Staff, Announces the Following Meeting

Name: ICD–9–CM Coordination and Maintenance Committee meeting.

Time and Date: 8:30 a.m.–6 p.m., September 27–28, 2007.

Place: Centers for Medicare and Medicaid Services (CMS) Auditorium, 7500 Security Boulevard, Baltimore, Maryland.

Status: Open to the public.

Purpose: The ICD–9–CM Coordination and Maintenance (C&M) Committee will hold its final meeting of the 2007 calendar year cycle on Thursday and Friday, September 27–28, 2007. The C&M meeting is a public forum for the presentation of proposed modifications to the International Classification of Diseases, Ninth-Revision, Clinical Modification.

Matters To Be Discussed

Tentative agenda items include:

Androgen insensitivity
Carcinoid tumors/neuroendocrine tumors
Decubitus ulcer expansion
Eosinophilic disorders
Fetal medicine
Functional incontinence
Heparin-induced thrombocytopenia
Isolated systolic hypertension
Keratitis (Acanthamoeba and Fusarium)
Leukemia in relapse
Necrotizing enterocolitis
Retrolental fibroplasia
Secondary diabetes
Ventilator-associated pneumonia
Wound disruption
Addenda (Diagnoses)
ICD–10–CM Update
Non-invasive positive pressure ventilation
Laparoscopic colectomy
Laparoscopic deployed inguinal hernia repair mesh
Oversewing of atrial appendage
Bi-ventricular replacement
Intra-aneurysm sac pressure
Direct aqueous oxygen infusion therapy
Kyphoplasty
Intravascular chemography
Intravascular pressure measurement
Percutaneous tracheostomy
Repair of the annulus fibrosus
Surgical gel implantation

Addenda (Procedures)

ICD–10–Procedure Classification System (PCS) update.

FOR FURTHER INFORMATION CONTACT: Amy Blum, Medical Systems Specialist, Classifications and Public Health Data Standards Staff, NCHS, 3311 Toledo Road, Room 2402, Hyattsville, Maryland 20782, e-mail *alb8@cdc.gov,* telephone 301–458–4106 (diagnosis), Mady Hue, Health Insurance Specialist, Division of Acute Care, CMS, 7500 Security Blvd., Baltimore, Maryland, 21244, e-mail *marilu.hue@cms.hhs.gov,* telephone 410–786–4510 (procedures).

Notice: Because of increased security requirements CMS has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show an official form of picture I.D., (such as a drivers license), and sign-in at the security desk upon entering the building.

Those who wish to attend a specific ICD–9–CM C&M meeting in the CMS auditorium must submit their name and organization for addition to the meeting visitor list. Those wishing to attend the September 27–28, 2007 meeting must submit their name and organization by September 20, 2007 for inclusion on the visitor list. This visitor list will be maintained at the front desk of the CMS building and used by the guards to admit visitors to the meeting. Those who attended previous ICD–9–CM C&M meetings will no longer be automatically added to the visitor list. You must request inclusion of your name prior to each meeting you attend.

Register to attend the meeting on-line at: *http://www.cms.hhs.gov/apps/events/.*

Notice: This is a public meeting. However, because of fire code requirements, should the number of attendants meet the capacity of the room, the meeting will be closed.

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 CDC and the Agency for Toxic Substances and Disease Registry.

Diane C. Allen,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. E7–16903 Filed 8–24–07; 8:45 am]

BILLING CODE 4160–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0304]

Preparation for International Conference on Harmonization Meetings in Yokohama, Japan; Public Meeting; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** on August 13, 2007 (72 FR 45250). The document announced a public meeting entitled ''Preparation for ICH meetings in Yokohama, Japan'' to provide information and receive comments on the International Conference on Harmonization (ICH) as well as the upcoming meetings in Yokohama, Japan. The topics to be discussed are the topics for discussion at the forthcoming ICH Steering Committee Meeting. The purpose of the meeting is to solicit public input prior to the next Steering Committee and Expert Working Groups meetings in Yokohama, Japan, October 27 through November 1, 2007, at which discussion of the topics underway and the future of ICH will continue.

FOR FURTHER INFORMATION CONTACT: For information regarding this notice and the original notice: Tammie Bell, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, e-mail: *Tammie.Bell2@fda.hhs.gov*, FAX: 301–827–0003.

SUPPLEMENTARY INFORMATION: In FR Doc. E7–15803, appearing on page 45250 in the **Federal Register** of Monday, August 13, 2007, the following correction is made:

1. On page 45250, in the third column, the second full paragraph is corrected to read ''Interested persons may present data, information, or views orally or in writing, on issues pending at the public meeting. Oral presentations from the public will be scheduled between approximately 2:30

p.m. and 3 p.m. Time allotted for oral presentations may be limited to 10 minutes. Those desiring to make oral presentations should notify the contact person by October 2, 2007, and submit a brief statement of the general nature of the evidence or arguments they which to present, the names and addresses, phone number, fax, and e-mail of proposed participants, and an indication of the approximate time requested to make their presentation.''

Dated: August 20, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–16892 Filed 8–24–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; Notice of Meeting Cancellation

Notice is hereby given of the cancellation of the Advisory Commission on Childhood Vaccines (ACCV) Meeting, September 7, 2007, 9 a.m. to 5 p.m., Parklawn Building (and via audio conference call), Conference Rooms G & H, 5600 Fishers Lane, Rockville, MD 20857, which was published in the **Federal Register** on August 15, 2007, 72 FR 45822–45823.

Dated: August 21, 2007.

Alexandra Huttinger,

Acting Director, Division of Policy Review and Coordination.

[FR Doc. E7–16868 Filed 8–24–07; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; 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 Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel; Tissue Engineering and Regenerative Medicine.

Date: September 11, 2007.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Charles H. Washabaugh, PhD, Scientific Review Administrator, Review Branch, NIAMS/NIH, 6701 Democracy Blvd., Room 816, Bethesda, MD 20892, 301 451–4838, *washabac@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS).

Dated: August 15, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–4158 Filed 8–24–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Recombinant DNA Advisory Committee.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Recombinant DNA Advisory Committee.

Date: September 17–18, 2007.

Time: September 17, 2007, 8 a.m. to 12 p.m.

Agenda: The Recombinant DNA Advisory Committee will review and discuss elected human gene transfer protocols as well as related data management activities. There will also be a discussion about new clinical safety information.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Auditorium, Bethesda, MD 20892.

Time: September 17, 2007, 12:30 p.m. to 6 p.m.

Agenda: Continued.

Place: National Institutes of Health, Building 31, Floor 5C, 31 Center Drive, Conference Room 6, Bethesda, MD 20892.

Time: September 18, 207, 8 a.m. to 12 p.m.

Agenda: Continued.

Place: National Institutes of Health, Building 31, Floor 6C, 31 Center Drive, Conference Room 6, Bethesda, MD 20892.

Contact Person: Laurie Lewallen, Advisory Committee Coordinator, Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Room 750, Bethesda, MD 20892–7985, 301–496–9838, *lewallla@od.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *http://www4.od.nih.gov/oba/,* where an agenda and any additional information for the meeting will be posted when available.

OMB's ''Mandatory Information Requirements for Federal Assistance Program Announcements'' (45 FR 39592, June 11, 1980) requires a statement concerning the official government programs contained in the Catalog of Federal Domestic Assistance. Normally NIH lists in its announcements the number and title of affected individual programs for the guidance of the public. Because the guidance in this notice covers virtually every NIH and Federal research program in which DNA recombinant molecule techniques could be used, it has been determined not be cost effective or in the public interest to attempt to list these programs. Such a list would likely require several additional pages. In addition, NIH could not be certain that every Federal program would be included as many Federal agencies, as well as private organizations, both national and international, have elected to follow the NIH Guidelines. In lieu of the individual program listing, NIH invites readers to direct questions to the information address above about whether individual programs listed in the Catalog of Federal Domestic Assistance are affected.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research General; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from

Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: August 15, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–4157 Filed 8–24–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2007–27813]

New MARPOL Annex I Pollution Prevention Regulations; Information and Compliance Policy

AGENCY: Coast Guard, DHS.

ACTION: Notice of policy.

SUMMARY: This notice informs the public about new requirements of revised Annex I of the International Convention for the Prevention of Pollution from Ships (MARPOL 73/78), their associated entry into force dates, and compliance requirements for U.S. vessels that are subject to the Convention.

FOR FURTHER INFORMATION CONTACT: For information concerning this notice, contact Lieutenant Commander Scott Muller, Project Manager, Office of Vessel Activities, Domestic Vessel Division (CG–3PCV–1), telephone 202–372–1220 or via e-mail at *Scott.W.Muller@uscg.mil.* If you have questions on viewing material to the DOT Docket Management Facility docket, call Ms. Renee V. Wright, Program Manager, Docket Operations, telephone 202–493–0402.

SUPPLEMENTARY INFORMATION: The International Convention for the Prevention of Pollution from Ships (MARPOL 73/78) is the primary international agreement aimed at reducing pollution of the marine environment from a variety of vessel-generated sources. Annex I to MARPOL 73/78, ''Regulations for the Prevention of Pollution by Oil,'' contains provisions intended to reduce both intentional and accidental discharges of oil. Annex I was codified into U.S. law by the Act to Prevent Pollution from Ships at Sea 33 U.S.C. Sec. 1901 *et seq.* and with implementing regulations of 33 CFR parts 151, 155 and 157.

The entire annex was revised by adoption of Resolution MEPC.117(52) on October 15, 2004, and entered into force on January 1, 2007. In addition to adding new regulations, MARPOL Annex I was revised to be more user-friendly. It separates, by chapter, the requirements for: Survey and certification, machinery spaces of all ships, cargo areas of oil tankers, oil pollution emergency plans, reception facilities, and fixed or floating platforms. Additionally, where applicable, chapters are further divided by subpart concerning construction, equipment and operational requirements. Two new regulations were included in the revision:

- Regulation 22 of revised Annex I, ''Pump-room bottom protection,'' establishes design requirements for pump-room double bottoms on oil tankers of 5,000 tons deadweight and above constructed on or after January 1, 2007.
- Regulation 23 of revised Annex I, ''Accidental oil outflow performance,'' establishes design requirements to protect against oil pollution in the event of grounding or collision for oil tankers with a building contract on or after January 1, 2007 (or delivery on or after January 1, 2010).

In addition, on March 24, 2006, IMO adopted Resolution MEPC.141(54) which provided additional amendments that further revised MARPOL Annex I, which will enter into force on August 1, 2007. These amendments include a new regulation 12A:

- Regulation 12A of revised Annex I, ''Oil fuel tank protection,'' establishes design requirements for protectively located fuel tanks for all ships with an aggregate oil fuel capacity of 600 cubic meters (m3) and above with a building contract on or after August 1, 2007 (or delivery on or after August 1, 2010).

Reason for Policy Notice

As a signatory to the MARPOL 73/78 the U.S. government has an obligation to act in accordance with the convention. This obligation includes implementing and enforcing the new amendments to the convention for both U.S. vessels and foreign flagged vessels operating in U.S. waters. Thus, vessels required to have an International Oil Pollution Prevention (IOPP) certificate by the convention will need to meet the new revised regulations. Because the new revisions affect certain vessels subject to existing U.S. regulations, found at 33 CFR parts 157 and 155, the Coast Guard is developing a proposed rulemaking to harmonize existing U.S. regulations with the new revisions to the convention. In the interim, as a party to MARPOL 73/78, the United States will enforce the new MARPOL Annex I regulations as follows:

(a) *U.S. flagged vessels that are required to hold an International Oil Pollution Prevention (IOPP) Certificate in accordance with 33 CFR 151.19:* All U.S. vessels required to hold an IOPP Certificate must meet all requirements set out in MARPOL 73/78, including the new requirements, as applicable, established in recent IMO resolutions MEPC.117(52) and MEPC.141(54) discussed above that have come into force.

(b) *U.S. flagged vessels that are not required to hold an IOPP Certificate:* These vessels need not presently comply with the new MARPOL Annex I regulations, adopted by IMO resolutions MEPC.117(52) and MEPC.141(54) above. However, vessel operators are encouraged to comply with these new regulations in light of the Coast Guard's intention to revise domestic regulations (33 CFR 157 and 155) that will implement IMO resolution MEPC.117(52) and MEPC.141(54).

(c) *Foreign vessels calling to the U.S. ports or terminals:* The Coast Guard will enforce all applicable MARPOL Annex I regulations, including the new regulations adopted by IMO resolutions MEPC.117(52) and MEPC.141(54) discussed above.

Authority: 33 U.S.C. 1903, 33 U.S.C. 1231, 33 U.S.C. 1321, E.O. 12777, Department of Homeland Security Delegation No. 0170.1.

Dated: August 20, 2007.

J.G. Lantz,

Acting Assistant Commandant for Prevention, U.S. Coast Guard.

[FR Doc. E7–16725 Filed 8–24–07; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AZ–933–07, 5410–KD–A507; AZA–33515]

Application for Conveyance of Federal Mineral Interests, Pima County, AZ

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of application.

SUMMARY: The surface owner of the lands described in this notice, aggregating approximately 320.00 acres, has filed an application for the purchase of the federally owned mineral interests in the lands. Publication of this notice temporarily segregates the mineral interest from appropriation under the public land laws, including the mining law.

DATES: Interested persons may submit written comments to the Bureau of Land Management (BLM) at the address stated below. Comments must be received by no later than October 11, 2007.

ADDRESSES: Bureau of Land Management, Arizona State Office, One North Central Avenue, Suite 800, Phoenix, Arizona 85004. Detailed information concerning this action, including appropriate environmental information, is available for review at the above address.

FOR FURTHER INFORMATION CONTACT: Vivian Titus, Land Law Examiner, at the above address or at 602–417–9598.

SUPPLEMENTARY INFORMATION: The surface owner of the following described lands has filed an application pursuant to section 209 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1719(b), for the purchase and conveyance of the federally owned mineral interest in the following described lands:

Gila and Salt River Base and Meridian, Pima County, Arizona

T. 20 S., R. 10 E.,
Sec. 9, E½E½;
Sec. 10, NE¼NE¼, SW¼NW¼, W½SW¼.

Total Acres 320.00 more or less.

Effective immediately, the BLM will process the pending application in accordance with the regulations stated in 43 CFR Part 2720. Written comments concerning the application must be received by no later than the date specified above in this notice for that purpose. The purpose for a purchase and conveyance is to allow consolidation of surface and subsurface minerals ownership where (1) there are no known mineral values or (2) in those instances where the Federal mineral interest reservation interferes with or precludes appropriate nonmineral development and such development is a more beneficial use of the land than the mineral development.

On August 27, 2007 the mineral interests owned by the United States in the above described lands will be segregated to the extent that they will not be subject to appropriation under the public land laws, including the mining laws. The segregative effect shall terminate upon issuance of a patent or deed of such mineral interest; upon final rejection of the mineral conveyance application; or August 27, 2009, whichever occurs first.

(Authority: 43 CFR 2720.1–1(b))

Dated: August 20, 2007.

Helen Hankins,

Associate State Director.

[FR Doc. E7–16872 Filed 8–24–07; 8:45 am]

BILLING CODE 4310–32–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[MT–072–1430–ET; MTM 95280]

Notice of Proposed Withdrawal and Opportunity for Public Meeting; Montana; Correction

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice; correction.

SUMMARY: The Bureau of Land Management published a Notice of Proposed Legislative Withdrawal in the **Federal Register** on August 7, 2007. The document contained an incorrect legal description.

FOR FURTHER INFORMATION CONTACT: Sandra Ward, 406–896–5052.

Correction

In the **Federal Register** of August 7, 2007, in FR Doc. E7–15366, on page 44174, in the third column, the legal description under Sec. 3, which reads ''S½N¼'', is corrected to read ''S½N½'', and under Sec. 4, which reads ''S½N¼'', is corrected to read ''S½N½''.

Dated: August 14, 2007.

Cindy Staszak,

Chief, Branch of Land Resources.

[FR Doc. E7–16905 Filed 8–24–07; 8:45 am]

BILLING CODE 4310–$$–P

DEPARTMENT OF THE INTERIOR

National Park Service

National Register of Historic Places; Notification of Pending Nominations and Related Actions

Nominations for the following properties being considered for listing or related actions in the National Register were received by the National Park Service before August 11, 2007. Pursuant to section 60.13 of 36 CFR part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded by United States Postal Service, to the National Register of Historic Places, National Park Service, 1849 C St., NW., 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service,1201 Eye St., NW., 8th floor, Washington, DC 20005; or by fax, 202–371–6447. Written or faxed comments should be submitted by September 11, 2007.

J. Paul Loether,

Chief, National Register of Historic Places/ National Historic Landmarks Program.

ARKANSAS

Ashley County

Crossett Municipal Auditorium, 1100 Main St., Crossett, 07000965
Crossett Municipal Building, 307–309 Main St., Crossett, 07000966

Baxter County

Rollins Hospital, 107 E. Main St., Gassville, 07000970

Boone County

Cricket and Crest Tunnels Historic District, Under and W of Old US 65, Omaha, 07000954

Bradley County

Hermitage City Hall and Jail, 112 S. Oak St., Hermitage, 07000956

Craighead County

Caraway, U.S. Sen. Hattie, Gravesite, Oaklawn Cemetery, 2349 W. Matthews Avenue Lane, Jonesboro, 07000976

Crawford County

Bryant–Lasater House, 770 N. Main St., Mulberry, 07000958

Crittenden County

Turrell City Hall, Old, 160 Eureka St., Turrell, 07000962

Faulkner County

Hendrix College Addition Neighborhood Historic District, Roughly bounded by Washington Ave., Fleming St., Harkrider St. and Winfield St., Conway, 07000973

Garland County

Hot Springs Central Avenue Historic District (Boundary Increase), 101 Park Ave., Hot Springs, 07000957
Williams, Hamp, Building, 500–504 Ouachita Ave., Hot Springs, 07000972

Izard County

Calico Rock Methodist Episcopal Church, 101 W. 1st., Calico Rock, 07000971

Marion County

Cotter Tunnel, Under US 62 E of Cty Rd. 724, Cotter, 07000961
Pyatt Tunnel, Underneath MC 4008 approx 1 mi. S of US 62, Pyatt, 07000953

Ouachita County

Clifton and Greening Street Historic District (Boundary Increase II), 622, 630 and 634 Clifton and 206 Dallas and 502 Greening, Camden, 07000955

Poinsett County

Tyronza Water Tower, (New Deal Recovery Efforts in Arkansas MPS), NW of jct. of Main St. and Oliver St., Tryonza, 07000963

Pope County

US 64, Old, Scotia Segment, (Arkansas Highway History and Architecture MPS), S

of US 64, E of Cedar Ln., London, 07000959

Prairie County

Castleberry Hotel, 61 Main St., De Valls Bluff, 07000960

De Valls Bluff Waterworks, (New Deal Recovery Efforts in Arkansas MPS), Jct. of Hazel and Rumbaugh Sts., De Valls Bluff, 07000969

Sevier County

Lockesburg Waterworks, (New Deal Recovery Efforts in Arkansas MPS), Jct. of Hickory and Azales Sts., Lockesburg, 07000964

Union County

Murphy—Hill Historic District, Roughly bounded by E. 5th St., N. Jefferson St., E. Peach St., N. Madison St., and E. Faulkner St., El Dorado, 07000974

Woodruff County

McCrory Waterworks, (New Deal Recovery Efforts in Arkansas MPS), Jct. of N. Fakes and W. Third, McCrory, 07000968

Yell County

Brearley Cemetery Historic Section, AR 27 approx. ½ mi. W of AR 22, Dardanelle, 07000975

ILLINOIS

Cook County, Edison Park, 6755 N. Northwest Hwy., Chicago, 07000990

INDIANA

Elkhart County

Violett—Martin House and Gardens, 2612 S. Main, Goshen, 07000978

Hamilton County

Sheridan Downtown Commercial Historic District, Roughly includes Main St. from E. 2nd to the Old Monon Railroad right-of-way, Sheridan, 07000979

Jackson County

Medora Covered Bridge, off IN 235, ½ mi. SE of Medora over the east fork of the White River, Medora, 07000977

Owen County

Spencer Public Library, 110 E. Market St., Spencer, 07000980

Washington County

Beck's Mill Bridge, Carries Beck's Mill Road over Mill Creek, Salem, 07000981

LOUISIANA

Orleans Parish

Pan-American Life Insurance Company Building, 2400 Canal St., New Orleans, 07000982

West Baton Rouge Parish

Brusly High School Gymnasium, 601 N. Kirkland Dr., Brusly, 07000983

MINNESOTA

Lake County

BENJAMIN NOBLE (Shipwreck), (Minnesota's Lake Superior Shipwrecks MPS), Address Restricted, Knife River, 07000984

SOUTH CAROLINA

Dillon County

Hamer, James W., House, 1253 Harllees Bridge Rd., Little Rock, 07000985

Greenville County

Hopkins Farm, 3717 Fork Shoals Rd., Simpsonville, 07000987

Jasper County

Grays Consolidated High School, US 278, Grays, 07000986

TEXAS

Armstrong County

Goodnight, Charles and Mary Ann (Molly), Ranch House, US287 and 5000 Blk. Cty Rd. 25, Goodnight, 07000988

Dallas County

Stoneleigh Court Hotel, 2927 Maple Ave., Dallas, 07000989

Request(s) for removal have been made for the following resources:

MINNESOTA

Scott County

Bridge No. L3040 (Minnesota Masonry-Arch Highway Bridges), Co. Rd. 51, N of MN 19, Belle Plain vicinity, 89001829

Steele County

Kaplan Apartments, 115 W. Rose St., Owatonna, 86001464

[FR Doc. E7–16865 Filed 8–24–07; 8:45 am]

BILLING CODE 4312–51–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

Sixth Public Meeting for Reclamation's *Managing for Excellence* Project

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of a public meeting and announcement of subsequent meetings to be held.

SUMMARY: The Bureau of Reclamation is holding a meeting to inform the public about the *Managing for Excellence* project. This meeting is the third to be held in 2007 to inform the public about the action items, progress, and results of the *Managing for Excellence* project and to seek broad public input and feedback. Subsequent meetings are anticipated and will be held in collaboration with the public.

DATES: September 25, 2007, 8 a.m. to 5 p.m., and September 26, 2007, 8 a.m. to 3 p.m.

ADDRESSES: Holiday Inn Portland Airport Hotel, 8439 Columbia Blvd., Portland, Oregon 97220.

FOR FURTHER INFORMATION CONTACT: Debbie Byers at (303) 445–2790.

SUPPLEMENTARY INFORMATION: The *Managing for Excellence* project will identify and address the specific 21st Century challenges Reclamation must meet to fulfill its mission to manage, develop, and protect water and related resources in an environmentally and economically sound manner in the interest of the American public. This project will examine Reclamation's core capabilities and the agency's ability to respond to both expected and unforeseeable future needs in an innovative and timely manner. This project will result in essential changes in a number of key areas, which are outlined in, *Managing for Excellence*—An Action Plan for the 21st Century Bureau of Reclamation. For more information regarding the project, Action Plan, and specific actions being taken, please visit the *Managing for Excellence* Web site at *http://www.usbr.gov/excellence*.

Registration

Although you may register the first day of the conference beginning at 7 a.m., we highly encourage you to register prior to the date of the meeting online at *http://www.usbr.gov/excellence*, or by phone at 303–445–2935.

Dated: August 13, 2007.

Ryan Serote,

Acting Deputy Commissioner—External and Intergovernmental Affairs.

[FR Doc. E7–16916 Filed 8–24–07; 8:45 am]

BILLING CODE 4310–MN–P

DEPARTMENT OF JUSTICE

[AAG/A Order No. 027–2007]

Privacy Act of 1974; System of Records

AGENCY: United States Marshals Service, Department of Justice.

ACTION: Notice of modified system of records.

SUMMARY: Pursuant to the provisions of the Privacy Act of 1974 (5 U.S.C. 552a), the United States Marshals Service (USMS), Department of Justice, is issuing public notice of its proposal to modify a system of records entitled, ''U.S. Marshals Service (USMS) Employee Assistance Program (EAP) Records, JUSTICE/USM–015.'' This notice was last published in the **Federal Register** in full on November 8, 1999, at 64 FR 60832, 47; and modified in part on January 31, 2001, at 66 FR 8425 and on January 25, 2007, at 72 FR 3410.

DATES: Title 5 U.S.C. 552a(e)(4) and (11) provide that the public be given a 30-

day period in which to comment on routine uses. The Office of Management and Budget (OMB), which has oversight responsibility under the Act, requires a 40-day period in which to review the system modifications. The public, OMB and Congress are invited to comment on the modifications to these systems. Please submit any comments by October 9, 2007. The proposed changes will be effective on that date, unless comments are received that result in a contrary determination.

ADDRESSES: Submit written comments to the Department of Justice (DOJ), ATTN: Joo Chung, Counsel, Privacy and Civil Liberties Office, Office of the Deputy Attorney General, Room 4259 Main RFK Building, Washington, DC 20530, or facsimile number 202–616–9627.

FOR FURTHER INFORMATION CONTACT: Ed Bordley, Attorney-Advisor, USMS, at 202–307–8571.

SUPPLEMENTARY INFORMATION: The system notice has been revised to reflect routine uses modified or added for consistency with other Department of Justice notices, and the removal of one routine use which was determined to be not applicable to this particular system of records. The system location address has been changed and reworded. The categories of records and purposes designation were modified to eliminate redundancy and superfluous information. The record access procedure designation was modified to reflect the changes in the categories of records.

In accordance with 5 U.S.C. 552a(r), the Department has provided a report on the modified system to OMB and the Congress. A description of the system is found below.

Dated: August 16, 2007.

Lee J. Lofthus,

Assistant Attorney General for Administration.

JUSTICE/USM–015

SYSTEM NAME:

U.S. Marshals Service (USMS) Employee Assistance Program (EAP) Records.

SECURITY CLASSIFICATION:

Limited official use.

SYSTEM LOCATION:

Primary system: Human Resources Division, U.S. Marshals Service, CS–3, Washington, DC 20530–1000. Contractor records are maintained at the respective offices of these providers; these addresses may be obtained by contacting the USMS Employee Assistance Program (EAP) Office.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Current and former employees of the USMS (and in limited cases, immediate family members) who have sought counseling or have been referred for counseling or treatment through the USMS EAP. The remainder of this notice will refer to all persons covered by this system as ''EAP client(s)''.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records include any record, written or electronic, which may assist in diagnosing, evaluating, counseling and/or treating an EAP client; or resolving an EAP client's complaint and/or management's concern (management consultation) regarding the EAP client's performance, attendance, or conduct issues. The records may contain the consent forms; intake/termination and outcome documents; case notes; pertinent psychosocial, medical and employment histories; medical tests or screenings, including drug and alcohol tests and information on positive drug tests generated by the Drug Free Workplace Program or treatment facilities; treatment and rehabilitation plans and recommendations; abeyance/back-to-work agreements; insurance data; behavioral improvement plans; and referral records. Where clinical referrals have been made, records may include information related to counseling, diagnosis, prognosis, treatment and evaluation, together with follow-up data that may be generated by the program providing the services. Records may also include those that can assist in the monitoring, managing, and evaluating the contractor's performance such as sanitized audit records of the EAP/Contractor Program.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 290dd, *et seq.* and 290ee, *et seq.*; 42 CFR 2.1, *et seq.*; E.O. 12564, 5 U.S.C. 3301 and 7901; 44 U.S.C. 3101 and Public Law 100–71, sec. 503 (July 11, 1987).

PURPOSE(S):

The EAP is a voluntary program designed to assist clients in obtaining help in handling personal problem(s) affecting job performance, and to provide emotional support and assistance during periods of crises. Records are maintained to document and monitor client's participation in the EAP program; to monitor compliance with abeyance and back-to-work agreements; to document the nature and effects of the employee's personal problem(s); and to manage and monitor contractor performance. Routine uses of records maintained in the system, including categories of users and the purpose of such uses:

Records or Information May be Disclosed:

(a) To appropriate state or local authorities to report, where required under state law, incidents of suspected child, elder or domestic abuse or neglect;

(b) To any person or entity to the extent necessary to prevent an imminent crime which directly threatens loss of life or serious bodily injury;

(c) To USMS contractors that provide counseling and other services through referrals from the EAP staff to the extent that it is appropriate, relevant, and necessary to enable the contractor to perform counseling, treatment, rehabilitation, and evaluation duties;

(d) To any person responsible for the care of an EAP client when the EAP client to whom the records pertain is mentally incompetent or under legal disability;

(e) To any person or entity to the extent necessary to meet a bona fide medical emergency;

(f) To appropriate agencies, entities, and persons when (1) The Department suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised; (2) the Department has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by the Department or another agency or entity) that rely upon the compromised information; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Department's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

Disclosure to Consumer Reporting Agencies:

Records in this system are not appropriate for disclosure to consumer reporting agencies.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Information is stored in locked metal safes and in computerized databases.

RETRIEVABILITY:

Records are retrieved by name of employee and, in limited cases immediate family members.

SAFEGUARDS:

In accordance with the requirements of 42 CFR 2.16, USMS EAP, contractor records are stored in a secure environment. Access to USMS EAP records is restricted to designated USMS EAP personnel, except as otherwise permitted by law or with the written consent of the individual. Vouchers prepared to effect payment for services rendered by the contractors in performance of the contract do not contain individual identifiers. Invoices prepared by contractors located outside the Washington, DC metropolitan area are sent by first-class mail to the designated member(s) of the local contractors contracted with the USMS. In turn, invoices or other records prepared in support of payment vouchers which contain individual identifiers are hand-carried by the local contractors to the EAP Administrator who retains the supporting documentation. Records are maintained in locked metal safes. Entry to headquarters is restricted by 24-hour guard service to employees with official and electronic identification.

Access to contractors records is restricted to a designated member(s) of the contractors, except as otherwise provided by law or with the written consent of the individual. Contractors records are stored in locked files also.

RETENTION AND DISPOSAL:

Records, paper or electronic, are retained for three years after the individual ceases contact with the USMS EAP and/or the contractor unless a longer retention period is necessary because of pending administrative or judicial proceedings. In such cases, the records are retained for six months after the case is closed. At that time the records are destroyed by shredding (General Records Schedules 26 and 36).

SYSTEM MANAGER(S) AND ADDRESS:

Employee Assistance Program Administrator, Health and Safety Team, Human Resources Division, United States Marshals Service, CS–3, Washington, DC 20530–1000.

NOTIFICATION PROCEDURE:

Same as ''Record access procedures.''

RECORD ACCESS PROCEDURES:

Address all requests for access to the USMS EAP records in writing to system manger identified above. Address all requests for records maintained by the contractor to these service providers. Address(es) of these service providers may be obtained by contacting the USMS EAP Office. Clearly mark the envelope and letter ''Privacy Act Request.'' Clearly indicate the name of the requester, nature of the record sought, and approximate date of the record. In addition, provide the required verification of identity (28 CFR 16.41(d)) and a return address for transmitting the information.

CONTESTING RECORD PROCEDURES:

Direct all requests to contest or amend information in accordance with the procedures outlined under ''Record access procedures.'' State clearly and concisely the information being contested, the reasons for contesting it, and the proposed amendment to the information sought. Clearly mark the letter and envelope ''Privacy Act Amendment Request.''

RECORD SOURCE CATEGORIES:

Records are generated by the EAP client who is the subject of the record; USMS EAP personnel; the contractors, and the specialized service providers; the USMS Human Resources Division; and the employee's supervisor. In the case of a confirmed, unjustified positive drug test, records may also be generated by the staff of the Drug-Free Workplace Program and the Medical Review Officer.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. E7–16894 Filed 8–24–07; 8:45 am]

BILLING CODE 4410–04–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—the Nanoparticle Flow Processing Consortium

Notice is hereby given that, on July 16, 2007, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Nanoparticle Flow Processing Consortium has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identities of the parties to the venture and (2) the nature and objectives of the venture. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Pursuant to Section 6(b) of the Act, the identities of the parties to the venture are: 3M Company, St. Paul, MN; The Proctor & Gamble Company, Cincinnati, OH; Corning Incorporated, Corning, NY; BASF Aktiengesellschaft, Ludwigshafen, Germany, and Imperial Chemical Industries PLC, London, United Kingdom. The general area of Nanoparticle Flow Processing Consortium's planned activity is to: (1) Develop, test, and validate computer-simulation technologies of near-term application that can improve the quality and reduce the cost of nanoparticle suspension/dispersion manufacture (including suspension stability and processibility); (2) transfer the technology developed under the Research and Development Program in a manner that offers the Consortium members opportunities for commercial advantage; and (3) develop methodologies and aptitude for modeling and simulation of multiscale phenomena intrinsic to the stability and dynamics of dense, nanoparticle suspensions. This development will be synergistic and applicable to many U.S. Department of Energy campaigns for simulation (viz. C6, ASC, and other science and technology initiatives like those underpinning MESA).

J. Robert Kramer II,

Director of Operations, Antitrust Division.

[FR Doc. 07–4166 Filed 8–24–07; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—National Center for Manufacturing Sciences, Inc.

Notice is hereby given that, on July 24, 2007, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), National Center for Manufacturing Sciences, Inc. (''NCMS'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Ahura Scientific, Inc., Wilmington, MA; Ben Franklin Technology Partners, Philadelphia, PA; Camber Corporation, Huntsville, AL; City of Detroit Information Technology Services Dept., Detroit, MI; Electro-Mechanical Associates, Inc., Ann Arbor, MI; H.A. Burrow Pattern Works, Inc., La Habra, CA; I.D. Systems, Inc., Hackensack, NJ; MichBio, Ann Arbor, MI; Oxonica plc, Mountain View, CA; Purdue University, West Lafayette, IN;

Radian Tool & Engineering, Troy, MI; and Savant Technology Group, Inc., Ann Arbor, MI have been added as parties to this venture. Also, Anautics, Inc., Oklahoma City, OK; Campfire Interactive, Inc., Ann Arbor, MI; Cleveland Advanced Manufacturing Program (CAMP), Cleveland, OH; Cor-Met Inc., Brighton, MI; Fraunhofer USA, Plymouth, MI; Integrated Technologies, Inc., Danville, VT; Leszynski Group Inc., Bellevue, WA; Midwest Thermal Spray, Farmington Hills, MI; and Raytheon Systems Company, McKinney, TX have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and NCMS intends to file additional written notification disclosing all changes in membership.

On February 20, 1987, NCMS filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on March 17, 1987 (52 FR 8375).

The last notification was filed with the Department of Justice on February 15, 2007. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on March 15, 2007 (72 FR 12198).

J. Robert Kramer II,

Director of Operations, Antitrust Division.

[FR Doc. 07–4165 Filed 8–24–07; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated April 17, 2007, and published in the **Federal Register** on April 30, 2007, (72 FR 21298), Amri Rensselaer, Inc. (formerly: Organichem Corporation), 33 Riverside Avenue, Rensselaer, New York 12144, made application by letter to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of Oxymorphone (9652), a basic class of controlled substance listed in schedule II.

The company plans on manufacturing the listed controlled substance in bulk for sale to its customer.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Amri Rensselaer, Inc. to manufacture the listed basic class of controlled substance is consistent with the public interest at this time. DEA has investigated Amri Rensselaer, Inc. to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823, and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic class of controlled substance listed.

Dated: August 16, 2007.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. E7–16856 Filed 8–24–07; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to § 1301.33(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on June 5, 2007, Boehringer Ingelheim Chemicals Inc., 2820 N. Normandy Drive, Petersburg, Virginia 23805, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the basic classes of controlled substances listed in schedule I and II:

Drug	Schedule
Tetrahydrocannabinols (7370)	I
Amphetamine (1100)	II
Methylphenidate (1724)	II
Methadone (9250)	II
Methadone Intermediate (9254)	II
Dextropropoxyphene, bulk (non-dosage forms) (9273).	II
Fentanyl (9801)	II

The company plans to manufacture the listed controlled substances in bulk for sale to its customers for formulation into finished pharmaceuticals.

Any other such applicant and any person who is presently registered with DEA to manufacture such a substance may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR 1301.33(a).

Any such written comments or objections being sent via regular mail should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), Washington, DC 20537, or any being sent via express mail should be sent to Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 2401 Jefferson Davis Highway, Alexandria, Virginia 22301; and must be filed no later than October 26, 2007.

Dated: August 16, 2007.

Joseph T. Rannazzisi,

Deputy Assistant Administraton, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. E7–16855 Filed 8–24–07; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application

Pursuant to 21 U.S.C. 958(i), the Attorney General shall, prior to issuing a registration under this Section to a bulk manufacturer of a controlled substance in schedule I or II and prior to issuing a regulation under 21 U.S.C. 952(a)(2) authorizing the importation of such a substance, provide manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore, in accordance with Title 21 Code of Federal Regulations (CFR), 1301.34(a), this is notice that on June 5, 2007, Boehringer Ingelheim Chemicals, Inc., 2820 N. Normandy Drive, Petersburg, Virginia 23805, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of Phenylacetone (8501), a basic class of controlled substance listed in schedule II.

The company plans to import the listed controlled substance to bulk manufacture amphetamine.

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic class of controlled substance may file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43 and in such form as prescribed by 21 CFR 1316.47.

Any such comments or objections being sent via regular mail should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), Washington, DC

20537, or any being sent via express mail should be sent to Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 2401 Jefferson Davis Highway, Alexandria, Virginia 22301; and must be filed no later than September 26, 2007.

This procedure is to be conducted simultaneously with, and independent of, the procedures described in 21 CFR 1301.34(b), (c), (d), (e) and (f). As noted in a previous notice published in the **Federal Register** on September 23, 1975, (40 FR 43745–46), all applicants for registration to import a basic class of any controlled substances in schedule I or II are and will continue to be required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a); 21 U.S.C. 823(a); and 21 CFR 1301.34(b), (c), (d), (e) and (f) are satisfied.

Dated: August 16, 2007.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. E7–16863 Filed 8–24–07; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application

Prior to issuing a registration under 21 U.S.C. 952(a) (2) (B), and in accordance with 21 CFR 1301.34 (a), this is notice that on July 20, 2007, Cerilliant Corporation, 811 Paloma Drive, Suite A, Round Rock, TX 78664, made application by renewal to the Drug Enforcement Administration (DEA) for registration as an importer of the basic classes of controlled substances listed in schedule I and II:

Drug	Schedule
Cathinone (1235)	I
Methcathinone (1237)	I
N-Ethylamphetamine (1475)	I
N,N-Dimethylamphetamine (1480)	I
Fenethylline (1503)	I
Gamma hydroxybutyric acid (2010).	I
Ibogaine (7260)	I
Lysergic acid diethylamide (7315)	I
Marihuana (7360)	I
Tetrahydrocannabinols (7370)	I
Mescaline (7381)	I
3,4,5-Trimethoxyamphetamine (7390).	I
4-Bromo-2,5-dimethoxyamphetamine (7391).	I
4-Bromo-2,5-dimethoxyphenethylamine (7392).	I
4-Methyl-2,5-dimethoxyamphetamine (7395).	I
2,5-Dimethoxyamphetamine (7396).	I
3,4-Methylenedioxyamphetamine (7400).	I
3,4-Methylenedioxy-N-ethylamphetamine (7404).	I
3,4-Methylenedioxymethamphetamine (7405).	I
4-Methoxyamphetamine (7411)	I
Alpha-methyltryptamine (7432)	I
Diethyltryptamine (7434)	I
Dimethyltryptamine (7435)	I
Psilocybin (7437)	I
Psilocyn (7438)	I
Phencyclidine (7471)	I
N-Benzylpiperazine (7493)	I
Etorphine (except HCl)(9056)	I
Heroin (9200)	I
Morphine-N-oxide (9307)	I
Normorphine (9313)	I
Pholcodine (9314)	I
Dextromoramide (9613)	I
Dipipanone (9622)	I
Trimeperidine (9646)	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Methylphenidate (1724)	II
Amobarbital (2125)	II
Pentobarbital (2270)	II
Secobarbital (2315)	II
Phenylacetone (8501)	II
Cocaine (9041)	II
Codeine (9050)	II
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Benzoylecgonine (9180)	II
Ethylmorphine (9190)	II
Meperidine (9230)	II
Methadone (9250)	II
Dextropropoxyphene, bulk (non-dosage forms) (9273).	II
Morphine (9300)	II
Thebaine (9333)	II
Levo-alphacetylmethadol (9648)	II
Oxymorphone (9652)	II
Poppy Straw Concentrate (9670)	II

The company plans to import small quantities of the listed controlled substances for the manufacture of analytical reference standards.

Any bulk manufacturers who are presently, or are applying to be, registered with DEA to manufacture such basic classes of controlled substances may file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43 and in such form as prescribed by 21 CFR 1316.47.

Any such comments or objections being sent via regular mail should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), Washington, DC. 20537; or any being sent via express mail should be sent to Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 2401 Jefferson-Davis Highway, Alexandria, Virginia 22301; and must be filed no later than September 26, 2007.

This procedure is to be conducted simultaneously with and independent of the procedures described in 21 CFR 1301.34(b), (c), (d), (e) and (f). As noted in a previous notice published in the Federal Register on September 23, 1975, (40 FR 43745–46), all applicants for registration to import a basic class of any controlled substances in Schedule I or II are and will continue to be required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a); 21 U.S.C. 823(a); and 21 CFR 1301.34(b), (c), (d), (e), and (f) are satisfied.

Dated: August 16, 2007.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. E7–16862 Filed 8–24–07; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Registration

By Notice dated June 7, 2007 and published in the **Federal Register** on June 20, 2007, (72 FR 34040), Chattem Chemicals, Inc., 3801 St. Elmo Avenue, Building 18, Chattanooga, Tennessee 37409, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of the basic classes of controlled substances listed in schedule II:

Drug	Schedule
Methamphetamine (1105)	II
Phenylacetone (8501)	II
Raw Opium (9600)	II
Concentrate of Poppy Straw (9670).	II

The company plans to import the listed controlled substances to

manufacture bulk controlled substances for sale to its customers.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and 952(a) and determined that the registration of Chattem Chemicals, Inc. to import the basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971, at this time. DEA has investigated Chattem Chemicals, Inc. to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above named company is granted registration as an importer of the basic classes of controlled substances listed.

Dated: August 16, 2007.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. E7–16860 Filed 8–24–07; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to § 1301.33(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on July 3, 2007, Chattem Chemicals, Inc., 3801 St. Elmo Avenue, Building 18, Chattanooga, Tennessee 37409, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the basic classes of controlled substances listed in schedule I and II:

Drug	Schedule
4-Methoxyamphetamine (7411)	I
Dihydromorphine (9145)	I
Difenoxin (9168)	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Methylphenidate (1724)	II
Pentobarbital (2270)	II
Codeine (9050)	II
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Hydrocodone (9193)	II
Meperidine (9230)	II
Dextropropoxyphene, bulk (non-dosage forms) (9273).	II
Morphine (9300)	II
Thebaine (9333)	II
Oxymorphone (9652)	II
Noroxymorphone (9668)	II
Alfentanil (9737)	II
Sufentanil (9740)	II
Fentanyl (9801)	II

The company plans to manufacture the listed controlled substances in bulk for distribution to its customers.

Any other such applicant and any person who is presently registered with DEA to manufacture such a substance may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR 1301.33(a).

Any such written comments or objections being sent via regular mail should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), Washington, DC 20537, or any being sent via express mail should be sent to Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 2401 Jefferson Davis Highway, Alexandria, Virginia 22301; and must be filed no later than October 26, 2007.

Dated: August 16, 2007.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. E7–16873 Filed 8–24–07; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to 1301.33(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on May 30, 2007, Chemic Laboratories, Inc., 480 Neponset Street, Building 7, Canton, Massachusetts 02021, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of Cocaine (9041), a basic class of controlled substance listed in schedule II.

The company plans to manufacture small quantities of the above listed controlled substance for distribution to its customers for the purpose of research.

Any other such applicant and any person who is presently registered with DEA to manufacture such a substance may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR 1301.33(a).

Any such written comments or objections being sent via regular mail should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), Washington, DC 20537, or any being sent via express mail should be sent to Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 2401 Jefferson Davis Highway, Alexandria, Virginia 22301; and must be filed no later than October 26, 2007.

Dated: August 16, 2007.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. E7–16854 Filed 8–24–07; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application

Pursuant to 21 U.S.C. 958(i), the Attorney General shall, prior to issuing a registration under this Section to a bulk manufacturer of a controlled substance in schedule I or II and prior to issuing a regulation under 21 U.S.C. 952(a)(2) authorizing the importation of such a substance, provide manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore, in accordance with Title 21 Code of Federal Regulations (CFR), 1301.34(a), this is notice that on July 19, 2007, CIMA Labs, Inc., 10000 Valley View Road, Attention: Jason Gardner, Eden Prairie, Minnesota 55344, made application by letter to the Drug Enforcement Administration (DEA) to be registered as an importer of Nabilone (7379), a basic class of controlled substance listed in schedule II.

The company plans to import the basic class of controlled substance for clinical trials and research.

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic class of controlled substance may file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43 and in such form as prescribed by 21 CFR 1316.47.

Any such comments or objections being sent via regular mail should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), Washington, DC 20537, or any being sent via express mail should be sent to Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 2401 Jefferson-Davis Highway, Alexandria, Virginia 22301; and must be filed no later than September 26, 2007.

This procedure is to be conducted simultaneously with and independent of the procedures described in 21 CFR 1301.34(b), (c), (d), (e) and (f). As noted in a previous notice published in the **Federal Register** on September 23, 1975, (40 FR 43745–46), all applicants for registration to import a basic class of any controlled substance listed in schedule I or II are, and will continue to be required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a), 21 U.S.C. 823(a), and 21 CFR 1301.34(b), (c), (d), (e) and (f) are satisfied.

Dated: August 16, 2007.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. E7–16871 Filed 8–24–07; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to § 1301.33(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on July 27, 2007, Cody Laboratories, 601 Yellowstone Avenue, Cody, Wyoming 82414, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the basic classes of controlled substances listed in schedule I and II:

Drug	Schedule
Dihydromorphine (9145)	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Amobarbital (2125)	II
Pentobarbital (2270)	II
Secobarbital (2315)	II
Phenylacetone (8501)	II
Cocaine (9041)	II
Codeine (9050)	II
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Diphenoxylate (9170)	II
Meperidine (9230)	II
Methadone (9250)	II
Oxymorphone (9652)	II
Alfentanil (9737)	II
Sufentanil (9740)	II
Fentanyl (9801)	II

The company plans on manufacturing the listed controlled substances in bulk for sale to its customers.

Any other such applicant and any person who is presently registered with DEA to manufacture such a substance may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR 1301.33(a).

Any such written comments or objections being sent via regular mail should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), Washington, DC 20537, or any being sent via express mail should be sent to Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 2401 Jefferson Davis Highway, Alexandria, Virginia 22301; and must be filed no later than October 26, 2007.

Dated: August 16, 2007.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. E7–16874 Filed 8–24–07; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated May 7, 2007, and published in the **Federal Register** on May 14, 2007, (72 FR 27151), Noramco Inc., 1440 Olympic Drive, Athens, Georgia 30601, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the basic classes of controlled substances listed in schedule I and II:

Drug	Schedule
Codeine-N-Oxide (9053)	I
Morphine-N-Oxide (9307)	I
Amphetamine (1100)	II
Methylphenidate (1724)	II
Codeine (9050)	II
Dihydrocodeine (9120)	II
Hydromorphone (9150)	II
Hydrocodone (9193)	II
Morphine (9300)	II
Thebaine (9333)	II
Opium, raw (9600)	II
Opium poppy (9650)	II
Oxymorphone (9652)	II
Alfentanil (9737)	II
Sufentanil (9740)	II
Carfentanil (9743)	II
Fentanyl (9801)	II

The company plans to manufacture small quantities of the Schedule I controlled substances for internal testing; the Schedule II controlled substances will be manufactured in bulk for distribution to its customers.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Noramco, Inc. to manufacture the listed basic class of controlled substance is consistent with the public interest at this time. DEA has investigated Noramco, Inc. to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. § 823, and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed.

Dated: August 16, 2007.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. E7–16858 Filed 8–24–07; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review: Comment Request

August 22, 2007.

The Department of Labor has submitted the following public information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35). Copies of this ICR, with applicable supporting documentation; including among other

things a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAMain* or by contacting Darrin King on 202–693–4129 (this is not a toll-free number)/e-mail: *king.darrin@dol.gov*.

Comments should be sent to Office of Information and Regulatory Affairs, Attn: John Kraemer, OMB Desk Officer for the Occupational Safety and Health Administration (OSHA), Office of Management and Budget, 725 17th Street, NW., Room 10235, Washington, DC 20503, Telephone: 202–395–4816 / Fax: 202–395–6974 (these are not a toll-free numbers), E-mail: *OIRA_submission@omb.eop.gov* within 30 days from the date of this publication in the **Federal Register.** In order to ensure the appropriate consideration, comments should reference the OMB Control Number (see below).

The OMB is particularly interested in comments which:

• 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;

• 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;

• Enhance the quality, utility, and clarity of the information to be collected; and

• 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.

Agency: Occupational Safety and Health Administration.

Type of Review: Extension without change of currently approved collection.

Title: Grantee Quarterly Progress Report.

OMB Control Number: 1218–0100.

Estimated Number of Respondents: 55.

Estimated Total Burden Hours: 2,640.

Affected Public: Private Industry: Not-for-profit institutions.

Description: The Grantee Quarterly Progress Report is used to collect information concerning activities conducted during the quarter by grantees under OSHA Harwood training grants. The information is used to monitor progress and the use of Federal grant funds.

Darrin A. King,

Acting Departmental Clearance Officer.

[FR Doc. E7–16907 Filed 8–24–07; 8:45 am]

BILLING CODE 4510–26– P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–60,843]

Clorox Services Company a Subsidiary of the Clorox Company, Oakland, CA; Notice of Negative Determination on Reconsideration

On June 4, 2007, the Department issued an Affirmative Determination Regarding Application for Reconsideration for the workers and former workers of the subject firm. The notice was published in the **Federal Register** on June 14, 2007 (72 FR 32915–32916).

The petition for the workers of Clorox Services Company, a subsidiary of the Clorox Company, Oakland, California engaged in information technology services, including application development and maintenance, data center operations, and network and end-user support was denied because the petitioning workers did not produce an article within the meaning of section 222 of the Act.

The petitioners filed a request for reconsideration in which they contend that the Department erred in its interpretation of work performed at the subject facility and convey that workers of the subject firm supported manufacturing of goods at affiliated incorporated subsidiaries of the Clorox Company.

The workers of the subject firm and a company official were contacted for clarification in regard to the nature of the work performed at the subject facility. The investigation on reconsideration revealed that workers of the subject firm supported production of various household and specialty articles at various subsidiaries of the Clorox Company on a company-wide scale.

The Department conducted an additional investigation to determine whether workers can be considered eligible for TAA as directly-impacted workers in support of production of household and specialty products, such as home cleaning, auto care, professional products, cat litter, dressings, sauces and seasonings.

The group eligibility requirements for directly-impacted (primary) workers under section 222(a) the Trade Act of 1974, as amended, can be satisfied in either of two ways:

I. Section (a)(2)(A) all of the following must be satisfied:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. The sales or production, or both, of such firm or subdivision have decreased absolutely; and

C. Increased imports of articles like or directly competitive with articles produced by such firm or subdivision have contributed importantly to such workers' separation or threat of separation and to the decline in sales or production of such firm or subdivision; or

II. Section (a)(2)(B) both of the following must be satisfied:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. There has been a shift in production by such workers' firm or subdivision to a foreign country of articles like or directly competitive with articles which are produced by such firm or subdivision; and

C. One of the following must be satisfied:

1. The country to which the workers' firm has shifted production of the articles is a party to a free trade agreement with the United States;

2. The country to which the workers' firm has shifted production of the articles is a beneficiary country under the Andean Trade Preference Act, African Growth and Opportunity Act, or the Caribbean Basin Economic Recovery Act; or

3. There has been or is likely to be an increase in imports of articles that are like or directly competitive with articles which are or were produced by such firm or subdivision.

The investigation revealed that workers of the subject firm provided technical support to the entire Clorox Company and all its domestic production facilities. The investigation of the U.S. production and sales of the Clorox Company, USA, revealed that criteria (I.B) and (II.B) were not met. According to the information provided by the company official, company-wide sales and production of household and specialty products, such as home cleaning, auto care, professional products, cat litter, dressings, sauces and seasonings did not decline from

2005 to 2006 and there was no shift in production of household and specialty products to a foreign source during the relevant time period.

Conclusion

After reconsideration, I affirm the original notice of negative determination of eligibility to apply for worker adjustment assistance for workers and former workers of Clorox Service Company, a subsidiary of the Clorox Company, Oakland, California.

Signed at Washington, DC, this 14th day of August, 2007.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E7–16888 Filed 8–24–07; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, as amended (19 U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers (TA–W) number and alternative trade adjustment assistance (ATAA) by (TA–W) number issued during the period of *August 6, 2007–August 10, 2007.*

In order for an affirmative determination to be made for workers of a primary firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of section 222(a) of the Act must be met.

I. Section (a)(2)(A) all of the following must be satisfied:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. The sales or production, or both, of such firm or subdivision have decreased absolutely; and

C. Increased imports of articles like or directly competitive with articles produced by such firm or subdivision have contributed importantly to such workers' separation or threat of separation and to the decline in sales or production of such firm or subdivision; or

II. Section (a)(2)(B) both of the following must be satisfied:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. There has been a shift in production by such workers' firm or subdivision to a foreign country of articles like or directly competitive with articles which are produced by such firm or subdivision; and

C. One of the following must be satisfied:

1. The country to which the workers' firm has shifted production of the articles is a party to a free trade agreement with the United States;

2. The country to which the workers' firm has shifted production of the articles to a beneficiary country under the Andean Trade Preference Act, African Growth and Opportunity Act, or the Caribbean Basin Economic Recovery Act; or

3. There has been or is likely to be an increase in imports of articles that are like or directly competitive with articles which are or were produced by such firm or subdivision.

Also, in order for an affirmative determination to be made for secondarily affected workers of a firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of section 222(b) of the Act must be met.

(1) Significant number or proportion of the workers in the workers' firm or an appropriate subdivision of the firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The workers' firm (or subdivision) is a supplier or downstream producer to a firm (or subdivision) that employed a group of workers who received a certification of eligibility to apply for trade adjustment assistance benefits and such supply or production is related to the article that was the basis for such certification; and

(3) Either—

(A) The workers' firm is a supplier and the component parts it supplied for the firm (or subdivision) described in paragraph (2) accounted for at least 20 percent of the production or sales of the workers' firm; or

(B) A loss or business by the workers' firm with the firm (or subdivision) described in paragraph (2) contributed importantly to the workers' separation or threat of separation.

In order for the Division of Trade Adjustment Assistance to issue a certification of eligibility to apply for Alternative Trade Adjustment Assistance (ATAA) for older workers, the group eligibility requirements of section 246(a)(3)(A)(ii) of the Trade Act must be met.

1. Whether a significant number of workers in the workers' firm are 50 years of age or older.

2. Whether the workers in the workers' firm possess skills that are not easily transferable.

3. The competitive conditions within the workers' industry (i.e., conditions within the industry are adverse).

Affirmative Determinations for Worker Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of section 222(a)(2)(A) (increased imports) of the Trade Act have been met.

TA–W–61,750; Data Trace Information Services, LLC, Software Development Division, Santa Ana, CA: June 19, 2006.

The following certifications have been issued. The requirements of section 222(a)(2)(B) (shift in production) of the Trade Act have been met.

TA W–61,757; Efore USA, Inc., SMT Department, On-Site Leased Workers of Version Staffing Agency, Irving, TX: June 13, 2006.

TA–W–61,765; Convergy's Information Management Group, Professional Services Group, Wilkes-Barre, PA: May 30, 2006.

The following certifications have been issued. The requirements of section 222(b) (supplier to a firm whose workers are certified eligible to apply for TAA) of the Trade Act have been met.

None.

The following certifications have been issued. The requirements of section 222(b) (downstream producer for a firm whose workers are certified eligible to apply for TAA based on increased imports from or a shift in production to Mexico or Canada) of the Trade Act have been met.

None.

Affirmative Determinations for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of section 222(a)(2)(A) (increased imports) and section 246(a)(3)(A)(ii) of the Trade Act have been met.

TA–W–61,781; ThyssenKrupp Crankshaft Company, LLC, Thyssenkrupp Garlach Company, Danville Forge Division, Danville, IL: June 22, 2006.

TA–W–61,834; Slinger Manufacturing Company, Slinger, WI: July 16, 2006.

TA–W–61,848; Kentucky Derby Hosiery, Gildan Plant 4, Wholly Owned Subsidiary of Gildan Activewear, Mt Airy, NC: July 18, 2006.

TA–W–61,848A; Kentucky Derby Hosiery, Fowler Road Plant, Wholly Owned Subsidiary of Gildan Activewear, Mt Airy, NC: July 18, 2006.

TA–W–61,665; Collins and Aikman, Dura Convertible Systems, Adrian, MI: June 11, 2006.

TA–W–61,667; J.D. Phillips Corporation, Alpena, MI: June 11, 2006.

TA–W–61,709; Sherman Pressure Casting Corp., North White Plains, NY: June 19, 2006.

TA–W–61,734; Taylor Togs, Inc., Sewing Plant, Micaville, NC: June 15, 2006.

TA–W–61,789; Fraser Papers Limited, Madawaska, ME: June 26, 2006.

TA–W–61,794; Rockland Industries, Inc., Baltimore, MD: July 2, 2006.

TA–W–61,810; B.G. Sulzle, Inc., On-Site Leased Workers of Contemporary Personnel, Services and Staffworks, North Syracuse, NY: July 9, 2006.

The following certifications have been issued. The requirements of section 222(a)(2)(B) (shift in production) and section 246(a)(3)(A)(ii) of the Trade Act have been met.

TA–W–61,842; Seton Company, Saxton Division, Seton Leather Partnership, Leased Workers from Spherion, Saxton, PA: February 25, 2007.

TA–W–61,859; Dura Automotive Systems, Inc., On-Site Leased Workers of Elwood Staffing, Employ. Plus and Manpower, Brownstown, IN: July 22, 2006.

TA–W–61,868; Mittal Steel Walker Wire, Inc., Ferndale, MI: July 23, 2006.

TA–W–61,893; G and K Services, Inc., Teamwear Manufacturing Division, Laurel, MS: July 25, 2006.

TA–W–61,893A; G and K Services, Inc., Teamwear Manufacturing Division, Richton, MS: July 25, 2006.

TA–W–61,776; Nordson Corporation, Talladega Plant, On Site Leased Workers of Manpower, Lincoln, AL: July 2, 2006.

TA–W–61,858; Polycom, Inc., Formerly Known as Spectralink Corp., On-Site Leased Workers From Bolder Staffin, Boulder, CO: July 19, 2006.

TA–W–61,885A; Littelfuse, Inc., Elk Grove, IL: July 20, 2006.

The following certifications have been issued. The requirements of section 222(b) (supplier to a firm whose workers are certified eligible to apply for TAA) and section 246(a)(3)(A)(ii) of the Trade Act have been met.

TA–W–61,912; Zach Hosiery, Inc., Thomasville, NC: July 31, 2006.

TA–W–61,914; Amandi Services, Inc., Leased Workers of Lab Ready, Mt. Pleasant, PA: July 31, 2006.

The following certifications have been issued. The requirements of section 222(b) (downstream producer for a firm whose workers are certified eligible to apply for TAA based on increased imports from or a shift in production to Mexico or Canada) and section 246(a)(3)(A)(ii) of the Trade Act have been met.

None.

Negative Determinations for Alternative Trade Adjustment Assistance

In the following cases, it has been determined that the requirements of 246(a)(3)(A)(ii) have not been met for the reasons specified.

The Department has determined that criterion (1) of section 246 has not been met. The firm does not have a significant number of workers 50 years of age or older.

TA–W–61,757; Efore USA, Inc., SMT Department, On-Site Leased Workers of Version Staffing Agency, Irving, TX.

The Department has determined that criterion (2) of section 246 has not been met. Workers at the firm possess skills that are easily transferable.

TA–W–61,765; Convergy's Information Management Group, Professional Services Group, Wilkes-Barre, PA: May 30, 2006.

The Department has determined that criterion (3) of section 246 has not been met. Competition conditions within the workers' industry are not adverse.

TA–W–61,750; Data Trace Information Services, LLC, Software Development Division, Santa Ana, CA.

Negative Determinations for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In the following cases, the investigation revealed that the eligibility criteria for worker adjustment assistance have not been met for the reasons specified.

Because the workers of the firm are not eligible to apply for TAA, the workers cannot be certified eligible for ATAA.

The investigation revealed that criteria (a)(2)(A)(I.A.) and (a)(2)(B)(II.A.) (employment decline) have not been met.

TA–W–61,734A; Taylor Togs, Inc., Sewing Plant, Taylorsville, NC.

TA–W–61,774; NxStage Medical, Inc., On-Site Temporary Workers of Microtech and Office Team, Lawrence, MA.

TA–W–61,823; Honeywell Aerospace Plymouth, Aerospace Division, A Subsidiary of Honeywell International, Plymouth, MN.

TA–W–61,885; Littelfuse, Inc., Electronic Business Unit, Des Plaines, IL.

TA–W–61,892; Centrilift, A Division of Baker Hughes, Inc., Claremore, OK.

The investigation revealed that criteria (a)(2)(A)(I.B.) (Sales or production, or both, did not decline) and (a)(2)(B)(II.B.) (shift in production to a foreign country) have not been met.

None.

The investigation revealed that criteria (a)(2)(A)(I.C.) (increased imports) and (a)(2)(B)(II.B.) (shift in production to a foreign country) have not been met.

TA–W–61,517; KI USA Corporation, Berea, KY.

TA–W–61,738; Simplicity Pattern Company, Inc., Niles, MI.

TA–W–61,771; Keeco LLC, Graphics Department, South San Francisco, CA.

TA–W–61,820; Warp Processing Co., Exeter, PA.

TA–W–61,826; Aluminum Color Industries, Inc., Lowellville, OH.

The workers' firm does not produce an article as required for certification under section 222 of the Trade Act of 1974.

TA–W–61,769; Renfro Corporation, Hot Sox Warehouse, Secaucus, NJ.

The investigation revealed that criteria of section 222(b)(2) has not been met. The workers' firm (or subdivision) is not a supplier to or a downstream producer for a firm whose workers were certified eligible to apply for TAA.

None.

I hereby certify that the aforementioned determinations were issued during the period of *August 6 through August 10, 2007.* Copies of these determinations are available for inspection in Room C–5311, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 during normal business hours or will be mailed to persons who write to the above address.

Dated: August 16, 2007.

Ralph Dibattista,

Director, Division of Trade Adjustment Assistance.

[FR Doc. E7–16884 Filed 8–24–07; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

Petitions have been filed with the Secretary of Labor under section 221 (a) of the Trade Act of 1974 (''the Act'') and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Division of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to section 221 (a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Division of Trade Adjustment Assistance, at the address shown below, not later than September 6, 2007.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Division of Trade Adjustment Assistance, at the address shown below, not later than September 6, 2007.

The petitions filed in this case are available for inspection at the Office of the Director, Division of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, Room C–5311, 200 Constitution Avenue, NW., Washington, DC 20210.

Signed at Washington, DC, this 14th day of August 2007.

Ralph DiBattista,

Director, Division of Trade Adjustment Assistance.

APPENDIX

[TAA petitions instituted between 8/6/07 and 8/10/07]

TA–W	Subject firm (petitioners)	Location	Date of institution	Date of petition
61932	Eaton Corporation (Comp)	Galesburg, MI	08/06/07	08/03/07
61933	Haines Service (Comp)	Lewiston, ME	08/06/07	08/02/07
61934	Maxtex Fibre Recycling Inc. (Wkrs)	Eden, NY	08/06/07	08/02/07
61935	Delta Apparel, Inc. (Comp)	Fayette, AL	08/06/07	08/03/07
61936	Gruber Systems (State)	Valencia, CA	08/06/07	08/02/07
61937	Wheatland Tube Company (State)	Little Rock, AR	08/06/07	08/02/07
61938	Superior Design and Engineering (Wkrs)	Sterling Heights, MI	08/06/07	08/02/07
61939	International Tooling (Wkrs)	Grand Rapids, MI	08/06/07	08/03/07
61940	Vertex Pharmaceuticals, Inc. (State)	Cambridge, MA	08/07/07	08/03/07
61941	Manufacturers Industrial Group, LLC (Comp)	Lexington, TN	08/07/07	08/02/07
61942	Best Textiles International Ltd. (Wkrs)	Cordele, GA	08/07/07	07/10/07
61943	WestPoint Home, Inc. (Comp)	Valley, AL	08/07/07	08/01/07
61944	Optical Communication Products, Inc. (Comp)	Woodland Hills, CA	08/07/07	08/06/07
61945	Delphi Corporation/Automotive Holdings Group (Comp)	Kettering, OH	08/07/07	08/03/07
61946	Atlantic Guest, Inc./dba Guest company (The) (State)	Meriden, CT	08/07/07	08/06/07
61947	Hater Industries/Charlevoix Manufacturing Co. (Comp)	Charlevoix, MI	08/07/07	08/06/07
61948	Chassis Supply Partners (Rep)	Columbia, TN	08/07/07	08/02/07
61949	Burke Mills, Inc. (Comp)	Valdese, NC	08/07/07	07/25/07
61950	Delphi Corporation (IUECWA)	Kettering, OH	08/08/07	08/07/07
61951	DI—Mar Industries (State)	West New York, NJ	08/08/07	08/07/07
61952	ICI Paints—Glidden Co. (The) (Union)	Reading, PA	08/08/07	08/07/07
61953	Eaton Corporation (Comp)	Portage, MI	08/08/07	08/06/07
61954	Unifi Kinston, LLC/Mundy Maintenance Services and Operations, LLC/OneSource (Comp).	Kinston, NC	08/08/07	08/07/07
61955	Q Dental Group PC (Wkrs)	Rochester, NY	08/08/07	08/01/07
61956	Toledo Commutator (Wkrs)	Owosso, MI	08/08/07	08/06/07
61957	Command Tooling Systems, LLC (State)	Ramsey, MN	08/09/07	08/08/07
61958	Philip Morris Products Int'l (BCTGM)	McKenney, VA	08/09/07	08/08/07
61959	Sewell Clothing Company, Inc. (Comp)	Bremen, GA	08/09/07	07/18/07
61960	Solutia, Inc. (State)	Sauget, IL	08/09/07	08/06/07
61961	Hickory House Furniture (Comp)	Newton, NC	08/09/07	08/01/07
61962	Hanesbrands, Inc. (Comp)	Winston-Salem, NC	08/09/07	08/07/07
61963	PennTecQ, Inc. (Comp)	Greenville, PA	08/09/07	08/07/07
61964	Reed Manufacturing Co., Inc. (Comp)	Tupelo, MS	08/09/07	08/08/07
61965	Stern Manufacturing (State)	Staples, MN	08/09/07	08/08/07
61966	Chemtura Corporation (Union)	Morgantown, WV	08/09/07	08/06/07
61967	G&C Foundry Company, Ltd. (The) (Comp)	Sandusky, OH	08/09/07	08/09/07
61968	Rockwell Automation (Comp)	Mayfield Heights, OH	08/10/07	08/09/07
61969	Nicholas and Stone Company (Comp)	Gardner, MA	08/10/07	08/08/07
61970	Belkin International, Inc. (Comp)	Compton, CA	08/10/07	08/09/07
61971	Youghiogheny Glass Company (Wkrs)	Connellsville, PA	08/10/07	08/09/07
61972	Metrolius Mountain Products (Comp)	Bend, OR	08/10/07	08/09/07
61973	Hill Hosiery Mill Inc./Hill Spinning Mill (Comp)	Thomasville, NC	08/10/07	08/09/07
61974	Ford Motor Company/Kentucky Truck Plant (Wkrs)	Louisville, KY	08/10/07	08/02/07

APPENDIX—Continued

[TAA petitions instituted between 8/6/07 and 8/10/07]

TA–W	Subject firm (petitioners)	Location	Date of institution	Date of petition
61975	R&R Manufacturing Company, Inc. (Comp)	Taunton, MA	08/10/07	08/09/07
61976	Intel Corp (State)	Hillsboro, OR	08/10/07	08/09/07

[FR Doc. E7–16883 Filed 8–24–07; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–61,696]

Medtronic, Inc. Cardiovascular Division, Santa Rosa, CA; Notice of Affirmative Determination Regarding Application for Reconsideration

On August 7, 2007, the U.S. Department of Labor (Department) received a request for administrative reconsideration of the Department's Notice of Negative Determination Regarding Eligibility to Apply for Worker Adjustment Assistance, applicable to workers and former workers of the subject firm. The negative determination was issued on July 19, 2007. The Department's Notice of determination was published in the **Federal Register** on August 2, 2007 (72 FR 42436). Workers produce cardiovascular stents.

The determination was based on the Department's findings that, during the relevant period, the subject firm did not import cardiovascular stents or shift production of cardiovascular stents overseas. The Department did not conduct a survey to determine whether the subject firm's major declining customers had increased their imports of stents because all of the stents produced at the subject firm were sold to a foreign firm.

In the request for reconsideration, workers alleged that the subject firm shifted ''medical device production'' overseas.

The Department has carefully reviewed the workers' request for reconsideration and has determined that the Department will conduct further investigation.

Conclusion

After careful review of the application, I conclude that the claim is of sufficient weight to justify reconsideration of the U.S. Department of Labor's prior decision. The application is, therefore, granted.

Signed at Washington, DC, this 16th day of August 2007.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E7–16887 Filed 8–24–07; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–61,584]

Randstad Inhouse Services On-Site Leased Workers at Maytag Corporation, Newton, IA; Notice of Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, as amended, an investigation was initiated on March 26, 2007 in response to a petition filed on behalf of workers of Randstad Inhouse Services, on-site leased workers at Maytag Corporation, Newton, Iowa.

The petitioning group of workers is covered by an active certification (TA–W–60,515 as amended) which expires on December 26, 2008. Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed at Washington, DC this 14th day of August 2007.

Richard Church,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E7–16886 Filed 8–24–07; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–61,708]

Sun Chemical Corporation, Winston-Salem, NC; Notice of Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, as amended, an investigation was initiated on June 19, 2007, in response to a worker petition filed by the State Workforce Employment Analyst on behalf of workers at Sun Chemical Corporation, Winston-Salem, North Carolina.

The Department issued a negative determination (TA–W–59,818) applicable to the petitioning group of workers on September 28, 2006. No new information or change in circumstances is evident which would result in a reversal of the Department's previous determination. Consequently, further investigation would serve no purpose, and the investigation has been terminated.

Signed in Washington, DC, this 13th day of August, 2007.

Richard Church,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E7–16889 Filed 8–24–07; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–61,418]

Temco Metal Company Including On-Site Leased Workers of Express Personnel, Clackamas, OR; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273), and section 246 of the Trade Act of 1974 (26 U.S.C. 2813), as amended, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance on June 12, 2007, applicable to workers of Temco Metal Company, Clackamas, Oregon. The notice was published in the **Federal Register** on June 28, 2007 (72 FR 35516).

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. The workers were engaged in the production of fuel tank components and accessories for class 8 trucks.

New information provided by the State agency representative shows that leased workers of Express Personnel were employed on-site at the

Clackamas, Oregon location of Temco Metal Company. The Department has determined that the Express Personnel workers were sufficiently under the control of Temco Metal Company to be considered leased workers.

Based on these findings, the Department is amending this certification to include temporary workers of Express Personnel working on-site at the Clackamas, Oregon location of the subject firm.

The intent of the Department's certification is to include all workers at Temco Metal Company, Clackamas, Oregon who were adversely affected as an upstream supplier for a trade certified primary firm.

The amended notice applicable to TA–W–61,418 is hereby issued as follows:

All workers of Temco Metal Company, including on-site leased workers of Express Personnel, Clackamas, Oregon, who became totally or partially separated from employment on or after April 27, 2006, through June 12, 2009, are eligible to apply for adjustment assistance under section 223 of the Trade Act of 1974, and are also eligible to apply for alternative trade adjustment assistance under section 246 of the Trade Act of 1974.

Signed at Washington, DC this 14th day of August 2007.

Richard Church,

Certifying Officer, Division, of Trade Adjustment Assistance.

[FR Doc. E7–16885 Filed 8–24–07; 8:45 am]

BILLING CODE 4510–FN–P

NATIONAL SCIENCE FOUNDATION

Notice of Permit Applications Received Under the Antarctic Conservation Act of 1978 (Pub. L. 95–541)

AGENCY: National Science Foundation.

ACTION: Notice of permit applications received under the Antarctic Conservation Act of 1978, Public Law 95–541.

SUMMARY: The National Science Foundation (NSF) is required to publish notice of permit applications received to conduct activities regulated under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act at Title 45 Part 670 of the Code of Federal Regulations. This is the required notice of permit applications received.

DATES: Interested parties are invited to submit written data, comments, or views with respect to this permit application by September 26, 2007. This application may be inspected by interested parties at the Permit Office, address below.

ADDRESSES: Comments should be addressed to Permit Office, Room 755, Office of Polar Programs, National Science Foundation, 4201 Wilson Boulevard, Arlington, Virginia 22230.

FOR FURTHER INFORMATION CONTACT: Nadene G. Kennedy at the above address or (703) 292–7405.

SUPPLEMENTARY INFORMATION: The National Science Foundation, as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541), as amended by the Antarctic Science, Tourism and Conservation Act of 1996, has developed regulations for the establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas requiring special protection. The regulations establish such a permit system to designate Antarctic Specially Protected Areas.

The applications received are as follows:

1. *Applicant:* Brent S. Stewart, Senior Research Biologist, Hubbs-SeaWorld Research Institute, 2595 Ingraham Street, San Diego, CA 92109. Permit Application No. 2008–013.

Activity for Which Permit Is Requested: Take and Import into the USA. The applicant plans to capture, tag, collect blood and tissue samples, and photograph up to 50 each of Ross, Crabeater, Weddell and Leopard seals. The samples will be taken to the U.S. for further study and analysis. The aim of the research is on ice-associated Antarctic phocid carnivores is to collect basic information on the reproductive biology and behavior, disease and pathology, populations genetics, immunogenetics, foraging ecology and seasonal migrations and distribution of these species.

Location: Sea ice habitats of the western Bellingshausen, Amundsen and eastern Ross seas.

Dates: September 1, 2007 to 31 October 2008.

2. *Applicant:* Mahlon C. Kennicutt, II, Director Sustainable Development, Texas A&M University, 1112 TAMU, College Station, TX 77843–112. Permit Application No. 2008–014.

Activity for Which Permit Is Requested: Take and enter an Antarctic Specially Protected Area (ASPA). The applicant proposes to visit Cape Bird, and enter Hut Point (ASPA 158) and Arrival Heights (ASPA 122) to collect soil samples and permafrost measurements. These sites are specifically targeted because of the nature of their geology, climatic influences and topography. One site has been chosen as a reference control area for the study of temporal and spatial scales of various types of disturbances in and around McMurdo Station, Antarctica. Arrival Heights has been sampled in past seasons and is slated to be sampled as part of the ongoing environmental monitoring program.

Location: Cape Bird, Hut Point (ASPA 158) and Arrival Heights (ASPA 122), Ross Island.

Dates: November 17, 2007 to December 31, 2007.

3. *Applicant:* Jill P. Zamzow, Biology Department, University of Alabama, Birmingham, AL 35294. Permit Application No. 2008–015.

Activity for Which Permit Is Requested: Take and Introduce Non-indigenous Species into Antarctica. The applicant proposes to use frozen fish bait (*Sardinops sagax, Scomber japonicus, and Trachurus symmetricus*) to catch Antarctic fish (Notothenia coriiceps). The captured fish will be used for gut-content surveys.

Location: Vicinity of Palmer Station, Antarctica.

Dates: February 1, 2008 to July 1, 2008.

4. *Applicant:* Brent S. Stewart, Senior Research Biologist, Hubbs-SeaWorld Research Institute, 2595 Ingraham Street, San Diego, CA 92109. Permit Application No. 2008–017.

Activity for Which Permit Is Requested: Take. The applicant proposes to document the breeding behaviors of Ross seals, Crabeater seals, Weddell seals and Leopard seals by direct observation, photo-documentation, and in-air and underwater recordings of vocal activity. The approach will be to observe and record these animals from a distance where incidental disturbance to them will be avoided or minimized and brief.

Location: Western Amundsen, Bellingshausen and eastern Ross seas, Antarctica.

Dates: September 1, 2007 to November 1, 2007.

Nadene G. Kennedy,

Permit Officer, Office of Polar Programs.

[FR Doc. E7–16866 Filed 8–24–07; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

Notice of Sunshine Act Meetings

Agency Holding the Meetings: Nuclear Regulatory Commission.

DATES: Weeks of August 27, September 3, 2007.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

ADDITIONAL MATTERS TO BE CONSIDERED:

Week of August 27, 2007—Tentative

Thursday, August 30, 2007

9 a.m.

Affirmation Session (Public Meeting) (Tentative)

a. Final Rule: 10 CFR Parts 30, 31, 32, and 150—Exemptions from Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements (RIN 3150–AH41) (Tentative)

b. Pacific Gas and Electric Co. (Diablo Canyon ISFSI), Docket No. 72–26–ISFSI, San Luis Obispo Mothers for Peace's Contentions and Request for Hearing Regarding Diablo Canyon Environmental Assessment Supplement (Tentative)

c. Southern Nuclear Operating Co. (Early Site Permit for Vogtle ESP Site)—Certified Question Regarding Conduct of Mandatory Hearing (Tentative)

Week of September 3, 2007—Tentative

Tuesday, September 4, 2007

2:30 p.m.

Briefing on Radioactive Materials Security and Licensing (Public Meeting) (Contact: Robert Lewis, 301–415–8722)

Additional Information

The Affirmation Session previously scheduled at 12:55 p.m. on August 30, 2007, has been rescheduled at 9 a.m. on August 30, 2007. Also, a third item for affirmation has been added, tentatively: Final Rule: 10 CFR parts 30, 31, 32, and 150—Exemptions from Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements (RIN 3150–AH41).

Briefing on Radioactive Materials Security and Licensing (Public Meeting) tentatively scheduled on September 28, 2007 at 9:30 a.m. has been rescheduled on September 4, 2007, at 2:30 p.m.

* * * * *

*The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings call (recording)—(301) 415–1292. Contact person for more information: Michelle Schroll, (301) 415–1662.

* * * * *

The NRC Commission Meeting Schedule can be found on the Internet at: *http://www.nrc.gov/what-we-do/policy-making/schedule.html.*

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The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (e.g. braille, large print), please notify the NRC's Disability Program Coordinator, Rohn Brown, at 301–415–2279, TDD: 301–415–2100, or by e-mail at *REB3@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

* * * * *

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 the distribution, please contact the Office of the Secretary, Washington, DC 20555 (301–415–1969). 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 *dkw@nrc.gov.*

Dated: August 21, 2007.

R. Michelle Schroll,

Office of the Secretary.

[FR Doc. 07–4201 Filed 8–23–07; 10:28 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon written request, copies available from: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extension: Rule 17a–3(a)(16), SEC File No. 270–452, OMB Control No. 3235–0508.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. Sec. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for extension of the previously approved collection of information discussed below.

Rule 17a–3(a)(16) (17 CFR 240.17a–3(a)(16)) under the Securities Exchange Act of 1934 (the ''Act'') (15 U.S.C. 78q *et seq.*) identifies the records required to be made by broker-dealers that operate internal broker-dealer systems. Those records are to be used in monitoring compliance with the Commission's financial responsibility program and antifraud and antimanipulative rules, as well as other rules and regulations of the Commission and the self-regulatory organizations. It is estimated that approximately 105 active broker-dealer respondents registered with the Commission incur an average burden of 2,835 hours per year (105 respondents multiplied by 27 burden hours per respondent equals 2,385 total burden hours) to comply with this rule. The average cost per hour is $197. Therefore the total cost of compliance for the respondents is $558,495.

Rule 17a–3(a)(16) does not contain record retention requirements. Compliance with the rule is mandatory. The required records are available only to the examination staff of the Commission and the self-regulatory organization of which the broker-dealer is a member. 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 control number.

Comments should be directed to (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503 or by sending an e-mail to: *David_Rostker@omb.eop.gov*; and (ii) R. Corey Booth, Director/Chief Information Officer, Securities and Exchange Commission, c/o Shirley Martinson, 6432 General Green Way, Alexandria, VA 22312 or send an e-mail to: *PRA_Mailbox@sec.gov*. Comments must be submitted within 30 days of this notice.

Dated: August 20, 2007.

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–16880 Filed 8–24–07; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

In the Matter of Environmental Safeguards, Inc., Garden Botanika, Inc., Northwestern Steel & Wire Co., Paul Harris Stores, Inc., Ultra Motorcycle Co., UStel, Inc., and Yarc Systems Corp.; Order of Suspension of Trading

August 23, 2007.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information

concerning the securities of Environmental Safeguards, Inc. because it has not filed any periodic reports since it filed a Form 10–QSB for the period ended June 30, 2004.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Garden Botanika, Inc. because it has not filed any periodic reports since it filed a Form 10–Q for the period ended October 28, 2000.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Northwestern Steel & Wire Co. because it has not filed any periodic reports since it filed a Form 10–Q for the period ended January 31, 2001.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Paul Harris Stores, Inc. because it has not filed any periodic reports since it filed a Form 10–Q for the period ended October 28, 2000.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Ultra Motorcycle Co. because it has not filed any periodic reports since it filed a Form 10–QSB for the period ended March 31, 2001.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of UStel, Inc. because it has not filed any periodic reports since it filed a Form 10–QSB for the period ended September 30, 1998.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Yarc Systems Corp. because it has not filed any periodic reports since it filed a Form 10–KSB for the period ended January 31, 2000.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above-listed companies.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the above-listed companies is suspended for the period from 9:30 a.m. EDT on August 23, 2007, through 11:59 p.m. EDT on September 6, 2007.

By the Commission.

Nancy M. Morris,

Secretary.

[FR Doc. 07–4200 Filed 8–23–07; 9:51 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–56287; File No. SR–CBOE–2007–41]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Order Approving Proposed Rule Change as Modified by Amendment No. 1 Thereto To Codify Pre-Existing Practices and To Amend and Supplement Rule 24.9

August 20, 2007.

On May 1, 2007, the Chicago Board Options Exchange, Incorporated (''CBOE'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposal to amend Rule 24.9, Terms of Index Options, to codify the pre-existing methodology used for determining the day on which the exercise settlement value of CBOE Volatility Index options and CBOE Increased-Value Volatility Index options (collectively,''Volatility Index options'') is calculated and to supplement the manner for determining the day on which the exercise settlement value of Volatility Index options is calculated in the event of an Exchange holiday.

The Exchange submitted Amendment No. 1 to the proposed rule change on June 7, 2007. The proposed rule change was published for comment in the **Federal Register** on July 16, 2007.[3] The Commission received no comments on the proposal. This order approves the proposed rule change as modified by Amendment No. 1.

In this proposal, CBOE proposed to amend Rule 24.9, Terms of Index Options, to codify the pre-existing methodology used for determining the day on which the exercise settlement value of Volatility Index options is calculated.[4] This day is also the expiration date for Volatility Index options and the business day immediately before the expiration date is the last trading day for Volatility Index options. The Exchange also proposed to supplement the manner for determining the day on which the exercise settlement value of Volatility Index options is calculated in the event of an Exchange holiday.

In general, each Volatility Index is calculated using the quotes of certain index option series (*e.g.*, S&P 500 Index (''SPX'') options) to derive a measure of volatility of the U.S. equity market. Under CBOE's current methodology, the day on which the exercise settlement value of a Volatility Index option is calculated and the expiration date of a Volatility Index option is the Wednesday that is thirty days prior to the third Friday of the calendar month immediately following the expiring month of the Volatility Index option.[5] Additionally, the Tuesday immediately before that Wednesday is the last trading day for Volatility Index options.

According to the CBOE, this methodology was chosen because it provides consistency by ensuring that Volatility Index options expire exactly thirty days before the expiration date of the options that are used to calculate the Volatility Indexes and reflects CBOE's belief that the settlement process works best if underlying option series with a single expiration month are used to calculate a Volatility Index. According to CBOE, if underlying options series in two expiration months are used, the number of options series used in the settlement process is markedly increased and the settlement process becomes more complex and cumbersome. Consequently, in this filing the Exchange proposed to amend the existing text of Rule 24.9, relating to the current methodology, to codify its pre-existing practice.

The Exchange further proposed to supplement the current methodology by providing a framework for determining the day on which the exercise settlement value for Volatility Index options will be calculated and the expiration date for Volatility Index options when the Exchange is closed on the third Friday of any given calendar month. Specifically, the Exchange proposed to amend Rule 24.9 to provide that if the third Friday of the month subsequent to the expiration of a Volatility Index option is an Exchange holiday, the exercise settlement value of the Volatility Index option will be calculated on the business day that is thirty days prior to the Exchange

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 56036 (July 10, 2007), 72 FR 38850 (July 16, 2007).

[4] *See* Securities Exchange Act Release No. 53342 (February 21, 2006), 71 FR 10086 (February 28, 2006) (SR–CBOE–2006–008); *See also* CBOE Regulatory Circular 2006–23 (describing methodology for determining date of calculation of exercise settlement value and expiration date).

[5] The options used to calculate the Volatility Indexes are traded on CBOE and generally expire on the third Friday of any given calendar month.

business day immediately preceding that Friday.[6] This would also be the expiration date for that Volatility Index option.

After carefully considering the proposal, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[7] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[8] which requires that an exchange have rules designed, among other things, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and in general to protect investors and the public interest.

The Commission believes that codifying CBOE's pre-existing methodology used for determining the day on which the exercise settlement value of Volatility Index options is calculated in Rule 24.9 will provide certainty and predictability for CBOE members and other market participants engaged in the trading of Volatility Index options. The Commission further believes that the Exchange's new procedure for determining the day on which the exercise settlement value for Volatility Index options will be calculated and the expiration date for Volatility Index options when the Exchange is closed due to an Exchange holiday is an appropriate supplement to the existing methodology.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[9] that the proposed rule change (File No. SR–CBOE–2007–41) be, and hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[10]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–16833 Filed 8–24–07; 8:45 am]

BILLING CODE 8010–01–P

[6] The Exchange represented that it was also proposing a similar change relating to the final settlement date for futures contracts on volatility indexes.

[7] In approving this rule change, the Commission notes that it has considered the proposal's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78s(b)(2).

[10] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–56289; File No. SR–CBOE–2007–95]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change as Modified by Amendment No. 1 Thereto Relating to the Exchange's Marketing Fee Program

August 20, 2007.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 1, 2007, the Chicago Board Options Exchange, Incorporated (''CBOE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been substantially prepared by the Exchange. On August 13, 2007, the CBOE submitted Amendment No. 1 to the proposed rule change.[3] CBOE has designated this proposal as one establishing or changing a due, fee, or other charge imposed by CBOE under section 19(b)(3)(A)(ii) of the Act[4] and Rule 19b–4(f)(2) thereunder,[5] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

CBOE proposes to amend its Marketing Fee Program. The text of the proposed rule change is available at the Exchange, the Commission's Public Reference Room, and *http://www.cboe.com.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change, and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. CBOE has substantially prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

CBOE proposes to amend its marketing fee program as follows. First, CBOE proposes to increase the total balance of the Excess Pool of funds that a DPM/LMM or Preferred Market-Maker can maintain. Currently, a DPM/LMM can maintain up to $25,000 in an Excess Pool of funds, and a Preferred Market-Maker can maintain up to $80,000 in an Excess Pool of funds. Going forward, CBOE proposes to increase both of those amounts to $100,000. CBOE believes that the allowable balance in the Excess Pool of funds should be the same for DPMs and Preferred Market-Makers, and increasing the balance will assist those firms in attracting order flow to CBOE.

Second, CBOE proposes to allow a DPM/LMM or Preferred Market-Maker to voluntarily elect to have funds refunded. For instance, if a DPM/LMM or Preferred Market-Maker paid out 80% or more of the funds collected in a given month but less than 100% of the funds collected, a DPM/LMM or Preferred Market-Maker could elect to refund the funds it did not use rather than having those funds be allocated to its Excess Pool. Or, a DPM/LMM or Preferred Market-Maker could elect to have some of the funds in its Excess Pool refunded. As is currently the case, any refunds would be made on a pro rata basis based upon contributions made by the Market-Makers, RMMs, DPMs, e-DPMs and LMMs in that month.

Third, CBOE proposes to impose an administrative fee to offset its costs in administering the marketing fee program and also to provide funds to the association of members[6] (''Association'') for its costs and expenses in supporting CBOE's marketing fee program and in seeking to bring order flow to CBOE. CBOE proposes to assess an administrative fee of .45% of the total amount of funds collected each month.

The Exchange intends to assess and collect the administrative fee of .45% on

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] In Amendment No. 1, the Exchange made minor clarifying changes to the purpose section and the proposed rule text of the proposed rule change.

[4] 15 U.S.C. 78s(b)(3)(A)(ii).

[5] 17 CFR 240.19b–4(f)(2).

[6] The Association is technically known as the DPM Association; however, its activities are not limited to assisting only DPM organizations. As noted above, through its business development activities it seeks to bring order flow to CBOE for the benefit of all CBOE liquidity providers.

the total amount of funds collected each month prior to making the remaining funds available to DPMs/LMMs and Preferred Market-Makers to attract order to CBOE. For example, if the Exchange's marketing fee in a given month results in the total collection of $100,000, the administrative fee of .45% would be assessed on the $100,000 resulting in $4,500 being generated as part of the administrative fee. The remaining funds in the amount of $95,500 would be made available to DPMs/LMMs and Preferred Market-Makers to attract orders to CBOE.

With respect to the portion of the fee that is intended to offset CBOE's overall costs related to the marketing fee program, CBOE notes that it previously assessed an administrative fee as part of its marketing fee program.[7] CBOE intends to allocate each month approximately 40% of the funds collected through the administrative fee to CBOE to offset CBOE's overall costs in administering the program; the balance collected by this fee would be allocated to the Association.

With respect to the portion of the fee that is intended to reimburse and provide funds to the Association for its costs and expenses in supporting CBOE's marketing fee program and in seeking to bring order flow to CBOE, CBOE notes that all DPMs can participate in the Association and support its business development activities. Additionally, through its support of the marketing fee program and business development, the Association seeks to bring order flow to CBOE that all members (Market-Makers, RMMs, LMMs, DPMs, and e-DPMs) may transact with. The funds allocated to the Association generally would be used to cover the Association's administrative costs and other costs such as travel and entertainment. Accordingly, CBOE believes that allocating a portion of the funds collected through this administrative fee to the Association is an equitable allocation of fees among CBOE members.

CBOE intends to closely monitor the amount of funds raised by this administrative fee and may propose amendments to the fee in the future as appropriate, so that the fee provides sufficient funds to adequately offset CBOE's costs in administering the marketing fee program and provide funds to the Association to cover its costs and expenses.

CBOE proposes to implement this change to the marketing fee beginning on August 1, 2007. CBOE is not amending its marketing fee program in any other respects.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with section 6(b) of the Act[8] in general, and furthers the objectives of section 6(b)(4) of the Act[9] in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges among CBOE members and other persons using its facilities.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing proposed rule change has been designated as a fee change pursuant to section 19(b)(3)(A)(ii) of the Act[10] and Rule 19b–4(f)(2)[11] thereunder, because it establishes or changes a due, fee, or other charge imposed by the Exchange. Accordingly, the proposal will take effect upon filing with the Commission. At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.[12]

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. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml);* or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2007–95 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F. Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2007–95. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). 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, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2007–95 and should be submitted on or before September 17, 2007.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[13]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–16836 Filed 8–24–07; 8:45 am]

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[7] *See* Securities Exchange Act Release No. 44469 (June 22, 2001), 66 FR 35301 (July 3, 2001) (SR–CBOE–2001–25).

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(4).

[10] 15 U.S.C. 78s(b)(3)(A)(ii).

[11] 17 CFR 240.19b–4(f)(2).

[12] For purposes of calculating the 60-day period within which the Commission may summarily abrogate the proposed rule change, the Commission considers the period to commence on August 13, 2007, the date on which the Exchange filed Amendment No. 1.

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–56291; File No. SR–CHX–2006–42]

Self-Regulatory Organizations; Chicago Stock Exchange, Inc.; Order Approving Proposed Rule Change, as Modified by Amendment No. 1 Thereto, To Modify Provisions Relating to Cross With Yield Orders

August 20, 2007.

I. Introduction

On December 22, 2006, the Chicago Stock Exchange, Inc. (''CHX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to permit participants submitting ''cross with yield'' orders to elect to yield to undisplayed interest in the Exchange's central matching engine (''Matching System''). On July 6, 2007, the Exchange filed Amendment No. 1 to the proposed rule change. The proposed rule change, as modified by Amendment No. 1, was published for comment in the **Federal Register** on July 20, 2007.[3] The Commission received no comments on the proposal. This order approves the proposed rule change, as amended.

II. Description of the Proposal

The Exchange permits participants to submit ''cross with yield'' orders into its Matching System. A cross with yield order is an order that contains an instruction to execute a cross transaction at a specific price, together with an instruction to yield interest on the buy, sell or either side of the order, as specified in the order, to any order already displayed in the Matching System at the same or better price, to the extent necessary to allow the cross transaction to occur.[4] The proposed rule change would amend the Exchange's definition of a ''cross with yield'' order to permit a CHX participant to elect to yield to undisplayed interest in the Matching System, including undisplayed portions of reserve size orders and any undisplayed orders, in addition to bids and offers that are displayed in the Matching System.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 56064 (July 13, 2007), 72 FR 39865.

[4] *See* CHX Rules, Article 1, Rule 2(h) and Article 20, Rules 4(b)(7) and 8(e).

III. Discussion

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and in particular, with Section 6(b)(5) of the Act,[5] which requires, among other things, that the rules of a national securities exchange be designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.[6]

The Commission notes that cross with yield orders are intended to provide an efficient means to execute a cross transaction at a particular price, yielding interest to orders in the Matching System that have priority. The Commission believes that the proposed rule change will expand the flexibility of this order type by providing a greater opportunity for orders being crossed to interact with all available market interest in the Exchange's Matching System. Accordingly, the Commission finds that the proposed rule change is consistent with the Act.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[7] that the proposed rule change (SR–CHX–2006–42), as amended, is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[8]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–16838 Filed 8–24–07; 8:45 am]

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[5] 15 U.S.C. 78f(b)(5).

[6] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition and capital formation. *See* 15 U.S.C. 78c(f).

[7] 15 U.S.C. 78s(b)(2).

[8] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–56294; File No. SR–NASDAQ–2007–024]

Self-Regulatory Organization; The NASDAQ Stock Market LLC; Order Approving Proposed Rule Change and Amendment No. 1 Thereto To Provide Additional Transparency To How Nasdaq Applies Its Public Interest Authority

August 21, 2007.

On March 16, 2007, The NASDAQ Stock Market LLC (''Nasdaq'') filed with the Securities and Exchange Commission (''Commission''), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to clarify how Nasdaq applies its public interest authority. On June 26, 2007, Nasdaq filed Amendment No. 1 to the proposed rule change. The proposed rule change, as amended, was published for comment in the **Federal Register** on July 17, 2007.[3] The Commission received no comments regarding the proposal.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[4] In particular, the Commission finds that the proposed rule change is consistent with section 6(b)(5) of the Act,[5] which requires that the rules of the an exchange be designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national securities system, and, in general, to protect investors and the public interest.

Nasdaq IM–4300 states that Nasdaq may use its authority under Nasdaq Rule 4300 to deny initial or continued listing when an individual with a history of regulatory misconduct is associated with an issuer. Nasdaq proposes to amend Nasdaq IM–4300 to provide additional transparency to how Nasdaq may use this authority pursuant to Nasdaq Rule 4300. Specifically, Nasdaq proposes to provide additional guidance to issuers by clarifying existing factors in Nasdaq IM–4300 that it will consider in applying such

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 56044 (July 11, 2007), 72 FR 39108.

[4] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[5] 15 U.S.C. 78f(b)(5).

authority. Nasdaq also proposes to add new language highlighting Nasdaq staff's willingness to discuss remedial measures with issuers. The Commission believes that this proposal is reasonably designed to enhance the transparency and integrity of the Nasdaq's initial or continued listing denial process.

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[6] that the proposed rule change (SR–NASDAQ–2007–024), as modified by Amendment No. 1, be, and it hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[7]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–16879 Filed 8–24–07; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–56290; File No. SR–NYSE–2007–75]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Adjust the Earnings of Companies for Purposes of its Earnings Standard by Reversing the Income Statement Effects of Changes in Fair Value of Financial Instruments Extinguished at the Time of Listing on a Six Month Pilot Basis

August 20, 2007.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Exchange Act''),[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on August 13, 2007, New York Stock Exchange LLC (the ''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission the proposed rule changes as described in Items I and II below, which items have been prepared by the Exchange. NYSE has designated the proposed rule change as constituting a ''non-controversial'' rule change under paragraph (f)(6) of Rule 19b–4,[4] which renders the proposal effective upon receipt of this filing by the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[6] 15 U.S.C. 78s(b)(2).

[7] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] 17 CFR 240.19b–4(f)(6).

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the earnings standard of Section 102.01C(I) of the Exchange's Listed Company Manual (the ''Manual'') on a six-month pilot program basis. The amendment will enable the Exchange to adjust the earnings of companies by reversing the income statement effects for all periods of any changes in fair value of financial instruments classified as a liability recorded by the company in earnings, provided such financial instrument is either being redeemed with the proceeds of an offering occurring in conjunction with the listing or converted into or exercised for common stock of the company at the time of listing.

The text of the proposed rule change is available on the Exchange's Web site (*http://www.nyse.com*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The NYSE has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the earnings standard of Section 102.01C(I) of the Manual on a six-month pilot program basis (the ''Pilot Program''). The amendment will enable the Exchange to adjust the earnings of companies listing in conjunction with an IPO by reversing the income statement effects for all periods of changes in fair value of financial instruments classified as a liability recorded by the company in earnings, provided such financial instrument is either being redeemed with the proceeds of an offering occurring in conjunction with the listing or converted into or exercised for common stock of the company at the time of listing.

Nonpublic companies engaging in pre-IPO financings often raise capital through the sale of preferred stock and warrants to purchase preferred stock. Preferred stock and preferred stock warrants are also sometimes issued by pre-IPO companies to service providers in lieu of cash compensation. Typically, at the time of the company's IPO, the preferred stock is converted into common stock and the preferred stock warrants are automatically exercised and the underlying preferred stock is converted into common stock of the company. In some cases, companies may also redeem some or all of the outstanding preferred stock with a portion of the proceeds from the IPO.

Some pre-IPO companies have determined that they must record in earnings changes in the fair value of certain financial instruments classified as liabilities. As the fair value of a pre-IPO company's equity often increases as the company gets closer to its IPO, many companies have had to record significant reductions in earnings associated with increases in the fair value of the preferred stock warrant liability. In certain cases, the impact on the company's earnings as reported under generally accepted accounting principles (''GAAP'') of the preferred stock liability causes otherwise qualified companies to fail to qualify under the Exchange's earnings standard. Under the Exchange's current rules, the Exchange cannot list these companies even though the preferred stock warrant liability will be extinguished at the time of the IPO by conversion into common stock or redemption out of the proceeds of the IPO.

The Exchange believes that it is appropriate to exclude the effects of changes in fair value of a financial instrument classified as a liability from a company's earnings where the financial instrument is being retired at the time of a company's listing either out of the proceeds of a concurrent offering or by conversion into common stock at the time of listing. The Exchange believes that adjusting company earnings for charges arising out of the changes in fair value of financial instruments that are retired with the proceeds of an offering occurring in conjunction with the listing or converted into common stock at the time of listing is consistent with the adjustments that are currently permitted under Section 102.01C for a number of other nonrecurring charges to earnings that are included in net income as recorded under GAAP, such as the exclusion of impairment charges on

long-lived assets, the exclusion of gains and losses on sales of a subsidiary's or investee's stock and the exclusion of in-process purchased research and development charges. The Exchange also believes that this adjustment is reasonable given the purpose of the earnings standard, which is to determine the suitability for listing of companies on a forward-looking basis.

2. Statutory Basis

The basis under the Exchange Act for this proposed rule change is the requirement under Section 6(b)(5)[5] that an exchange have rules that are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to, and perfect the mechanism of a free and open market and, in general, to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Exchange Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change: (i) Does not significantly affect the protection of investors or the public interest; (ii) does not impose any significant burden on competition; and (iii) does not become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Exchange Act[6] and Rule 19b–4(f)(6) thereunder.[7]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Exchange Act[8] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[9] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay. The Commission hereby grants the request.[10] The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because the proposed rule change is consistent with other adjustments the Exchange makes when evaluating applicants on a forward-looking, post-IPO basis under the existing earnings standard in Section 102.01C(I) of the Listed Company Manual, and the proposal will take effect as a Pilot Program, allowing the Commission to evaluate the suitability of the proposal during the pilot period.[11]

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate the rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Exchange Act.

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 Exchange Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send e-mail to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2007–75 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2007–75. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro/shtml*). 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, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing will also be available for inspection and copying at the principal office of the NYSE. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File number SR–NYSE–2007–75 and should be submitted on or before September 17, 2007.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[12]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–16837 Filed 8–24–07; 8:45 am]

BILLING CODE 8010–01–P

[5] 15 U.S.C. 78f(b)(5).

[6] 15 U.S.C. 78s(b)(3)(A).

[7] 17 CFR 240.19b–4(f)(6). Pursuant to Rule 19b–4(f)(6)(iii) under the Exchange Act, the Exchange is required to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied the five-day pre-filing requirement.

[8] 17 CFR 240.19b–4(f)(6).

[9] 17 CFR 240.19b–4(f)(6)(iii).

[10] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[11] Not later than 60 days prior to the expiration of the Pilot Program, the NYSE should provide the Commission with information regarding the nature of the adjustments that have been made to the financial statements of individual companies that have listed on the Exchange using the proposed rule change.

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–56288; File No. SR–OCC–2007–06]

Self-Regulatory Organizations; The Options Clearing Corporation; Order Granting Approval of a Proposed Rule Change Relating to Credit Default Basket Options

August 20, 2007.

I. Introduction

On April 20, 2007, The Options Clearing Corporation (''OCC'') filed with the Securities and Exchange Commission (''Commission'') a

proposed rule change pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and on June 16, 2007, amended the proposed rule change. Notice of the proposal was published in the **Federal Register** on June 27, 2007 for a 15-day comment period.[2] No comment letters were received. This order approves the proposed rule change.

II. Description

The purpose of the proposed rule change is to permit OCC to clear and settle credit default basket options (''CDBOs''), which are options related to the creditworthiness of an issuer or guarantor (''reference entity'') of one or more specified debt securities (''reference obligations''). CDBOs are proposed to be traded by the Chicago Board Options Exchange (''CBOE'').[3] Characteristics of CDBOs are described below, followed by an explanation of the specific rule changes being implemented by OCC in order that it may clear and settle them.

Description of Credit Default Basket Options

CDBOs are structured as binary options with an automatic exercise feature.[4] They are very similar to Credit Default Options (''CDOs'') that were recently approved for trading by CBOE and for clearing by OCC except that CDBOs are based upon multiple reference entities instead of a single reference entity.[5] A CDBO will be automatically exercised and an exercise settlement amount will be payable if a ''credit event'' occurs with respect to any one of the reference entities at any time prior to the last day of trading. As in the case of a CDO, a ''credit event'' is generally defined as any failure to pay on any of the reference obligations or any other occurrence that constitutes an ''event of default'' or a ''restructuring'' under the terms of any of the reference obligations of a particular reference entity and that the listing exchange has determined is a credit event for purposes of the CDBO.

CDBOs may be thought of as a bundle of CDOs in that there is a fixed exercise settlement amount that is determined for each of the reference entities included in the basket of reference entities underlying the CDBO. The exercise settlement amount may be the same for all of the reference entities or it may be different for each one.

CDBOs come in two types: multiple payout CDBOs and single payout CDBOs. A multiple payout CDBO is automatically exercised each time there is a credit event affecting any one of the reference entities. Once the CDBO has been exercised with respect to that reference entity such reference entity is removed from the basket. In the unlikely event that a CDBO is exercised with respect to all of the reference entities in the basket, the expiration of the CDBO would be accelerated. A single payout CDBO, on the other hand, is automatically exercised only the first time that a credit event is confirmed with respect to any one of the reference entities. A single payout CDBO cannot be exercised again with respect to any other reference entity, and its expiration date would be accelerated. With either a multiple payout CDBO or a single payout CDBO, the exercise settlement amount will be the exercise settlement amount that is assigned by the listing exchange to the reference entity affected by the credit event.

By-Law and Rule Amendments Applicable to CDOs

In order to accommodate trading in CDBOs, OCC is amending the By-Law Article and Rule Chapter that it adopted for the clearance and settlement of CDOs.

1. Terminology—Article I, Section 1 and Article XIV, Section 1 of the By-Laws

The definition of ''option contract'' in Article I of the By-Laws is amended to include CDBOs. ''Adjustment event'' and ''credit event'' are defined in Article XIV by reference to the rules of the listing exchange. The terms ''credit event confirmation'' and ''credit event confirmation deadline'' are used, respectively, to refer to the notice that must be provided by the listing exchange or other reporting authority to OCC that a credit event has occurred (and that a CDBO will therefore automatically be exercised) and to the deadline for receipt of such notice if it is to be treated as having been received on the business day on which it is submitted. Credit event confirmations received after the credit event confirmation deadline on the expiration date but before the expiration time will be given effect but may result in delayed exercise settlement.

OCC is also defining the term ''exercise settlement amount'' in Article XIV for purposes of CDBOs. The exercise settlement amount of a CDBO is the amount specified by the listing exchange that will be paid in settlement when a CDBO is automatically exercised as a result of a credit event affecting a particular reference entity. The exercise settlement amount for each reference entity will be determined by the exchange at the time of listing when the exchange fixes the other variable terms for the options of a particular class or series.

OCC is replacing the definitions of ''variable terms,'' ''premium,'' and ''multiplier'' in Article I of the By-Laws with revised definitions in Article XIV, Section 1 that are applicable to CDBOs. The term ''class'' is also redefined in Article XIV, Section 1. To be within the same class, CDBOs must have the same reporting authority, which OCC anticipates will ordinarily be the listing exchange. This is necessary because of the degree of discretion that the reporting authority will have in determining whether a credit event has occurred.

Other terms that were created or amended for CDOs will be modified to apply to CDBOs as well.

2. Terms of Cleared Contracts—Article VI, Section 10(e)

A new paragraph (e) is added to Article VI, Section 10 so that an exchange is required to designate the exercise settlement amount and expiration date for a series of CDBOs at the time the series is opened for trading. Section 10(e) also reminds the reader that CDBOs are subject to adjustment under Article XIV.

3. Rights and Obligations—Article XIV, Section 2

Article XIV, Section 2A defines the general rights and obligations of holders and writers of CDBOs. As noted above, the holder of a CDBO that is automatically exercised has the right to receive the fixed exercise settlement amount from OCC, and the assigned writer has the obligation to pay that amount to OCC.

4. Adjustments of Credit Default Basket Options—Article XIV, Section 3; Determination of Occurrence of Credit Event—Article XIV, Section 4

Article XIV, Section 3 provides for adjustment of CDBOs in accordance with the rules of the listing exchange. CBOE's rules provide for adjustment of

[1] 15 U.S.C. 78s(b)(1).

[2] Securities Exchange Act Release No. 55939 (June 21, 2007), 72 FR 35291.

[3] Securities Exchange Act Release Nos. 55938 (June 21, 2007), 72 FR 35523 (June 28, 2007) (notice of filing of proposed rule change); 56275 (August 17, 2007) (order approving proposed rule change) [File No. SR–CBOE–2007–26].

[4] ''Binary'' options (also sometimes referred to as ''digital'' options) are ''all-or-nothing'' options that pay a fixed amount if automatically exercised and otherwise pay nothing.

[5] Securities Exchange Act Release No. 55871 (June 6, 2007), 72 FR 32372 (June 12, 2007) [File No. SR–CBOE–2006–84]. See also Securities Exchange Act Release No. 55872 (June 6, 2007), 72 FR 32693 (June 13, 2007) [File No. SR–OCC–2007–01].

CDBOs in the case of certain corporate events affecting the reference obligations, and OCC proposes simply to defer to the rules and to the determinations of the listing exchange pursuant to its rules. Accordingly, as in the case of CDOs, OCC will have no responsibility for adjustment determinations with respect to CDBOs.

Similarly, Section 4 provides that the listing exchange for a class of CDBOs will have responsibility for determining the occurrence of a credit event that will result in the automatic exercise of the CDBOs of that class with respect to a particular reference entity. The listing exchange has the obligation to provide a credit event confirmation to OCC in order to trigger the automatic exercise.

5. Exercise and Settlement—Chapter XV of the Rules and Rule 801

CDBOs will not be subject to the exercise-by-exception procedures applicable to most other options under OCC's Rules but instead will be automatically exercised prior to or at expiration if the specified criterion for exercise is met. The procedures for the automatic exercise of CDBOs, as well as their assignment and settlement (including during periods when a clearing member is suspended), are set forth in Rules 1501 through 1505 of new Chapter XV and in revised Rule 801(b).

6. Special Margin Requirements—Rule 601; Deposits in Lieu of Margin—Rule 1506

As in the case of CDOs, OCC will not initially margin CDBOs through its ''STANS'' system in the same way that other options are margined. Because of the fixed payout feature of CDOs and CDBOs, further systems development is needed to accommodate these options in STANS on a portfolio basis. Until such development is completed, elements of STANS will be used to determine the expected liquidating value of each class of CDBOs and CDOs by extracting certain information regarding the default probability from the listed equity options on the common stock of the reference entity and the market price of the CDBOs and CDOs. Expected liquidating values can then be derived from simulated price movements in the stock over a range of values. Thus, general principles of STANS will be applied, but each class of CDBOs and CDOs will be treated as a separate portfolio and will not be included within the entire portfolio of a particular account. An exception to this will be in the case where a firm has a net long position in CDBO or CDO contracts that is not required to be segregated and the risk computed under this methodology is less than 100% of the premium value of the net long position. In such a situation, the excess long value will be used to cover requirements associated with other cleared contracts. This margin methodology will result in a more conservative risk estimate than if the contracts were fully integrated in STANS since offsets in the risk calculation between these products and others will not be recognized except to the extent of any excess long value. Ultimately, CDBOs will be incorporated into the STANS system and will be valued and margined on a risk basis.

OCC does not propose to accept escrow deposits in lieu of clearing margin for CDBOs. Therefore, Rule 1506 states that Rule 610, which otherwise would permit such deposits, does not apply to CDBOs.

7. Acceleration of Expiration Date—Rule 1507

This provision permits OCC to accelerate the expiration date of a single payout CDBO when the option is deemed to have been automatically exercised on any day prior to the expiration date and to accelerate the expiration date of a multiple payout CDBO when the option is deemed to have been automatically exercised with respect to every reference entity underlying such option prior to the expiration date.

III. Discussion

Section 17A(b)(3)(F) of the Act requires that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions.[6] The Commission finds the proposed rule change to be consistent with Section 17A(b)(3)(F) of the Act because it is designed to promote the prompt and accurate clearance and settlement of transactions in, including exercises of, credit default basket options. The proposed rule change is also consistent with Section 17A(b)(3)(F) of the Act because it is designed to remove impediments to and perfect the mechanism of a national system for the prompt and accurate clearance and settlement of such transactions.[7] These purposes are accomplished by having the clearance and settlement of CDBOs take place at OCC with OCC applying substantially the same rules and procedures to CDBOs as it applies to similar transactions in other cash-settled options.

IV. Conclusion

On the basis of the foregoing, the Commission finds that the proposed rule change is consistent with the requirements of the Act and in particular Section 17A of the Act and the rules and regulations thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the proposed rule change (File No. SR–OCC–2007–06) be and hereby is approved.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[8]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–16839 Filed 8–24–07; 8:45 am]

BILLING CODE 8010–01–P

[6] 15 U.S.C. 78q–1(b)(3)(F).

[7] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[8] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

Houston District Advisory Council; Public Federal Meeting

Pursuant to the Federal Advisory Committee Act, Appendix 2 of Title 5, United States code, Public Law 92–463, notice is hereby given that the U.S. Small Business Administration, Houston District Advisory Council will hold a federal public meeting on Tuesday, September 25, 2007 starting at 11 a.m. The meeting will be held at the U.S. Small Business Administration, Houston District Office, 8701 Gessner, Suite 1200, Houston, TX 77074.

The purpose of the meeting is to discuss the following topics: (1) District Office update and goals; performance and rankings; (2) 2007 Mid America Conference; (3) SBA's 7(a), 504, 8(a) programs and Patriot Express Loan Program; (4) Small Business Week and Small Business Development Center; and (5) SCORE updates.

Anyone wishing to attend or to make a presentation must contact Alfreda Crawford, Business Development Specialist, U.S. Small Business Administration, Houston District Office, 8701 Gessner, Suite 1200, Houston, TX 77074; phone (713) 773–6555; fax (202) 481–0150; E-mail: *alfreda.crawford@sba.gov*.

Matthew Teague,

Committee Management Officer.

[FR Doc. 07–4160 Filed 8–24–07; 8:45 am]

BILLING CODE 8025–01–M

SMALL BUSINESS ADMINISTRATION

Availability of SBA Draft Strategic Plan for Fiscal Years 2008–2012 and Request for Public Comment

AGENCY: U.S. Small Business Administration.

ACTION: Notice of availability; request for comment.

SUMMARY: This notice announces the availability of the Small Business Administration's draft Strategic Plan. The Government Performance and Results Act of 1993 requires that Federal agencies update their strategic plans every three years and, in doing so, solicit the views and suggestions of those entities potentially affected by or interested in the plan. Therefore, the Agency is interested in receiving comments on our draft Strategic Plan.

DATES: Comments must be received by September 10, 2007. If comments are received late, we will consider them to the extent practicable.

ADDRESSES: To access the draft strategic plan, go to *http://www.sba.gov/aboutsba/budgetsplans/serv_budget_strategicplan.html.* You can provide your comments on-line through the Web site or by e-mail to *Performancereports@sba.gov.* If you wish to send written comments or have any questions, please direct them to: Gordon Goeke, U.S. Small Business Administration, Strategic Plan Comments, Office of the Chief Financial Officer, 409 Third Street, SW., Suite 6000, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Gordon Goeke, Financial Specialist, Office of Chief Financial Officer, (202) 205–6449.

SUPPLEMENTARY INFORMATION: The Government Performance and Results Act requires that each Federal agency update their strategic plan every three years, (5 U.S.C. 306), and submit their plan to the Congress. This draft Strategic Plan describes our mission, strategic goals, objectives, and means and strategies to achieve those goals. To access the draft strategic plan, go to *http://www.sba.gov/aboutsba/budgetsplans/serv_budget_strategicplan.html.* For those who may not have Internet access, a paper copy can be requested from the contact point, Gordon Goeke.

Public Participation Policy

It is the policy of the Agency to ensure that public participation is an integral and effective part of SBA activities and that decisions are made with the benefit of significant public perspectives. The Agency recognizes the many benefits to be derived from public participation for both stakeholders and SBA. Public participation provides a means for SBA to gather a diverse collection of opinions, perspectives, and values from the broadest spectrum possible, enabling the Agency to make more informed decisions. Likewise, public participation benefits stakeholders by creating an opportunity to provide input on decisions that affect their communities and our nation.

We anticipate publishing the final SBA Strategic Plan on September 28, 2007, and making it available on the Internet at that time.

Authority: 5 U.S.C. 306.

Dated: August 21, 2007.

Jennifer E. Main,

Chief Financial Officer.

[FR Doc. E7–16917 Filed 8–24–07; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice: 5903]

30-Day Notice of Proposed Information Collection: DS–156, Nonimmigrant Visa Application, OMB Control Number 1405–0018

ACTION: Notice of request for public comment and submission to OMB of proposed collection of information.

SUMMARY: The Department of State has submitted the following information collection request to the Office of Management and Budget (OMB) for approval in accordance with the Paperwork Reduction Act of 1995.

- *Title of Information Collection:* Nonimmigrant Visa Application.
- *OMB Control Number:* 1405–0018.
- *Type of Request:* Extension of a Currently Approved Collection.
- *Originating Office:* Bureau of Consular Affairs (CA/VO).
- *Form Number:* DS–156.
- *Respondents:* Nonimmigrant visa applicants.
- *Estimated Number of Respondents:* 12,000,000.
- *Estimated Number of Responses:* 12,000,000.
- *Average Hours Per Response:* 1 hour.
- *Total Estimated Burden:* 12,000,000 hours per year.
- *Frequency:* Once per respondent.
- *Obligation to Respond:* Required to Obtain or Retain a Benefit.

DATES: Submit comments to the Office of Management and Budget (OMB) for up to 30 days from August 27, 2007.

ADDRESSES: Direct comments and questions to Katherine Astrich, the Department of State Desk Officer in the Office of Information and Regulatory Affairs at the Office of Management and Budget (OMB), who may be reached at 202–395–4718. You may submit comments by any of the following methods:

- *E-mail: Katherine_T._Astrich@omb.eop.gov.* You must include the DS form number, information collection title, and OMB control number in the subject line of your message.
- *Mail (paper, disk, or CD-ROM submissions):* Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503.
- *Fax:* 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed information collection and supporting documents, to Lauren Prosnik of the Office of Visa Services, U.S. Department of State, 2401 E. Street, NW., L–603, Washington, DC 20522, who may be reached at (202) 663–2951.

SUPPLEMENTARY INFORMATION: We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary to properly perform our functions.
- Evaluate the accuracy of our estimate of the burden of the proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond,

Abstract of Proposed Collection

Form DS–156 is completed by aliens seeking nonimmigrant visas to the U.S. The Department will use the DS–156 to elicit information necessary to determine an applicant's visa eligibility.

Methodology

The DS–156 is completed by applicants online or, in exceptional circumstances, applicants may submit a paper application to posts abroad. The applicant prints the application and a 2–D barcode. When the applicant appears at the interview the barcode is scanned and the information electronically received.

Dated: August 6, 2007.

Stephen A. Edson,

Deputy Assistant Secretary, Bureau of Consular Affairs, Department of State.

[FR Doc. E7–16900 Filed 8–24–07; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF STATE

[Public Notice 5885]

Advisory Committee on Historical Diplomatic Documentation Notice of Meeting

SUMMARY: The Advisory Committee on Historical Diplomatic Documentation will meet in the Department of State, 2201 ''C'' Street NW., Washington, DC, September 24–25, 2007, in Conference Room 1498. Prior notification and a valid government-issued photo ID (such as driver's license, passport, U.S. government or military ID) are required for entrance into the building. Members of the public planning to attend must notify Steven Galpern, Office of the Historian (202–663–1130) no later than September 20, 2007 to provide date of birth, valid government-issued photo identification number and type (such as driver's license number/state, passport number/country, or U.S. government ID number/agency or military ID number/branch), and relevant telephone numbers. If you cannot provide one of the enumerated forms of ID, please consult with Steven Galpern for acceptable alternative forms of picture identification.

The Committee will meet in open session from 1:30 p.m. through 3 p.m. on Monday, September 24, 2007, in the Department of State, 2201 ''C'' Street, NW., Washington, DC, in Conference Room 1498, to discuss declassification and transfer of Department of State records to the National Archives and Records Administration and the status of the *Foreign Relations* series. The remainder of the Committee's sessions from 3:15 p.m. until 4:30 p.m. on Monday, September 24, 2007, and 8 a.m. until 12 p.m. on Tuesday, September 25, 2007, will be closed in accordance with Section 10(d) of the Federal Advisory Committee Act (Pub. L. 92–463). The agenda calls for discussions of agency declassification decisions concerning the *Foreign Relations* series and other declassification issues. These are matters not subject to public disclosure under 5 U.S.C. 552b(c)(1) and the public interest requires that such activities be withheld from disclosure.

Questions concerning the meeting should be directed to Marc J. Susser, Executive Secretary, Advisory Committee on Historical Diplomatic Documentation, Department of State, Office of the Historian, Washington, DC, 20520, telephone (202) 663–1123, (e-mail *history@state.gov*).

Dated: August 13, 2007.

Marc Susser,

Executive Secretary, Department of State.

[FR Doc. E7–16901 Filed 8–24–07; 8:45 am]

BILLING CODE 4710–11–P

DEPARTMENT OF STATE

[Public Notice 5859]

International Security Advisory Board (ISAB) Meeting Notice; Closed Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. app 2 § 10(a)(2), the Department of State announces a meeting of the International Security Advisory Board (ISAB) to take place on October 1, 2007, at the Department of State, Washington, DC.

Pursuant to section 10 (d) of the Federal Advisory Committee Act, 5 U.S.C. app 2 § 10 (d), and to 5 U.S.C. 552b (c)(1), it has been determined that this Board meeting will be closed to the public in the interest of national defense and foreign policy because the Board will be reviewing and discussing matters classified in accordance with Executive Order 12958.

The purpose of the ISAB is to provide the Department with a continuing source of independent advice on all aspects of arms control, disarmament and international security, and related aspects of public diplomacy. The agenda for this meeting will include classified discussions related to the Board's ongoing studies on current U.S. policy and issues regarding international security and nuclear proliferation.

For more information, contact Brandy Buttrick, Deputy Executive Director of the International Security Advisory Board, Department of State, Washington, DC 20520, telephone: (202) 647–9336.

Dated: August 14, 2007.

George W. Look,

Executive Director, International Security Advisory Board, Department of State.

[FR Doc. E7–16902 Filed 8–24–07; 8:45 am]

BILLING CODE 4710–27–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD 2007 29076]

Information Collection Available for Public Comments and Recommendations

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Maritime Administration's (MARAD's) intention to request extension of approval for three years of a currently approved information collection.

DATES: Comments should be submitted on or before October 26, 2007.

FOR FURTHER INFORMATION CONTACT: Murray Bloom, Maritime Administration, 1200 New Jersey Avenue, SE., Washington, DC 20590. Telephone: (202) 366–5164; or e-mail: *Murray.Bloom@dot.gov.* Copies of this collection can also be obtained from that office.

SUPPLEMENTARY INFORMATION:

Title of Collection: Part 380, Subpart B—Application for Designation of Vessels as American Great Lakes Vessels.

Type of Request: Extension of currently approved information collection.

OMB Control Number: 2133–0521.

Form Numbers: None.

Expiration Date of Approval: Three years from the date of approval by the Office of Management and Budget.

Summary of Collection of Information: In accordance with Public Law 101–624, the Secretary of Transportation issued requirements for the submission of applications for designation of vessels as American Great Lakes Vessels. Owners who wish to have this designation must certify that their vessel(s) meets certain criteria established in 46 CFR part 380.

Need and Use of the Information: Application is mandated by statute to establish that a vessel meets statutory criteria for obtaining the benefits of eligibility to carry preference cargoes.

Description of Respondents: Shipowners of merchant vessels.

Annual Responses: One response.

Annual Burden: 1.25 hours.

Comments: Comments should refer to the docket number that appears at the top of this document. Written comments may be submitted to the Docket Clerk, U.S. DOT Dockets, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590. Comments also

may be submitted by electronic means via the Internet at *http://dms.dot.gov/submit.* Specifically address whether this information collection is necessary for proper performance of the functions of the agency and will have practical utility, accuracy of the burden estimates, ways to minimize this burden, and ways to enhance the quality, utility, and clarity of the information to be collected. All comments received will be available for examination at the above address between 10 a.m. and 5 p.m. EDT (or EST), Monday through Friday, except Federal holidays. An electronic version of this document is available on the World Wide Web at *http://dms.dot.gov.*

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov.*

Authority: 49 CFR 1.66.

By Order of the Maritime Administrator.

Dated: August 21, 2007.

Daron T. Threet,

Secretary, Maritime Administration.

[FR Doc. E7–16864 Filed 8–24–07; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2007–29039]

Requested Administrative Waiver of the Coastwise Trade Laws

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Invitation for public comments on a requested administrative waiver of the Coastwise Trade Laws for the vessel ADIOS.

SUMMARY: As authorized by Public Law 105–383 and Public Law 107–295, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below. The complete application is given in DOT docket MARAD–2007–29039 at *http://dms.dot.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with Public Law 105–383 and MARAD's regulations at 46 CFR part 388 (68 FR 23084; April 30, 2003), that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

DATES: Submit comments on or before September 26, 2007.

ADDRESSES: Comments should refer to docket number MARAD–2007–29039. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://dmses.dot.gov/submit/.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except Federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://dms.dot.gov.*

FOR FURTHER INFORMATION CONTACT: Joann Spittle, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue, SE., Room W21–203, Washington, DC 20590. Telephone 202–366–5979.

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel ADIOS is:

Intended Use: ''Charters off the coast of Florida.''

Geographic Region: ''South Florida.''

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov.*

Dated: August 17, 2007.

By order of the Maritime Administrator.

Daron T. Threet,

Secretary, Maritime Administration.

[FR Doc. E7–16861 Filed 8–24–07; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2007–29038]

Requested Administrative Waiver of the Coastwise Trade Laws

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Invitation for public comments on a requested administrative waiver of the Coastwise Trade Laws for the vessel BEACH HOUSE.

SUMMARY: As authorized by Public Law 105–383 and Public Law 107–295, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below. The complete application is given in DOT docket MARAD–2007–29038 at *http://dms.dot.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with Public Law 105–383 and MARAD's regulations at 46 CFR Part 388 (68 FR 23084; April 30, 2003), that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR Part 388.

DATES: Submit comments on or before September 26, 2007.

ADDRESSES: Comments should refer to docket number MARAD–2007–29038. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140,

1200 New Jersey Avenue, SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://dmses.dot.gov/submit/* . All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://dms.dot.gov.*

FOR FURTHER INFORMATION CONTACT: Joann Spittle, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue, SE., Room W21–203, Washington, DC 20590. Telephone 202–366–5979.

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel BEACH HOUSE is:

Intended Use: ''Less than 5% use, uninspected 6 passenger.''

Geographic Region: ''Washington, Oregon, California, Hawaii, and Florida.''

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov.*

Dated: August 17, 2007.

By order of the Maritime Administrator.

Daron T. Threet,

Secretary, Maritime Administration.

[FR Doc. E7–16851 Filed 8–24–07; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2007 29040]

Requested Administrative Waiver of the Coastwise Trade Laws

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Invitation for public comments on a requested administrative waiver of the Coastwise Trade Laws for the vessel BLUEWATER.

SUMMARY: As authorized by Public Law 105–383 and Public Law 107–295, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below. The complete application is given in DOT docket MARAD–2007–29040 at *http://dms.dot.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with Public Law 105–383 and MARAD's regulations at 46 CFR Part 388 (68 FR 23084; April 30, 2003), that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR Part 388.

DATES: Submit comments on or before September 26, 2007.

ADDRESSES: Comments should refer to docket number MARAD–2007–29040. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://dmses.dot.gov/submit/.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://dms.dot.gov.*

FOR FURTHER INFORMATION CONTACT: Joann Spittle, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue, SE., Room W21–203, Washington, DC 20590. Telephone 202–366–5979.

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel BLUEWATER is:

Intended Use: ''To carry up to 12 passengers on San Francisco Bay day cruise.''

Geographic Region: ''San Francisco Bay.''

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov.*

Dated: August 16, 2007.

By order of the Maritime Administrator.

Daron T. Threet,

Secretary, Maritime Administration.

[FR Doc. E7–16859 Filed 8–24–07; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2007–29041]

Requested Administrative Waiver of the Coastwise Trade Laws

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Invitation for public comments on a requested administrative waiver of the Coastwise Trade Laws for the vessel TIN TIN.

SUMMARY: As authorized by Public Law 105–383 and Public Law 107–295, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below. The complete application is given in DOT docket MARAD–2007–29041 at *http://dms.dot.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with Public Law 105–383 and MARAD's regulations at 46 CFR Part 388 (68 FR 23084; April 30, 2003), that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the

comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR Part 388.

DATES: Submit comments on or before September 26, 2007.

ADDRESSES: Comments should refer to docket number MARAD–2007–29041. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://dmses.dot.gov/submit/*. All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://dms.dot.gov.*

FOR FURTHER INFORMATION CONTACT: Joann Spittle, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue, SE., Room W21–203, Washington, DC 20590. Telephone 202–366–5979.

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel TIN TIN is:

Intended Use: ''Slipstream Maritime Services, LLC will operate Tin Tin as a chartered vessel for up to 6 passengers. Trips will range from one to five days and are specifically designed as therapeutic experiential sailing trips with sailing instruction included.''

Geographic Region: ''Puget Sound, WA.''

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov.*

Dated: August 16, 2007.

By order of the Maritime Administrator.

Daron T. Threet,

Secretary, Maritime Administration.

[FR Doc. E7–16857 Filed 8–24–07; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[USCG–2007–28535]

Atlantic Sea Island Group LLC, Safe Harbor Energy Liquefied Natural Gas Deepwater Port License Application

AGENCY: Maritime Administration, DOT.

ACTION: Notice of application.

SUMMARY: The Coast Guard and the Maritime Administration announce that they have received an application for the licensing of a natural gas deepwater port, and that the application appears to contain the required information. This notice summarizes the applicant's plans and the procedures that will be followed in considering the application.

DATES: The Deepwater Port Act of 1974, as amended, requires any public hearing on this application to be held not later than 240 days after this notice, and requires a decision on the application to be made not later than 90 days after the final public hearing.

ADDRESSES: The public docket for USCG–2007–28535 is maintained by the: Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Ave., SE., West Building Ground Floor W12–140, Washington, DC 20590–0001.

Docket contents are available for public inspection and copying, at this address, in room W12–140, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Facility's telephone is 202–366–9329, its fax is 202–493–2251, and its website for electronic submissions or for electronic access to docket contents is *http://dms.dot.gov.*

FOR FURTHER INFORMATION CONTACT: Mary K. Jager, U.S. Coast Guard, telephone: 202–372–1454, e-mail: *Mary.K.Jager@uscg.mil* or Andrew Tibbetts, U.S. Maritime Administration, telephone: 202–366–5473, e-mail: *andrew.tibbetts@dot.gov.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone: 202–493–0402.

SUPPLEMENTARY INFORMATION:

Receipt of Application

On May 8, 2007, the Coast Guard and the Maritime Administration received an application from Atlantic Sea Island Group LLC (ASIG), Chrysler Building, 405 Lexington Avenue, 26th Floor, New York, NY 10174; for all Federal authorizations required for a license to own, construct, and operate a deepwater port governed by the Deepwater Port Act of 1974, as amended, 33 U.S.C. 1501 *et seq.* (the Act). On August 15, 2007, we determined that the application appears to contain all information required by the Act.

Background

According to the Act, a deepwater port is a fixed or floating manmade structure other than a vessel, or a group of structures, located beyond State seaward boundaries and used or intended for use as a port or terminal for the transportation, storage, and further handling of oil or natural gas for transportation to any State.

A deepwater port must be licensed by the Maritime Administrator (by delegated authority of the Secretary of Transportation, published on June 18, 2003 (68 FR 36496)). Statutory and regulatory requirements for licensing appear in 33 U.S.C. 1501 *et seq.* and in 33 CFR part 148. Under delegations from and agreements between the Secretary of Transportation and the Secretary of Homeland Security, applications are processed by the Coast Guard and the Maritime Administration. Each application is considered on its merits.

The Act requires adherence to a strict timeline for processing an application. Once we determine that an application contains the required information, we must hold public hearings on the application within 240 days, and the Maritime Administrator must render a decision on the application within 330 days. We will publish additional **Federal Register** notices to inform you of these public hearings and other procedural milestones, including environmental review. The Maritime Administrator's decision, and other key documents, will be filed in the public docket.

At least one public hearing must take place in each adjacent coastal State. For purposes of the Act, New York is the adjacent coastal State for this application. Other States can apply for adjacent coastal State status in accordance with 33 U.S.C. 1508(a)(2).

Summary of the Application

Atlantic Sea Island Group LLC (ASIG), proposes to own, construct, and operate a deepwater port, named Safe Harbor Energy, in the Federal waters of the Atlantic Outer Continental Shelf in the area known as the New York Bight region in MMS lease area NK18–12 block 6655. The proposed location is approximately 13.5 miles south of the City of Long Beach on Long Island and 23 miles southeast of New York Harbor entrance, in an area between the Ambrose-to-Nantucket and Hudson

Canyon-to-Ambrose shipping lanes, located at approximately 40°23′ N and 73°36′ E, in water depth of between 60 and 70 feet.

The deepwater port, Safe Harbor Energy, consists of three components: An island to be constructed of natural sand, gravel, and rock materials surrounded by armored breakwaters, consisting of prefabricated caissons, armor units, and rock; an LNG receiving, storage, and regasification facility; and a subsea pipeline that would transport the natural gas to an offshore connection with the Transcontinental Gas Pipeline Corporation's pipeline system. The pipeline would consist of two parallel 36-inch-diameter pipe segments extending 12.8 miles from the island. Safe Harbor Energy will include berthing and offloading space for two conventional LNG vessels with capacity of 70,000 m^3 to 270,000 m^3. Additionally, it would accommodate support vessels including docking/firefighting tugs and crew support launches. The storage portion would include four (4) 180,000 m^3 full-containment storage tanks. The regasification equipment would be an ambient air heat exchange type. Safe Harbor Energy would have an average throughput capacity of approximately 1.15 billion standard cubic feet per day (bscfd).

A shore based facility will be used to facilitate movement of personnel, equipment, supplies, and disposable materials between the port and shore.

Construction of the deepwater port would be expected to take approximately five (5) years; with startup of commercial operations following construction, should a license be issued. The deepwater port would be designed, constructed, and operated in accordance with applicable codes and standards and would have an expected operating life of approximately 25 years.

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000, (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov.*

Authority: 49 CFR 1.66.

By Order of the Maritime Administrator.

Dated: August 17, 2007.

Daron T. Threet,

Secretary, Maritime Administration.

[FR Doc. E7–16875 Filed 8–24–07; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Docket No. AB–55 (Sub-No. 680X)]

CSX Transportation, Inc.—Abandonment Exemption—in Portsmouth County, VA

CSX Transportation, Inc. (CSXT), has filed a notice of exemption under 49 CFR part 1152 subpart F—*Exempt Abandonments* to abandon a 0.50-mile rail line on its Southern Region, Florence Division, Portsmouth Subdivision, from railroad milepost SA 0.28 to railroad milepost SA 0.78, in Portsmouth, Portsmouth County, VA. The line traverses United States Postal Service Zip Code 23704.

CSXT has certified that: (1) No local traffic has moved over the line for at least 2 years; (2) any overhead traffic on the line can be rerouted over other lines; (3) no formal complaint filed by a user of rail service on the line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Board or with any U.S. District Court or has been decided in favor of complainant within the 2-year period; and (4) the requirements at 49 CFR 1105.7 (environmental report), 49 CFR 1105.8 (historic report), 49 CFR 1105.11 (transmittal letter), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line R. Co.—Abandonment—Goshen,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on September 26, 2007, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[1] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),[2] and trail use/rail banking requests under 49 CFR 1152.29 must be filed by September 6, 2007. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by September 17, 2007, with the Surface Transportation Board, 395 E. Street, SW., Washington, DC 20423–0001.

A copy of any petition filed with the Board should be sent to CSXT's representative: Steven C. Armbrust, 500 Water Street, J–150, Jacksonville, FL 32202.

If the verified notice contains false or misleading information, the exemption is void *ab initio.*

CSXT has filed environmental and historic reports addressing the effects, if any, of the abandonment on the environment and historic resources. SEA will issue an environmental assessment (EA) by August 31, 2007. Interested persons may obtain a copy of the EA by writing to SEA (Room 1100, Surface Transportation Board, Washington, DC 20423–0001) or by calling SEA, at (202) 245–0305. [Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1–800–877–8339.] Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), CSXT shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the line. If consummation has not been effected by CSXT's filing of a notice of consummation by August 27, 2008, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov.*

Decided: August 20, 2007.

[1] The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Section of Environmental Analysis (SEA) in its independent investigation) cannot be made before the exemption's effective date. *See Exemption of Out-of-Service Rail Lines,* 5 I.C.C.2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

[2] Each OFA must be accompanied by the filing fee, which currently is set at $1,300. *See* 49 CFR 1002.2(f)(25).

By the Board, Joseph H. Dettmar, Acting Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. E7–16867 Filed 8–24–07; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Docket No. AB–33 (Sub-No. 256X); STB Docket No. AB–585 (Sub-No. 2X)]

Union Pacific Railroad Company—Abandonment Exemption—in Dallas County, TX; Dallas, Garland & Northeastern Railroad Company—Discontinuance of Service Exemption—in Dallas County, TX

On August 7, 2007, Union Pacific Railroad Company (UP) and Dallas, Garland & Northeastern Railroad Company (DGNO), jointly filed with the Surface Transportation Board (Board) a petition under 49 U.S.C. 10502 for exemption from the provisions of 49 U.S.C. 10903. UP seeks to abandon and DGNO seeks to discontinue service over the Trinity Industrial Lead, between milepost 0.0 near Terminal Junction and milepost 4.1 near Mockingbird Lane, a distance of 4.1 miles in Dallas County, TX. The line traverses United States Postal Service Zip Codes 75207 and 75247, and includes no stations.

The line does not contain Federally granted rights-of-way. Any documentation in UP's or DGNO's possession will be made available promptly to those requesting it.

The interest of railroad employees will be protected by the conditions set forth in *Oregon Short Line R. Co.—Abandonment—Goshen,* 360 I.C.C. 91 (1979).

By issuance of this notice, the Board is instituting an exemption proceeding pursuant to 49 U.S.C. 10502(b). A final decision will be issued by November 23, 2007.

Any offer of financial assistance (OFA) under 49 CFR 1152.27(b)(2) will be due no later than 10 days after service of a decision granting the petition for exemption. Each offer must be accompanied by a $1,300 filing fee. *See* 49 CFR 1002.2(f)(25).

All interested persons should be aware that, following abandonment of rail service and salvage of the line, the line may be suitable for other public use, including interim trail use. Any request for a public use condition under 49 CFR 1152.28 or for trail use/rail banking under 49 CFR 1152.29 will be due no later than September 17, 2007. Each trail use request must be accompanied by a $200 filing fee. *See* 49 CFR 1002.2(f)(27).

All filings in response to this notice must refer to STB Docket No. AB–33 (Sub-No. 256X) and AB–585 (Sub-No. 2X) and must be sent to: (1) Surface Transportation Board, 395 E Street, SW., Washington, DC 20423–0001; and (2) Mack H. Shumate, Jr., 101 North Wacker Drive, Room 1920, Chicago, IL 60606, and Louis E. Gitomer, 600 Baltimore Ave., Suite 301, Towson, MD 21204. Replies to the petition are due on or before September 17, 2007.

Persons seeking further information concerning abandonment procedures may contact the Board's Office of Public Services at (202) 245–0230 or refer to the full abandonment or discontinuance regulations at 49 CFR part 1152. Questions concerning environmental issues may be directed to the Board's Section of Environmental Analysis (SEA) at (202) 245–0305. [Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1–800–877–8339.]

An environmental assessment (EA) (or environmental impact statement (EIS), if necessary), prepared by SEA will be served upon all parties of record and upon any agencies or other persons who commented during its preparation. Other interested persons may contact SEA to obtain a copy of the EA (or EIS). EAs in these abandonment proceedings normally will be made available within 60 days of the filing of the petition. The deadline for submission of comments on the EA will generally be within 30 days of its service.

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov.*

Decided: August 20, 2007.

By the Board, Joseph H. Dettmar, Acting Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. E7–16881 Filed 8–24–07; 8:45 am]

BILLING CODE 4915–01–P

Federal Register

Monday,
August 27, 2007

Part II

Environmental Protection Agency

40 CFR Parts 52 and 81

Approval and Promulgation of Implementation Plans; Designation of Areas for Air Quality Planning Purposes; State of California; PM–10; Affirmation of Determination of Attainment for the San Joaquin Valley Nonattainment Area; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA–R09–OAR–2006–0583; FRL–8459–2]

Approval and Promulgation of Implementation Plans; Designation of Areas for Air Quality Planning Purposes; State of California; PM–10; Affirmation of Determination of Attainment for the San Joaquin Valley Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: In a final rule published in the **Federal Register** on October 30, 2006, EPA determined that the San Joaquin Valley nonattainment area (SJV or the Valley) in California attained the National Ambient Air Quality Standards (NAAQS) for particulate matter with an aerodynamic diameter less than or equal to a nominal 10 micrometers (PM–10). Since that final determination of attainment, the State has flagged several exceedances of the PM–10 standard in 2006 as being caused by exceptional events, i.e., high winds, and requested that these data be excluded from attainment determinations. EPA is proposing to concur with the State's request to flag these exceedances and thus to exclude that data from use in determining PM–10 attainment for the SJV. EPA is also proposing to exclude from use in determining attainment for the SJV exceedances recorded at a monitor located at the Santa Rosa Rancheria, tribal lands within the boundaries of the SJV, on two bases: The exceedances occurred while the monitor was operating in very close proximity to construction activities and, as such, the monitor was not properly sited during that time for purposes of comparison to the NAAQS; and the exceedances were caused by an exceptional event. EPA is proposing to concur with the Santa Rosa Rancheria Tribe's request to flag these exceedances as due to an exceptional event. As a result, EPA is proposing to affirm its determination that the SJV has attained the PM–10 standard based on EPA's evaluation of quality-assured data through December 2006. In addition to providing the public with an opportunity to comment on EPA's evaluation and proposed concurrence on flagged exceedances that occurred through the end of calendar year 2006, EPA is in this proposed rule addressing issues raised in petitions for reconsideration and withdrawal of EPA's 2006 determination of attainment, filed by Earthjustice on behalf of the Sierra Club, Latino Issues Forum and others.

DATES: Written comments must be received on or before September 26, 2007.

ADDRESSES: Submit comments, identified by docket number EPA–R09–OAR–2006–0583, by one of the following methods:

(1) Federal eRulemaking portal: *http://www.regulations.gov.* Follow the on-line instructions.

(2) E-mail: *lo.doris@epa.gov.*

(3) Mail or deliver: Doris Lo (AIR–2), U.S. Environmental Protection Agency Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Instructions: All comments will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through the *www.regulations.gov* or e-mail. *www.regulations.gov* is an anonymous access system, and EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send e-mail directly to EPA, your e-mail address will be automatically captured and included as part of the public comment. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Docket: The index to the docket for this action is available electronically at *www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (e.g., copyrighted material), and some may not be publicly available in either location (e.g., CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed directly below.

FOR FURTHER INFORMATION CONTACT: Doris Lo, EPA Region IX, (415) 972–3959, *lo.doris@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, wherever ''we,'' ''us,'' or ''our'' are used, we mean EPA.

Table of Contents

I. Background

On October 17, 2006, EPA finalized its determination that the SJV attained the NAAQS for PM–10, and on October 30, 2006, EPA published this determination in the **Federal Register**. 71 FR 63642. This determination was based upon monitored air quality data for the PM–10 NAAQS [1] during the years 2003–2005 and all available quality-assured data through July 31, 2006. For a more detailed discussion of the related background for the SJV, please refer to the proposed and final rules at 71 FR 40952 (July 19, 2006) and 71 FR 63642. Shortly before EPA issued the determination of attainment, EPA learned of preliminary data indicating that exceedances had occurred on

[1] EPA's final determination of attainment addressed both the 24-hour and annual PM–10 standards; however, on October 17, 2006, effective on December 18, 2006, EPA revoked the annual PM–10 standard. 71 FR 61144.

September 22, 2006, at several monitors, and that the State intended to flag [2] them as caused by natural events and to request that EPA concur with these flags. EPA stated that because the data were preliminary and because they may qualify as natural events, EPA would proceed with its determination of attainment at that time. EPA further indicated that once quality-assured data were available EPA would review those data and consider whether the determination of attainment should be withdrawn.

Since the October 2006 final determination of attainment, EPA has obtained information regarding the PM–10 exceedances summarized in Table 1, which were recorded at various monitors within the boundaries of the SJV:

TABLE 1.—SUMMARY OF EXCEEDANCES EVALUATED FOR TODAY'S PROPOSED RULE

Date of exceedance	Monitor location (type(s))	Concentration (μg/m3)
September 22, 2006	Corcoran (FRM, FEM)*	215, 261
	Bakersfield-Golden (FRM, FEM)	157, 170
	Oildale (FRM)	162
October 25, 2006	Corcoran (FEM)	304
	Bakersfield-Golden State Highway (FEM)	193
December 8, 2006	Corcoran (FEM)	162
	Bakersfield-Golden State Highway (FEM)	213
September 14, 2006	Santa Rosa Rancheria (FRM)	190
September 20, 2006	Santa Rosa Rancheria (FRM)	158
October 26, 2006	Santa Rosa Rancheria (FRM)	157

* FRM = Federal Reference Method; FEM = Federal Equivalent Method.[3]

On April 24, 2007, the State submitted to EPA documentation supporting its claim that the September 22, 2006 exceedances were caused by high winds and wildfires. This submittal was supplemented with additional documentation on July 10, 2007. On May 1, 2007, the State submitted to EPA documentation supporting its claim that the October 25, 2006 exceedances were caused by high winds. On June 12, 2007, the State submitted to EPA documentation supporting its claim that the December 8, 2006 exceedances were caused by high winds. The State believes that all of these exceedances qualify as natural events and that the data should thus be excluded from consideration in the attainment determination.

On July 9, 2007, EPA met with a representative of the Santa Rosa Rancheria EPA to discuss exceedances recorded on September 14, September 20 and October 26, 2006. The Tribe has flagged these exceedances as being caused by an exceptional event related to construction activities and EPA has compiled documentation to support that claim.

II. EPA's Proposed Actions

In this proposed rule, EPA is proposing to concur with the State's request to flag exceedances of the PM–10 standard within the SJV on September 22, October 25 and December 8, 2006 as being caused by exceptional events, i.e., high winds, and thus to exclude these data from use in determining PM–10 attainment for the SJV. EPA is also proposing to exclude exceedances recorded at the Santa Rosa Rancheria, tribal lands within the SJV, on September 14, September 20 and October 26, 2006 from use in determining attainment for the SJV, on two bases: (1) The exceedances occurred while the monitor was operating in very close proximity to construction activities and, as such, the monitor was not properly sited during that time for purposes of comparison to the NAAQS; and (2) the exceedances were caused by an exceptional event, i.e., construction activity in very close proximity to the monitor. The Tribe has flagged those exceedances, and EPA is proposing to concur with those flags.

As a result, EPA is proposing to affirm its October 2006 attainment determination based on its evaluation of quality-assured data from September 14 through December 31, 2006. After receiving and considering all relevant public comments on our proposed rule, we will publish our final determination as to whether we will concur with the State's and Tribe's requests to flag the exceedances discussed above as affected by exceptional events and to exclude them from consideration in our attainment determination. We will also publish our determination as to whether we will exclude the exceedances at the Santa Rosa Rancheria as a result of the monitor siting. EPA is not taking comment in these proposed actions on any issues that were the subject of the 2006 attainment determination rulemaking except to the extent that they affect EPA's ability to determine that the SJV continued to attain the PM–10 standard through 2006.

In this proposed rule we are also addressing relevant issues raised in the petition for reconsideration and petition to withdraw the determination of attainment filed by the Latino Issues Forum and others.

In our 2006 attainment determination we stated that if, after the September 22, 2006 data were quality-assured, and after further evaluating the State's request for exclusion of these data, we determine that the data do not qualify for exclusion and we believe that if included that they would establish that the area is in violation of the NAAQS, EPA would proceed with appropriate rulemaking action to withdraw its determination of attainment. 71 FR 63642. Both EPA's natural/exceptional events policies and its exceptional events rule anticipate that the Agency will concur or nonconcur on a state's request to exclude data by letter rather than rulemaking.

[2] Once air quality data have been submitted to EPA, it is possible to ''flag'' specific values for various purposes. ''Data flagging'' refers to the act of making a notation in a designated field of an electronic data record. The principal purpose of the data flagging system in the Air Quality System (AQS) data base is to identify those air quality measurements for which special attention or handling is warranted. These include, but are not limited to, those measurements that are influenced by exceptional events. See 71 FR 12592, 12598 (March 10, 2006).

[3] A federal reference method (FRM) is an air sample collection and analysis method which follows the procedures detailed in the appendices to 40 CFR part 50. A federal equivalent method (FEM) is an air sampling collection and analysis method which does not follow the reference procedures in 40 CFR part 50, but has been certified and designated by the EPA as obtaining ''equivalent'' results.

Generally we would initiate rulemaking following an attainment determination for an area only if we had preliminarily concluded that a withdrawal of that determination would be appropriate. That is not the case here. However, in this instance both because EPA had indicated in its final action that it would reassess the attainment determination once it had quality-assured data for the September 22, 2006 exceedances and because of the issues raised by the petitions pending before the Agency and discussed below, we are proposing to concur with the State's and Tribe's requested flags and affirm our 2006 attainment determination via notice and comment rulemaking. Because we generally make determinations of attainment on a calendar year basis, our proposed rule addresses quality assured exceedances from September 14 through December 31, 2006. Moreover the petitions address exceedances within this timeframe.

III. Summary of Litigation and Administrative Proceedings

Earthjustice filed three petitions related to EPA's determination of attainment for the SJV. On December 27, 2006, Earthjustice, on behalf of Latino Issues Forum, Medical Advocates for Healthy Air and Sierra Club, filed in the U.S. Court of Appeals for the 9th Circuit a petition for review of EPA's October 2006 determination under the Clean Air Act that the SJV has attained the PM–10 standard. *Latino Issues Forum* v. *EPA,* No. 06–75831 (9th Cir.). On December 29, 2006, Earthjustice also filed with EPA a petition for reconsideration of our attainment determination. In the petition, Earthjustice alleges, among other things, that EPA improperly ignored September 22, 2006 PM–10 exceedances in the SJV that were not subject to public notice and comment. Finally, on March 21, 2007, Earthjustice filed a petition for withdrawal of our attainment determination. In this petition, Earthjustice alleges that the attainment determination must be withdrawn because, among other things, the exceedances that occurred in September and October 2006 do not qualify as exceptional events. EPA addresses issues raised in both of these administrative petitions in this proposed rule.

IV. EPA's Exceptional Events Rule

On March 22, 2007, EPA issued a final rule governing the review and handling of air quality data influenced by exceptional events. 72 FR 13560. The rule became effective on May 21, 2007 and implements section 319 of the CAA, as amended by section 6013 of the Safe Accountable Flexible Efficient-Transportation Equity Act: A Legacy for Users (SAFE–TEA–LU) of 2005. In the rule, EPA establishes procedures and criteria related to the identification, evaluation, interpretation, and use of air quality monitoring data related to the ozone and particulate matter NAAQS where states petition EPA to exclude data that are affected by exceptional events from certain regulatory actions under the CAA. The rule is codified at 40 CFR 50.1, 50.14, and 51.920. 72 FR at 13580–13581.

In the preamble to the final rule, EPA also addresses its applicability to Indian Tribes. Where, as here, the Santa Rosa Rancheria Tribe operates an air quality monitor only in order to gather data for informational purposes but does not implement other programs such as mitigating the effects of exceptional events, it is EPA's responsibility to ensure that any exclusion or discounting of data in Indian country areas comports with the rule's procedures and requirements. EPA intends to work with tribes on the implementation of the rule. 72 FR at 13563.

In 1986 and 1996 EPA issued guidance to address the use of data influenced by exceptional and natural events: ''Guidance on the Identification and Use of Air Quality Data Affected by Exceptional Events'' (July 1986) and ''Areas Affected by PM–10 Natural Events,'' May 30, 1996. CAA Section 319, as amended by SAFE–TEA–LU, states that these guidance documents continue to apply until the effective date of a final regulation promulgated under section 319(b)(2). See CAA Section 319(b)(4). SAFE–TEA–LU did not however address those situations where EPA had not made a determination prior to the effective date of the rule whether an exceptional event had occurred after a state had flagged data and submitted a demonstration in a timely manner to show that such data reflected NAAQS exceedances that were caused by an exceptional event. In these circumstances, EPA believes that in the interests of equity and administrative efficiency, a state seeking to exclude data affected by exceptional events should, for a limited period of time, be able to choose to comply with either the provisions of the rule or those of the guidance documents for a limited period of time. This approach would have some advantages, such as allowing the state to avoid duplicating its demonstration process and completing the decisionmaking process already underway. EPA believes that it is reasonable to use this approach until December 31, 2007 to complete the transition from the policies to the rule. However, unless the state in the circumstances described above, specifically requests that EPA evaluate a natural or exceptional event demonstration under the guidance documents, EPA will presume that the rule applies.

Under 40 CFR 50.14(j), an ''exceptional event,'' with specified exceptions not relevant here, is defined as one ''that affects air quality, is not reasonably controllable or preventable, is an event caused by human activity that is unlikely to recur at a particular location or a natural event, and is determined by the Administrator in accordance with 40 CFR 50.14 ['treatment of air quality monitoring data influenced by exceptional events'] to be an exceptional event.'' A ''natural event'' is defined as one ''in which human activity plays little or no direct causal role.'' 40 CFR 50.14(k).[4]

The rule establishes a multi-step process for identification by states, tribes and local agencies of data and submission of the requisite demonstrations to EPA. 72 FR at 13571. In short, a state must notify EPA of its intent to exclude measured exceedances of a NAAQS as being due to an exceptional event by ''flagging'' the data in EPA's AQS database. 40 CFR 50.14(c)(2)(i). For PM–10, the state should submit the flags, accompanied by an initial description of the event, by July 1st of the calendar year following the year in which the flagged measurement occurred. 40 CFR 50.14(c)(2)(iii). A state that has flagged data as being due to an exceptional event and is requesting its exclusion must, after notice and opportunity for public comment, submit a demonstration that to EPA's satisfaction shows that the flagged event caused a specific concentration in excess of the NAAQS at the particular location to justify data exclusion. This demonstration must be submitted to EPA within 3 years of the calendar quarter following the event, but no later than 12 months prior to an EPA regulatory decision. A state must submit the public comments it received along with its demonstration to EPA. 40 CFR 50.14(c)(3)(i).

[4] In the preamble to the final rule, EPA discusses specific types of natural events, including high wind events (i.e., those that affect ambient particulate matter concentrations through the raising of dust or through the re-entrainment of material that has been deposited). See 72 FR at 13565–13566 and 13576–13577. EPA's interpretation of the rule with respect to high winds is addressed in section V. below.

In the preamble to the final rule, EPA explained that it will generally review the state's demonstration and provide a concurrence or nonconcurrence on the flag in the AQS database within 60 days of the state's complete submission. EPA expects that, in most cases, this time period should be sufficient to review and provide a concurrence or nonconcurrence regarding a state's request to exclude data affected by an exceptional event. However, for more complex demonstrations, EPA may require additional time to make its decision and will notify the state of the additional time required. 72 FR at 13571. Upon its concurrence on a flag, EPA will exclude the data from use in determinations of NAAQS exceedances and violations. 40 CFR 50.14(b).

The requirements for the demonstration to justify data exclusion that the state must submit, in this instance, to EPA are set forth at 40 CFR 50.14(a), (b)(1), and (c)(3)(iii). In order to be considered for exclusion, the state must show that the event satisfies the criteria in section 50.1(j), there is a clear causal connection between the exceedances and the claimed exceptional event, the event is associated with measured concentration in excess of normal historical fluctuations including background and there would have been no exceedance ''but for'' the event. 40 CFR 50.14(c)(iii)(A)–(D).

One of the requirements of section 50.1(j) is that the exceptional event must be shown to affect air quality, which is met by establishing that the event is associated with a measured exceedance in excess of normal historical fluctuations, including background. 40 CFR 50.14(c)(iii)(B). In addition, as noted above there must be a clear causal relationship between the measurement under consideration and the event that is claimed to have affected the air quality in the area. 40 CFR 50.14(c)(iii)(C). Air quality impact and causal connection may be shown through a number of methods including modeling and speciation analysis. EPA will evaluate whether an event affected air quality and caused a particular concentration using the weight of available evidence and considering the historical frequency of such measured concentrations. States must compare contemporary concentrations with distribution of historical values and these may be presented on a seasonal or other temporal basis. 40 CFR 50.14(a)(2) and (c)(3)(iii)(A) and (C); 72 FR at 13569.

Also, air quality data may not be excluded except where states, tribes, or local agencies show, through a weight of evidence approach, that exceedances or violations of applicable standards would not have occurred ''but for'' the influence of exceptional events. 40 CFR 50.14(c)(3)(iii)(D). 72 FR at 13570–13571. Finally, states must demonstrate that they have provided an opportunity for public comment and must submit any public comments it received to EPA. 40 CFR 50.14(c)(3)(i) and (iv).

States, tribes, or local agencies must also demonstrate that the claimed exceptional event meets the other requirements of § 50.1(j)—that the event is not reasonably preventable or controllable and that the event is either caused by human activity that is unlikely to recur at a particular location or is a natural event. In this instance, the claimed events are high winds, i.e. natural events, and construction, i.e., an event caused by human activity that is unlikely to recur at the particular location.

In order to concur on a state's request to exclude data, EPA must determine that the state's submission is complete and demonstrates to EPA's satisfaction that the exceptional event caused the exceedances. Although states must meet the minimum requirements (e.g. ''but for'' test), EPA did not specify a minimum level of documentation in the rule because the facts and circumstances could vary depending on, among others, meteorology, and geography. Instead, EPA illustrated through examples the kind of information that states could consider in meeting the demonstration requirements of the rule. In describing the documentation process and requirement, EPA also stated that acceptable documentation would be determined through consultation with the EPA regional offices. 72 FR at 13573.

Finally, under 40 CFR 51.930, a state requesting to exclude air quality data due to exceptional events must take appropriate and reasonable actions, including public notification, public education and implementation of measures, to protect public health from exceedances or violations of the NAAQS.

V. EPA's Evaluation of Flagged Exceedances

The State and Tribe have not specifically requested that EPA evaluate the September 14 through December 31, 2006 exceedances (which occurred before the effective date of the Exceptional Events Rule) under EPA's natural events policy or exceptional events policy. Therefore we are evaluating the State's submittals and the Santa Rosa Rancheria exceedances under the Exceptional Events Rule to determine whether they meet both the procedural requirements and the technical criteria for showing that the exceedances are exceptional. We will discuss whether the State's submittal and the exceedances at Santa Rosa Rancheria meet each of these requirements and criteria separately. For each of the exceedances being discussed in today's proposal, EPA bases its evaluation on the procedural requirements and technical criteria and mitigation requirements of the Exceptional Events Rule, as discussed above and summarized below:

Procedural Requirements:

- Data are flagged in EPA's AQS database.
- Public had an opportunity to review and comment on the state's documentation.
- The documentation was submitted to EPA.
- EPA concurs with the state's demonstration.

Technical Criteria:

- The state must show that the event satisfies the criteria in 40 CFR 50.1(j).[5]
- There is a clear causal connection between the exceedance and the claimed exceptional event.
- The event is associated with measured concentration in excess of normal historical fluctuations including background.
- There would have been no exceedances ''but for'' the event.

Mitigation Requirements:

- Provide for prompt public notification of exceedance events.
- Provide for public education on how to minimize exposure.
- Provide for the implementation of appropriate measures to protect the public.

A. September 22, 2006 Exceedances at Corcoran, Bakersfield, and Oildale

The 24-hour PM–10 NAAQS was exceeded at three monitoring locations on September 22, 2006: The Corcoran monitoring site recorded concentrations of 215 $\mu g/m^3$ and 261 $\mu g/m^3$ with a FRM sampler and a FEM automated continuous analyzer,[6] respectively; the

[5] Section 50.1(j) provides the regulatory definition of an exceptional event. ''Exceptional event'' means an event that affects air quality, is not reasonably controllable or preventable, is an event caused by human activity that is unlikely to recur at a particular location or a natural event, and is determined by the Administrator in accordance with 40 CFR 50.14 to be an exceptional event. It does not include stagnation of air masses or meteorological inversions, a meteorological event involving high temperatures or lack of precipitation, or air pollution relating to source noncompliance.

[6] The FEM monitor currently operated at the Corcoran site is an automated continuous analyzer known as a Tapered Element Oscillating Microbalance (TEOM).

Bakersfield-Golden State Highway monitoring site recorded concentrations of 157 μg/m^3 and 170 μg/m^3 with its FRM sampler and FEM (TEOM) analyzers, respectively; and the Oildale monitoring site recorded a concentration of 162 μg/m^3 with its FRM sampler.

The State concludes that three sources of PM–10 contributed to exceedances of the 24-hour PM–10 NAAQS on this day: Wind-entrained dust from sources in the central and southern SJV, which is identified as the primary source of PM–10; wind-entrained dust from regional sources from the northern SJV; and emissions related to several wildfires which are identified as secondary sources of PM–10.[7] Based on the evidence submitted, EPA agrees with the State's demonstration that high wind-entrained dust from sources in the central and southern SJV caused the exceedances at the three monitoring locations on September 22, 2006.

We do not however agree with the State that emissions from wildfires or regionally transported dust from the northern SJV were significant contributors.

After evaluating the State's demonstration under the technical criteria established in the Exceptional Events Rule, EPA finds that for the Corcoran, Bakersfield and Oildale areas, the State does not demonstrate that emissions from wildfires had a significant impact on the PM–10 concentrations recorded on September 22, 2006. None of the fires cited in the documentation was within the boundaries of the SJV. Further, an independent review of PM–2.5 speciation data collected at Bakersfield and Fresno on the days preceding and after September 22 shows no unusual concentrations of carbon. See *http://www.epa.gov/cgi-bin/htmSQL/mxplorer/query_spe.hsql.* If the fires had had a significant effect on PM–10 concentrations, there would have been evidence of increased carbon (one of the chemical constituents of wood smoke) in the speciation data. The documentation submitted by the State includes mostly anecdotal evidence of the wildfires' impact and satellite photographs showing smoke over parts of California. The anecdotal evidence consists of newspaper reports of reduced visibility due to smoke and the odor of wood smoke, as well as observations from trained weather observers at Lemoore Naval Air Station.[8] EPA finds that the documentation lacks data linking the fires to the concentrations given the distance of the fires and the lack of corroborating speciation data and satellite photographs of the smoke, and newspaper reports do not rise above general or anecdotal evidence to establish a clear causal relationship between the exceedances on September 22, 2006 and the emissions from wildfires.

Similarly, EPA believes that the State's documentation that regional sources of entrained dust impacted monitors in the Corcoran and Bakersfield areas does not show a clear causal relationship between the exceedances and regional transport of PM–10 from the northern SJV. EPA bases this conclusion on its review of the documentation which indicates that while there were high hourly averaged winds and gusts in the northern central valley of California, the State did not present any facts, corroborating evidence or any convincing argument to demonstrate how PM–10 from this area could have reached the southern SJV in concentrations sufficient to contribute to an exceedance of the 24-hour PM–10 NAAQS.

Because EPA does not agree with the State's conclusions with respect to regional transport of PM–10 from the northern SJV and with respect to wildfires, in the following discussion regarding the September 22, 2006 exceedances we refer only to the State's conclusion that these exceedances were caused by wind-entrained dust from sources in the central and southern SJV.

1. Procedural Requirements

a. Data Are Flagged in EPA's AQS Database

All of the September 22, 2006 exceedances were flagged in EPA's AQS database as of July 2007.

b. Public Had an Opportunity To Review and Comment on the State's Documentation

In February 2007, the SJV Air Pollution Control District (SJVAPCD or District) notified the public in local newspapers and on its Web site of the availability of the document entitled ''Natural Event Documentation, High Winds, Corcoran and Bakersfield, California, September 22, 2006,'' SJV Unified Air Pollution Control District, February 2007 and requested public comments by March 5, 2007.

The SJVAPCD subsequently revised the February 2007 document and submitted to the California Air Resources Board (CARB) ''Natural Event Documentation, Corcoran, Oildale and Bakersfield, California, September 22, 2006,'' SJV Unified Air Pollution Control District, April 20, 2007 (NED for September 22, 2006) and posted it on its Web site.

SJVAPCD thereafter provided additional information to CARB in ''Addendum, Natural Event Documentation, Corcoran, Oildale and Bakersfield, California, September 22, 2006,'' SJV Unified Air Pollution Control District, May 23, 2007 (NED Addendum for September 22, 2006) and posted it on its Web site.

The District indicated that no public comments were received during the public process.

c. The Documentation Was Submitted to EPA

The NED for September 22, 2006 and the NED Addendum for September 22, 2006 were subsequently submitted by the State to EPA on April 24, 2007 and July 10, 2007, respectively, and are the documents upon which EPA is basing its evaluation below.

d. EPA Concurs With the State's Demonstration

In this proposed rule, EPA is proposing to concur with the State's demonstration in the NED for September 22, 2006 and the NED Addendum for September 22, 2006 that high wind-entrained dust from the central and southern SJV caused the exceedances at the three monitoring locations on September 22, 2006.

2. Technical Criteria

a. Did this event satisfy the criteria in section 50.1(j) of the Rule?

The State needs to show that the September 22, 2006 event, wind-entrained dust from sources in the central and southern SJV, affected air quality in the Corcoran and Bakersfield areas,[9] was not reasonably controllable or preventable, was a natural event, and is determined by EPA through the process established in the Rule to be an exceptional event. We believe the State has supported its claims that wind-driven dust from sources of PM–10 in the central and southern SJV was the cause of the September 22, 2006 exceedances, as discussed in detail below.

[7] ''Natural Event Documentation, Corcoran, Oildale, and Bakersfield, California, September 22, 2006'', April 20, 2007 (NED for September 22, 2006) at 10.

[8] NED for September 22, 2006 at 11, Table 3, 14 and 37–44.

[9] The Bakersfield-Golden State Highway and Oildale monitors are approximately 3.5 miles apart. For the purposes of this discussion, the analysis for the Bakersfield-Golden State Highway and Oildale monitors is the same.

i. Affected Air Quality

For an event to qualify as an exceptional event, the state must show that the event affected air quality. This criterion can be met by establishing that the event is associated with a measured exceedance in excess of normal historical fluctuations, including background, and there is a causal connection between the event and the exceedance. The demonstration of a clear causal relationship is necessary to establish that the event affected air quality and is also a separate statutory requirement as discussed above.

In the NED for September 22, 2006 and the NED Addendum for September 22, 2006, the State provides documentation that the measured exceedances on September 22, 2006 were in excess of normal historical fluctuations. See subsection c. below. The State also establishes a causal connection between the high winds recorded at Lemoore and the high concentrations recorded at the Corcoran, Bakersfield, and Oildale monitors. The State's demonstration of the clear causal relationship between the event and the exceedances on this day is discussed in greater detail in subsection b. below.

ii. Not Reasonably Controllable or Preventable

Section 50.1(j) of the Exceptional Events Rule requires that for an event to qualify as an exceptional event, whether natural or anthropogenic, a state must show that the event was not reasonably preventable or controllable. Here this requirement is met by demonstrating that despite reasonable and appropriate measures in place, the September 22, 2006 wind event caused the exceedances. During this event there were no other unusual dust-producing activities occurring in the SJV and anthropogenic emissions were approximately constant before, during and after the event. In addition, the State shows that reasonable and appropriate measures were in place, including Regulation VIII (the District's general fugitive dust rules) and Rule 4550 which limits fugitive dust emissions specifically from agricultural operations through Conservation Management Practices.[10] Moreover, EPA has approved the District's best available control measure (BACM) demonstration for all significant sources of PM–10 in the SJV as meeting CAA section 189(b)(1)(B).[11]

iii. Was a Natural Event

In the preamble to the Exceptional Events Rule EPA states that ambient particulate matter concentrations due to dust being raised by unusually high winds will be treated as due to uncontrollable natural events where (1) the dust originated from nonanthropogenic sources, or (2) the dust originated from anthropogenic sources within the State, that are determined to have been reasonably well-controlled at the time that the event occurred, or from anthropogenic sources outside the State. 72 FR at 13576. In the preamble EPA also explains that ''[s]tates must provide appropriate documentation to substantiate why the level of wind speed associated with the event in question should be considered unusual for the affected area during the time of year that the event occurred.'' *Id.* at 13566.

On September 22, 2006, the wind-entrained dust originated from anthropogenic sources within California, *i.e.*, from usual dust-generating activities such as agricultural and industrial operations.[12] We discuss the fugitive dust control measures in place in the SJV on September 22 above.

With respect to the wind speed, EPA concurs with the State's demonstration that the wind speeds in the central SJV were unusually high on September 22, 2006.[13] Meteorological data show that the winds at Lemoore reached speeds of 29 mph with gusts of approximately 40 mph. According to the State, the Department of Water Resources' extreme annual wind statistics indicate that the mean annual peak gust for Lemoore is 42 mph.[14] Thus wind gusts observed at Lemoore were unusually high because they are close to the typical highest annual value of 42 mph. The State also provides documentation that shows that winds of approximately 18 mph will entrain and transport dust.[15] Winds greater than this speed occurred at Lemoore and Kettleman Hills, and were responsible for transporting this entrained dust. Meteorological data indicate that the wind direction was from the north and northwest and hence the entrained dust at that wind speed was transported towards Corcoran. Winds at Corcoran were not as intense during the peak hours at Lemoore. Table 3 of the State's submittal indicates the winds at Corcoran at 10 a.m. were 9 mph with gusts to 12 mph.[16] These wind speeds, though not sufficient to erode dust, were sufficient to keep the entrained and transported dust from the high winds at Lemoore suspended for the period during which the exceedances occurred.

iv. Determined by EPA To Be an Exceptional Event

Finally, EPA must determine through the process established in the Exceptional Events Rule whether an exceptional event occurred. We believe that the State has met the procedural requirements of the rule including flagging of the data, submission of demonstration, evidence of the public opportunity to review and comment on the demonstration and mitigation requirements as discussed in section V.A.1. and 3. of this proposed rule. We further believe that the State has also met the technical criteria in the Exceptional Events Rule as discussed in section V.A.2. Therefore, we are proposing to concur with the State's determination that an exceptional event, i.e., a high wind event, occurred resulting in the exceedances on September 22, 2006.[17]

b. Does the State's documentation show a clear causal connection between the exceedances and the claimed exceptional event?

Under 40 CFR 50.14(c)(3)(iii)(B), a state's demonstration must establish a clear causal relationship between the measured exceedance and the claimed exceptional event. In addressing this requirement for the September 22, 2006 exceedances, the State identifies a source region for the PM–10, an area northwest of Corcoran around the area of Lemoore. The State provides a convincing demonstration showing that the winds in the area of the central SJV were of sufficient speeds to erode soils and entrain dust and that the wind direction moved the PM–10 southeast towards Corcoran and further to the Bakersfield area.

Meteorological measurements in Lemoore show that this area had the highest hourly averaged winds in the SJV that day, peaking at 10 a.m. with a speed of 29 mph from the NNW and gusts at the same time reaching 37

[10] NED for September 22, 2006 at 32.

[11] 69 FR 30006, 30035 (May 26, 2004); 71 FR 7683 (February 14, 2006).

[12] NED for September 22, 2006 at 32–33.

[13] NED for September 22, 2006 at 29; NED Addendum for September 22, 2006 at section 4.

[14] NED for September 22, 2006 at 29.

[15] NED for September 22, 2006 at 13; David Bush, T&B Systems Contribution to CRPAQS Initial Data Analysis of Field Program Measurements, Final Report Contract 2002–06PM Technical & Business Systems, Inc., November 9, 2004 (Bush Report).

[16] NED Addendum for September 22, 2006 at 11, Table 3.

[17] Generally EPA concurs or nonconcurs by letter with requests to flag data as caused by exceptional events. See our explanation in section II. above regarding why we are proceeding by a rulemaking here.

mph.[18] Lemoore is approximately 25 miles northwest of Corcoran. Meteorological measurements were also obtained from a site at Kettleman Hills, which showed a peak hourly wind at 11 am of 20 mph from the NNW with gusts up to 32 mph.[19] Kettleman Hills is approximately 28 miles west of Corcoran. The wind speed, direction, time and distance from monitors indicate that the high winds at Lemoore entrained the dust carrying it toward Corcoran.[20] The State cites a 2002 California Regional PM–10/PM–2.5 Air Quality Study (2002 CRPAQS study) that established a dust-generating wind speed threshold of 17.8 mph to support its conclusion that these wind speeds were sufficient to erode soils and entrain dust into the atmosphere as well as to exacerbate the entrainment of dust from the anthropogenic activities.[21]

At about 9:30 a.m. and 10:30 a.m. the District received complaints about dust emissions in Lemoore.[22] This was at the time of peak winds in Lemoore. The District followed up on the complaints but did not issue notices of violation. The State indicates that there were PM–10 generating activities in the area of Lemoore on the morning of September 22, 2006 but that these activities were typical for the area and subject to the District's fugitive dust regulations.[23]

The State shows a clear relationship between the wind speeds at Lemoore and Kettleman Hills and increased concentrations at the Corcoran monitoring site. The documentation clearly shows that as hourly average wind speeds increased at the three meteorological sites, hourly concentrations at Corcoran also increased. The peak hourly concentrations at Corcoran were at 10 a.m. and 11 a.m. (725 μg/m^3 and 695 μg/m^3, respectively).[24] These concentrations coincide with the highest winds at Lemoore and Kettleman Hills.

The winds at Corcoran showed the same pattern of increasing wind speeds but at a lower intensity. Hourly average winds at Corcoran peaked at 8 a.m. at 11 mph with a peak average minute gust of 15 mph. While these wind speeds were not high enough to erode and entrain soil, based on the wind speed threshold referenced above, they were sufficient to keep the coarse particles suspended in the atmosphere. The winds were also consistently from the northwest, which demonstrates that the coarse particles which impacted Corcoran originated in the areas northwest of the monitor, e.g. Lemoore where the winds were unusually high.

Using the threshold wind speed in the 2002 CRPAQS study, the State shows that most of the PM–10 was generated upwind of the Corcoran site and then transported to the Corcoran area.[25] Based on available data, wind speeds at Corcoran were not high enough to generate dust on their own but were high enough to sustain the entrainment of PM–10 from upwind areas.

The wind-driven dust from sources in the central and southern SJV, beginning in Lemoore, also impacted the Bakersfield area on September 22, 2006. The State provides the analysis and supporting information needed to demonstrate that the winds between the Corcoran and Bakersfield areas were of sufficient intensity to transport the plume of PM–10 from Corcoran to the Bakersfield and Oildale monitors. The Bakersfield area monitors began to record hourly concentrations in excess of the level of the 24-hour PM–10 NAAQS two hours after the peak Corcoran hourly PM–10 concentration, with the Bakersfield hourly PM–10 concentrations peaking five hours after the Corcoran peak hourly PM–10 concentration. In order to transport a plume of dust from Corcoran to the Bakersfield area, approximately 55 miles, wind speeds would have to average approximately 11 mph in order for the maximum amount of PM–10 to impact the Bakersfield area monitors five hours later.[26] The winds at Alpaugh, which is located between Corcoran and Bakersfield, averaged 11 mph.[27] As would be expected, the concentration of PM–10 in the Bakersfield area was lower than in Corcoran, but still significant enough to exceed the NAAQS. The lower PM–10 concentrations at Bakersfield are likely due to the dispersion of the dust plume and possibly deposition of a portion of the dust particles along the path from the Corcoran area to Bakersfield.

The State's demonstration for September 22, 2006 includes information on wind speed and direction [28] that shows the correlation between the hourly wind speeds at meteorological sites in Alpaugh and Bakersfield-Meadows Airfield and the hourly PM–10 concentrations recorded in the Bakersfield area.[29]

The State also includes the results of a basic meteorological model known as Hybrid Single-Particle Lagrangian Integrated Trajectory model (HYSPLIT).[30] It is important to note that while this modeling is not meant to quantify the particle concentration recorded in the Bakersfield area, it does offer support of the State's demonstration that the winds on September 22, 2006 were of the appropriate intensity and direction to move a plume of dust from the central SJV to the Bakersfield area.

c. Did the State demonstrate that the event is associated with measured concentration in excess of normal historical fluctuations including background?

For EPA to concur with a state's claim that an exceptional event caused an exceedance, one of the requirements that the state must meet is to show that the event is associated with concentrations that are beyond the normal historical fluctuations. See 40 CFR 50.14(c)(3)(iii)(C).

The NED for September 22, 2006 and NED Addendum for September 22, 2006 include sections that show the unusualness of the concentrations recorded on that date. Section 4 of the Addendum includes Figure A–5 that compares the peak 24-hour PM–10 concentrations recorded at Corcoran, Bakersfield and Oildale during the month of September for the years 2000 through 2006.[31]

The FRM monitor at the Corcoran site has mostly operated on a once-in-every-three-days schedule since 2000.[32] The Corcoran FRM has collected 786 samples since 2000 and has recorded only four exceedances of the 24-hour PM–10 NAAQS.[33] A further analysis shows that, with the exception of a flagged natural event in 2004, 24-hour

[18] NED for September 22, 2006 at 11, Table 3.

[19] *Id.*

[20] *Id.*

[21] *Id.* at 13; Bush Report.

[22] NED for September 22, 2006 at 33, Table 15.

[23] *Id.* at 5 and 32–33.

[24] *Id.* at 11, Table 3.

[25] *Id.* at 13; Bush Report.

[26] NED Addendum for September 22, 2006 at 7.

[27] *Id.* at 8, Table A–1.

[28] NED Addendum for September 22, 2006 at 8, Table A–1.

[29] The Oildale monitoring site does not record hourly PM–10 concentrations but uses a manual PM–10 sampler that provides only 24-hour average concentrations. The Bakersfield-Golden State Highway monitoring site utilizes both a manual sampler for average 24-hour PM–10 concentrations and a continuous PM–10 analyzer to provide hourly concentrations. Since the Bakersfield-Golden State Highway site and the Oildale site are relatively close to each other (see footnote 9 above), we believe it is appropriate to use the Bakersfield-Golden State Highway continuous analyzer to characterize the temporal distribution of hourly concentrations at both sites.

[30] NED Addendum for September 22, 2006 at 10.

[31] NED Addendum for September 22, 2006 at 14.

[32] From September 1, 2000 to March 22, 2001 the Corcoran monitor operated on a once-in-every-six-days schedule.

[33] PM–10 Raw Data Report Corcoran 2000–2006, EPA AQS Database, July 30, 2007.

PM–10 concentrations exceeded a level of 100 μg/m³ only three times during the month of September for a seven year period, i.e, when we look at the 59 samples collected during the September for the past seven years, a concentration greater than 100 μg/m³ occurred only five percent of the time.[34] Exceedances of the NAAQS have occurred twice in September, which is less than four percent of the days sampled. Comparisons for the month of September are more relevant than for the entire year because September has the highest concentration of dust but does not typically have the highest PM–10 concentrations, which occur in the winter season. Dust is typically less than 50% of the PM–10 during September.[35] During the winter season nitrates are the largest contributor, particularly in the southern part of the central valley.

For Bakersfield, which utilizes a FRM operating on a once-in-every-six-days schedule, 413 samples were collected since the year 2000. During this time the NAAQS was exceeded three times. Again, when we look at data collected during the September months from 2000 to 2006, only one day out of 33 days sampled recorded a level greater than 100 μg/m³ (128 μg/m³ on September 18, 2003), three percent of the time.[36]

For Oildale, also operating a FRM on a once-every-six-days schedule, 432 samples were collected from 2000 to 2006. The PM–10 NAAQS was exceeded once during this seven-year period. During the September months, only one day out of 35 days sampled recorded a level greater than 100 μg/m³ (111 μg/m³ on September 14, 2006), less than three percent of the time.[37]

d. Did the State demonstrate that there would have been no exceedance ''but for'' the event?

As discussed above, to qualify as an exceptional event the state must also demonstrate that there would have been no exceedance ''but for'' the event. 40 CFR 50.14 (c)(3)(iii)(D). To meet this ''but for'' criterion, states must include analyses to demonstrate that an exceedance or violation would not have occurred but for the event. Such analyses do not require a precise estimate of the estimated air quality impact from the event. 72 FR at 13570.

To meet this ''but for'' criterion, the State first shows that there were no unusual activities occurring in the affected areas in the Valley on September 22, 2006 that could have resulted in the exceedances. Specifically, based on information from District field staff and discussions with representatives of agricultural and industrial operations in the Valley, anthropogenic emissions were approximately constant in the Valley immediately before, during and after the event. The State indicates that there were PM–10 generating activities, such as agricultural and construction operations, in the area of Lemoore on the morning of September 22, 2006. These types of activities are typical for the area.[38]

The State next indicates that the greatest fraction of PM–10 at the Corcoran and Bakersfield sites on September 22 consisted of particles in the size fraction between PM–10 and PM–2.5.[39] This information indicates that geologic dust, as opposed to secondary PM or PM from combustion sources, was the primary contributor to the exceedances. The fraction of coarse particles at Corcoran and Bakersfield on September 22 was 89% and 79% respectively.[40] These values must be compared to the typical geologic values for the Valley during September of approximately 30 μg/m³ which are less than 50% of the measured PM–10.[41] Based on the reported 89% value, the estimated geologic material for Corcoran was approximately 190 to 230 μg/m³ for September 22, 2006. The corresponding values for Bakersfield were 123–134 μg/m³. Compared to the typical September value of approximately 30 μg/m³, the September 22, 2006 values represent an excess geologic contribution of approximately 160 to 200 μg/m³ for Corcoran and approximately 94 to 104 for Bakersfield. If the typical value of 30 μg/m³ were used instead of the high estimated geologic values derived from the PM–10–2.5 size fraction, the resulting ''adjusted'' PM–10 values for Corcoran and Bakersfield would be 50–65 μg/m³. This result favorably compares to the typical average September concentration of less than 60 μg/m³. Allowing for a PM–10 geologic value of 60 μg/m³, which is twice the September norm, would only yield an ''adjusted'' concentration of 84 to 96 μg/m³. All of these sets of adjusted values for September 22 are consistent with the aforementioned historical September levels which rarely exceeded 100 μg/m³, showing that very few days in Bakersfield and Corcoran over the period 2000–2006 exceeded the level of 100 μg/m³.

In addition, the NED for September 22, 2006 includes Table 2 that lists the PM–10 24-hour average concentrations recorded using continuous analyzers for the days immediately preceding and after September 22, 2006.[42] This table indicates that 24-hour average PM–10 concentrations at Corcoran were over 100% higher on September 22 as compared to September 20, 21, 23, and 24. At Bakersfield, concentrations on September 22 were over 100% higher than on September 20 and September 24 and 86% higher than on September 21. Compared to September 23 the increase was 14%.

Finally, as discussed above, there were reasonable and appropriate measures in place to control PM–10 in the SJV on September 22, 2006, Regulation VIII and Rule 4550.[43] Moreover, EPA has approved the District's BACM demonstration for all significant sources of PM–10 in the SJV as meeting CAA section 189(b)(1)(B).[44] Furthermore, District staff performed 46 inspections in the Valley on September 22 to ensure that regulated sources were complying with the District's fugitive dust rules.[45] The District's Natural Events Action Plan, discussed below, also addresses the reasonable and appropriate measures that the District has implemented to address high wind events in the SJV.

Based on the weight of evidence presented, EPA concludes that the State's documentation demonstrates that the exceedances at Corcoran, and Bakersfield and Oildale on September 22, 2006 would not have occurred but for the wind event on this day.

3. Mitigation Requirements

Under 40 CFR 51.930, a state requesting to exclude air quality data due to exceptional events must take appropriate and reasonable actions, including public notification, public education, and implementation of measures, to protect public health from exceedances or violations of the NAAQS.

The SJVAPCD adopted the ''Natural Events Action Plan for High Wind Events in the San Joaquin Valley Air

[34] 138 μg/m³ on September 9, 2004, a 102 μg/m³ on September 24, 2004 and a 112 μg/m³ on September 23, 2006; See *Id.*

[35] ''What are the Sources of Particulate Matter'', Presentation by Karen L. Magliano, California Air Resources Board, May 17, 2006 (Magliano Presentation).

[36] PM–10 Raw Data Report Bakersfield Golden 2000–2006, EPA AQS Database, July 30, 2007.

[37] PM–10 Raw Data Report Oildale 2000–2006, EPA AQS Database, July 26, 2007.

[38] NED for September 22, 2006 at 32–33.

[39] *Id.* at 32, Figure 13.

[40] *Id.*

[41] Magliano Presentation.

[42] NED for September 22, 2006 at 9.

[43] *Id.* at 32.

[44] 69 FR 30006, 30035 (May 26, 2004); 71 FR 7683 (February 14, 2006).

[45] NED for September 22, 2006 at 45–46.

Basin'' (NEAP) on February 16, 2006. The NEAP provides the SJVAPCD's approach to forecasting high wind events, notifying the public prior to the event and educating the public on how to minimize exposure during high wind events. The document also discusses measures that are in place to help minimize exposure to elevated PM–10 levels. EPA believes that the detailed processes and measures described in the NEAP satisfy the mitigation requirements under 40 CFR 51.930.

a. Provide for Prompt Public Notification of Exceedance Events

Section 6 of the NEAP provides the meteorological forecasting criteria that the SJVAPCD uses to determine whether or not to declare NEAP episodes. When the criteria indicate that a NEAP episode should be declared, the SJVAPCD has a public notification program, discussed in Section 7 of the NEAP, which involves informing the local media, SJVAPCD staff and community groups.

b. Provide for Public Education on How To Minimize Exposure

Section 7 of the NEAP provides a list of precautions that can be taken to limit exposure during a NEAP episode. The list includes keeping windows shut, using air conditioners or heaters on the recycle/recirculating air mode, limiting strenuous activity, and other precautions. Section 8 of the NEAP discusses the SJVAPCD's general public outreach program on NEAP episodes which includes developing and providing a brochure and information about NEAP episodes by means of community events, health fairs, schools and civic engagements.

c. Provide for the Implementation of Appropriate Measures To Protect the Public

Section 10 of the NEAP discusses the SJVAPCD's measures that reduce PM–10 emissions. These measures, including those approved by EPA as BACM for the SJV, in combination with the SJVAPCD's process for declaring NEAP episodes and educating the public on how to minimize their exposure during a NEAP episode, meet the requirements for appropriate measures to protect the public during high wind exceptional events.

Conclusion

EPA believes that the high winds in the area of Lemoore on September 22, 2006 were an exceptional event as defined in 40 CFR 50.1(j). EPA also believes that the State has provided a sufficient weight of evidence demonstration to show that these high winds generated and transported PM–10 from the area of Lemoore to Corcoran, causing an exceedance of the 24-hour PM–10 NAAQS. Winds between Corcoran and the Bakersfield area were sufficient to transport the dust that originated in the Lemoore area such that they caused the monitors at Bakersfield-Golden State Highway and Oildale to also exceed the NAAQS. The documentation submitted by the State demonstrates that but for the high winds in the area of Lemoore, the Corcoran, Bakersfield and Oildale monitors would not have exceeded the 24-hour PM–10 NAAQS on September 22, 2006. Because EPA believes that the State has satisfied the provisions of the Exceptional Events Rule, EPA proposes to concur with the State's request to flag these exceedances as being due to exceptional events and to exclude the data from consideration in determining whether the area has attained the PM–10 standard.

B. October 25, 2006 Exceedances at Corcoran and Bakersfield

On October 25, 2006, the SJV recorded exceedances of the 24-hour PM–10 NAAQS at two sites, Corcoran and Bakersfield-Golden State Highway, using continuous PM–10 analyzers designated as FEM monitors.[46] The 24-hour average concentrations recorded were 304 μg/m^3 at Corcoran and 193 μg/m^3 at Bakersfield-Golden State Highway. The conditions that contributed to these exceedances were very similar to those that occurred on September 22, 2006. Based on the evidence submitted, EPA agrees with the State's demonstration that high wind-entrained dust from the central and southern SJV caused the exceedances at the two monitoring locations on October 25, 2006.

1. Procedural Requirements

a. Data Are Flagged in EPA's AQS Database

The October 25, 2006 exceedances were flagged in EPA's AQS database as of July 2007.

[46] The District operates Tapered Element Oscillating Microbalance (TEOM) continuous automated analyzers at these two sites in addition to the manual high-volume Federal Reference Method (FRM) monitors. The FRMs operate at a less than everyday schedule, as allowed by EPA regulations, but neither of the FRM monitors was operating on October 25, 2006. The District operates the continuous analyzers so that they may report daily PM–10 air quality data to the public.

b. Public Had an Opportunity To Review and Comment on the State's Documentation

In February 2007, the SJVAPCD notified the public in local newspapers and on its Web site of the availability of the document entitled ''Natural Event Documentation, High Winds, Corcoran and Bakersfield, California, October 25, 2006,'' SJV Unified Air Pollution Control District, February 2007 and requested public comments by March 5, 2007.

The SJVAPCD subsequently revised the February 2007 document and submitted to CARB the ''Natural Event Documentation, Corcoran and Bakersfield, California, October 25, 2006,'' San Joaquin Valley Unified Air Pollution Control District, April 23, 2007 (NED for October 25, 2006), and posted it on its Web site.

The SJVAPCD indicated that no public comments were received during its public process.

c. The Documentation Was Submitted to Epa

The NED for October 25, 2006 was submitted by the State to EPA on May 1, 2007 and is the document upon which EPA is basing its evaluation below.

d. EPA Concurs With the State's Demonstration

In this proposed rule, EPA is proposing to concur with the State's demonstration in the NED for October 25, 2006 that high wind-entrained dust caused the exceedances at the two monitoring sites.

2. Technical Criteria

a. Did this event satisfy the criteria in section 50.1(j) of the Rule?

i. Affected Air Quality

For an event to qualify as an exceptional event, the state must show that the event affected air quality. This criterion can be met by establishing that the event is associated with a measured exceedance in excess of normal historical fluctuations, including background, and there is a causal connection between the event and the exceedance. The demonstration of a clear causal relationship is necessary to establish that the event affected air quality and is also a separate statutory requirement as discussed above.

In the NED for October 25, 2006, the State provides documentation that the measured exceedances recorded on October 25, 2006 were in excess of normal historical fluctuations. See subsection c. below. The State also establishes a causal connection between

the high winds recorded at Lemoore and the high concentrations at the monitors recorded at Corcoran and Bakersfield. The State's demonstration of the clear causal relationship between the exceptional event and the exceedances on this day is discussed in greater detail in subsection b. below.

ii. Not Reasonably Controllable or Preventable

Section 50.1(j) requires that for an event to qualify as an exceptional event, whether natural or anthropogenic, a state must show that the event was not reasonably preventable or controllable. Here this requirement is met by demonstrating that despite reasonable and appropriate measures in place, the October 25, 2006 wind event caused the exceedances. During this event, there were no other unusual dust-producing activities occurring in the SJV and anthropogenic emissions were approximately constant before, during and after the event. In addition, the State showed that reasonable and appropriate measures were in place, including Regulation VIII (the District's general fugitive dust rules) and Rule 4550 which limits fugitive dust emissions specifically from agricultural operations through Conservation Management Practices.[47] Moreover, EPA has approved the District's BACM demonstration for all significant sources of PM–10 in the SJV as meeting CAA section 189(b)(1)(B).[48]

iii. Was a Natural Event

In the preamble to the Exceptional Events Rule, EPA states that ambient particulate matter concentrations due to dust being raised by unusually high winds will be treated as due to uncontrollable natural events where (1) the dust originated from nonanthropogenic sources, or (2) the dust originated from anthropogenic sources within the State, that are determined to have been reasonably well-controlled at the time that the event occurred, or from anthropogenic sources outside the State. 72 FR at 13576. In the preamble EPA also explains that ''[s]tates must provide appropriate documentation to substantiate why the level of wind speed associated with the event in question should be considered unusual for the affected area during the time of year that the event occurred.'' *Id.* at 13566.

The wind-entrained dust on October 25, 2006 originated from anthropogenic sources within California, i.e., from usual dust-generating activities such as agricultural and industrial operations.[49] We discuss the fugitive dust control measures in place in the SJV on October 25 above.

With respect to the wind speed, EPA concurs with the State's demonstration that the wind speeds in the central SJV were unusually high on October 25, 2006.[50] Table 1 of the NED for October 25, 2006 lists the wind speeds in the Hanford and Lemoore areas. The peak hourly averaged winds were in the range of 29 to 31 mph at Lemoore, with gusts reaching 40 mph. Peak hourly winds at Hanford were lower, in the range of 17 to 18 mph, but still in line with the threshold wind speed of 17.8 mph. Hanford also recorded peak gusts of 22 to 30 mph during the 10 a.m. to 12 noon period.[51] Tables 8, 9, and 11 of the NED for October 25, 2006 also include information on wind speeds throughout the central valley of California and the central and southern SJV.[52] The documentation also states that wind speeds of these intensities are relatively rare in the southwestern part of the SJV and occur less than 5% of the time, based on long-term monitoring records.[53]

EPA concurs with the State's demonstration in the NED for October 25, 2006 that the wind speeds occurring in the central SJV were unusually high on October 25, 2006. While the winds at Corcoran were not as high as those in Lemoore and Hanford, as described in the State's documentation, the winds at Corcoran during the peak hourly PM–10 concentrations (8 a.m. to 11 a.m.) ranged from 10 to 13 mph, which are unusual for this time of year in that area. These wind speeds, though not sufficient to erode dust, were sufficient to keep the entrained and transported dust from the high winds at Lemoore suspended for the period during which the exceedances occurred.

iv. Determined by EPA To Be an Exceptional Event

Finally, EPA must determine through the process established in the Exceptional Events Rule whether an exceptional event occurred. We believe that the State has met the procedural requirements of the Rule including flagging of the data, submission of demonstration, evidence of the public opportunity to review and comment on the demonstration and mitigation requirements as discussed at section V.B.1. and 3. of this proposed rule. We further believe that the State has also met the technical criteria of the Rule as discussed at section V.B.2. of this proposed rule. Therefore we are proposing to concur with the State's determination that an exceptional event, i.e., a high wind event, occurred resulting in the exceedances on October 25, 2006.

b. Does the State's documentation show a clear causal connection between the exceedances and the claimed exceptional event?

Under 40 CFR 50.14(c)(3)(iii)(B), a state's demonstration must establish a clear causal relationship between the measured exceedances and the claimed exceptional event. In addressing this requirement for the October 25, 2006 exceedances, the NED for October 25, 2006 submitted by the State identifies the area northwest of Corcoran as the source of PM–10 during the October 25, 2006 event. Winds in the Lemoore area were again in excess of the threshold wind speed for eroding and entraining dust as discussed above. Table 1 of the NED for October 25, 2006 shows a clear correlation between the wind speeds in the Hanford and Lemoore areas and the increased hourly concentrations at Corcoran.[54] In fact the peak wind speeds at Lemoore and Hanford, which occurred between 10 a.m. and 12 noon at Lemoore, coincide with the peak hourly concentrations at Corcoran. The peak hourly averaged winds were in the range of 29 to 31 mph at Lemoore, with gusts reaching 40 mph. Peak hourly winds at Hanford were lower, in the range of 17 to 18 mph, but still in line with the threshold wind speed of 17.8 mph. Hanford also recorded peak gusts during the 10 a.m. to 12 noon period of 22 to 30 mph. Figure 2 of NED for October 25, 2006 compares the hourly wind speed and PM–10 concentration data from Corcoran with the hourly wind speed data from Lemoore in a graphical format.[55] This graphic shows the almost perfect correlation between increased wind speeds at Corcoran and Lemoore with the increased PM–10 hourly concentrations at Corcoran.

The dust plume that affected the Corcoran monitoring site on October 25, 2006 continued moving south and ultimately impacted the continuous PM–10 analyzer operating at the Bakersfield-Golden State Highway monitoring site. The State provides information on wind speed and direction from the Alpaugh meteorological monitoring station,

[47] NED for October 25, 2006 at 29.

[48] 69 FR at 30035; 71 FR 7683.

[49] NED for October 25, 2006 at 29.

[50] *Id.* at sections 4 and 5.

[51] *Id.* at 11.

[52] *Id.* at 22–23.

[53] *Id.* at 24.

[54] NED for October 25, 2006 at 11.

[55] *Id.* at 12.

located between Corcoran and Bakersfield about 16 miles south southeast of the Corcoran monitoring site.[56] Between the hours of 9 a.m. and 4 p.m., wind speeds at Alpaugh averaged about 12 mph.[57] Since the meteorological data measured at Alpaugh is taken at 2 meters Above Ground Level (AGL), the average wind speed at 10 meters AGL is about 15 mph.[58] EPA believes this average wind speed would have been sufficient to keep the dust plume suspended, and that it facilitated the transport of the dust plume to the Bakersfield area.

The data in Table 1 of the NED for October 25, 2006 show the Bakersfield hourly PM–10 concentrations beginning to exceed the level of the 24-hour PM–10 NAAQS at 11 a.m. (177 μg/m^3) and peaking between the hours of 2 p.m. and 5 p.m. (415 μg/m^3 and 416 μg/m^3, respectively). Figure 4 provides a graph of PM–10 hourly concentrations for three continuous PM–10 analyzers operated by the District at Corcoran, Bakersfield-Golden State Highway, and Tracy.[59] The graph shows hourly PM–10 concentrations at Bakersfield-Golden State Highway slowly increasing through the morning hours of October 25 until 8 a.m. Hourly concentrations increase at a higher rate between 8 a.m. and 1 p.m., mirroring the increase at Corcoran, but not as dramatic. As the Corcoran hourly concentrations are dropping between 11 a.m. 4 p.m. we see a corresponding sharp increase in hourly concentrations at Bakersfield-Golden State Highway. This behavior of the hourly concentrations supports the State's explanation that the dust plume that first affected Corcoran traveled south over a period of several hours and then impacted the Bakersfield monitor.

As with the September 22, 2006 event, the State includes for the October 25, 2006 event the results of a basic meteorological model known as the Hybrid Single-Particle Lagrangian Integrated Trajectory model (HYSPLIT).[60] It is important to note that while this modeling is not meant to quantify the particle concentration recorded in the Bakersfield area, it does support the State's demonstration that the winds on October 25, 2006 were of the appropriate intensity and direction to move a plume of dust from the central SJV to the Bakersfield area.

c. Did the State demonstrate that the event is associated with measured concentrations in excess of normal historical fluctuations including background?

For EPA to concur with a state's claim that an exceptional event caused an exceedance, one of the requirements that the state must meet is to show that the event is associated with concentrations that are beyond the normal historical fluctuations. See 40 CFR 50.14(c)(3)(iii)(C).

The State provides data on PM–10 levels on the days before and after October 25, 2006. PM–10 concentrations before and after October 25, 2006 were significantly lower than the concentration recorded on October 25, 2006. An EPA review of continuous PM–10 data from Corcoran and Bakersfield-Golden State Highway showed that 24-hour average concentrations from October 1, when the TEOM continuous analyzers began reporting data, through October 24 did not exceed 100, and while there were a number of higher concentrations on the days after October 25, not counting the exceedances recorded on December 8, 2006, which are discussed further below in subsection d, the PM–10 concentrations at Corcoran and Bakersfield-Golden State Highway fell to mostly less than 100 again from October 28 through June 30, 2007.[61]

Historically we can compare data from these continuous analyzers only with the separate manual FRM samplers operated at the sites. When we look at typical PM–10 concentrations recorded in the month of October from 2000 to 2006 the maximum value recorded at Bakersfield was 116 μg/m^3 measured on October 16, 2001 and the maximum non-exceedance value recorded at Corcoran was 150 μg/m^3 measured on October 31, 2006.[62] These concentrations indicate that the exceedances recorded on October 25, 2006 were unusual and not representative of typical high concentrations recorded at these monitoring locations.

d. Did the State demonstrate that there would have been no exceedance ''but for'' the event?

As discussed previously, to qualify as an exceptional event the State must also demonstrate that there would have been no exceedance ''but for'' the event. 40 CFR 50.14(c)(3)(iii)(D). To meet this ''but for'' requirement, the state must include analyses to demonstrate that an exceedance or violation would not have occurred but for the event. Such analyses do not require a precise estimate of the estimated air quality impact from the event. 72 FR at 13570.

To meet this ''but for'' requirement the State first shows that there were no unusual activities occurring in the affected areas in the Valley that could have resulted in the exceedances. Specifically, based on information from District field staff and discussions with representatives of agricultural and industrial operations in the Valley, anthropogenic emissions were approximately constant in the Valley immediately before, during and after the event. The District staff observed no unusual emissions other than those associated with the wind event. The PM–10 generating activities were BACM-controlled sources that are usual for the area.[63] District staff conducted 90 inspections throughout the SJV on October 25 to ensure sources were in compliance with District air pollution rules.[64]

The State notes in the NED for October 25, 2006 that the PM–2.5 to PM–10 ratio on this day was very low, which indicates that mostly coarse PM was present on the filter, supporting its claim that the concentrations recorded on this day were affected by a blowing dust event.[65]

When we examine the typical make-up of PM–10 in the SJV during October we generally see particle concentrations that are mostly in the size fraction of PM–2.5, roughly 60–65%, with the remaining mass being particles in the PM–10–2.5 size fraction.[66] Typically, fugitive dust is the major constituent of the PM–10–2.5 size fraction and makes up about 25 to 35% of the total PM–10. When we look at a comparison of PM–2.5 and PM–10 concentrations recorded on October 25, 2006, we find that the PM–10–2.5 portion of the total PM–10 represents about 93% of the total PM–10 at Corcoran and 85 percent of total PM–10 at Bakersfield. This high percentage of PM–10–2.5, which is mostly fugitive dust, is atypical for this time of year and supports the State's demonstration that the PM–10 concentrations on this day consisted of mostly coarse geologic material.

We can also look at the days immediately preceding and following

[56] *Id.* at 22–26.

[57] *Id.* at 58.

[58] *Id.* at 24–26.

[59] *Id.* at 14.

[60] *Id.* at 27.

[61] ''Continuous PM–10 Data Collected with TEOMs, Data Reported to EPA's AIRNOW Website,'' July 30, 2007, Excel Spreadsheet, Bob Pallarino.

[62] Corcoran exceeded the 24-hour NAAQS on October 29, 2002 with a value of 168 μg/m^3; PM–10 Raw Data Reports, Corcoran 2000–2006 and Bakersfield-Golden 2000–2006.

[63] NED for October 25, 2006 at 7 and 29.

[64] *Id.* at 35.

[65] *Id.* at 28.

[66] Magliano Presentation.

the exceedance day to see if the concentrations on October 25 were unusual. The PM–10 concentrations recorded on October 25 at Corcoran and Bakersfield were over three times higher than they were on October 24.[67] PM–10 concentrations after the event decreased dramatically and by October 28, PM–10 concentrations at both sites were below 100. See also the discussion of the historical levels at these monitors set forth in subsection c. above, which further demonstrates that the concentrations recorded on October 25 were unusual.

Finally, as discussed above, there were reasonable and appropriate measures in place to control PM–10 in the SJV on October 25, 2006, Regulation VIII and Rule 4550.[68] Moreover, EPA has approved the District's BACM demonstration for all significant sources of PM–10 in the SJV as meeting CAA section 189(b)(1)(B).[69] Section 9.2 of the NED for October 25, 2006 indicates that the District staff performed 90 inspections on that date to ensure that regulated sources were complying with District fugitive dust rules.[70] The District's Natural Events Action Plan, discussed in section V.A.3. above, also addresses the reasonable and appropriate measures that the District has implemented to address high wind events in the SJV.

Based on the weight of evidence presented, EPA concludes that the State's documentation demonstrates that the exceedances at Corcoran and Bakersfield on October 24, 2006 would not have occurred but for the wind event on this day.

3. Mitigation Requirements

See section V.A.3. above.

Conclusion

EPA believes that the high winds in the area of Lemoore on October 25, 2006, were an exceptional event as defined in 40 CFR 50.1(j). EPA also believes that the State has provided a sufficient weight of evidence demonstration to show that these high winds generated and transported PM–10 from the area of Lemoore to Corcoran, causing an exceedance of the 24-hour PM–10 NAAQS. Winds between Corcoran and the Bakersfield area were sufficient to transport the dust that originated in the Lemoore area such that they caused the monitor at Bakersfield-Golden State Highway to also exceed the NAAQS. The documentation submitted by the State demonstrates that but for the high winds in the area of Lemoore, the Corcoran and Bakersfield monitors would not have exceeded the 24-hour PM–10 NAAQS on October 25, 2006. Because EPA believes the State has satisfied the provisions of the Exceptional Events Rule, EPA proposes to concur with the State's request to flag these exceedances as being due to exceptional events and to exclude the data from consideration in determining whether the area has attained the PM–10 standard.

C. December 8, 2006 Exceedances at Corcoran and Bakersfield

The SJV recorded exceedances of the 24-hour PM–10 NAAQS on December 8, 2006 at two sites, Corcoran and Bakersfield-Golden State Highway, using continuous PM–10 analyzers designated as FEM monitors. The 24-hour average PM–10 concentrations recorded were 162 $\mu g/m^3$ at Corcoran and 213 $\mu g/m^3$ at Bakersfield-Golden State Highway.

The State demonstrates that unusually high winds in the Bakersfield area eroded and entrained dust that impacted the continuous PM–10 analyzer at Bakersfield. Unlike September 22 and October 25, 2006, the winds in the SJV on this day were generally from the southwest, south and southeast, transporting dust northward and ultimately impacting the continuous PM–10 analyzer at Corcoran. Based on the evidence submitted, EPA agrees with the State's demonstration that high wind-entrained dust caused the exceedances at the two monitoring locations on December 8, 2006.

1. Procedural Requirements

a. Data Are Flagged in EPA's AQS Database

The December 8, 2006 exceedances were flagged in EPA's AQS database as of July 2007.

b. Public had an opportunity to review and comment on the State's documentation

In February 2007, the SJVAPCD notified the public in local newspapers and on its Web site of the availability of the document entitled ''Natural Event Documentation, High Winds, Corcoran and Bakersfield, California, December 8, 2006,'' SJV Unified Air Pollution Control District, February 2007 and requested public comments by March 5, 2007.

The SJVACPD subsequently revised the February 2007 document and submitted to the California Air Resources Board (CARB) the ''Natural Event Documentation, Corcoran and Bakersfield, California, December 8, 2006,'' SJV Unified Air Pollution Control District, May 23, 2007 and posted it on its Web site.

SJVAPCD thereafter made revisions per CARB's request and submitted to CARB the ''Natural Event Documentation, Corcoran and Bakersfield, California, December 8, 2006,'' SJV Unified Air Pollution Control District, June 6, 2007 (NED for December 8, 2006) and posted it on its Web site.

The District indicated that no public comments were received during the public process.

c. The Documentation Was Submitted to EPA

The NED for December 8, 2006 was subsequently submitted by the State to EPA on June 12, 2007 and is the document upon which EPA is basing its evaluation below.

d. EPA Concurs With the State's Demonstration

In this proposed rule, EPA is proposing to concur with the State's demonstration in the NED for December 8, 2006 that high wind-entrained dust caused the exceedances at the two monitoring locations on December 8, 2006.

2. Technical Criteria

a. Did this event satisfy the criteria in section 50.1(j) of the Rule?

As with the previous events discussed in this proposed rule, the State needs to show that this event, identified in the NED for December 8, 2006 as unusually high winds, affected air quality in the Corcoran and Bakersfield areas, was not reasonably controllable or preventable, was a natural event, and is determined by EPA to be an exceptional event.

i. Affected Air Quality

For an event to qualify as an exceptional event, the state must show that the event affected air quality. This criterion can be met by establishing that the event is associated with a measured exceedance in excess of normal historical fluctuations, including background and there is a causal connection between the event and the exceedance. This demonstration of a causal connection is necessary to establish that the event affected air quality and is also a separate statutory requirement as discussed above.

In the NED for December 8, 2006, the State provides documentation that these measured exceedances were in excess of normal historical fluctuations. See subsection c. below. The State also establishes a causal connection between

[67] NED for October 25, 2006 at 16, Table 3.

[68] *Id.* at 29.

[69] 69 FR at 30035; 71 FR 7683.

[70] NED for October 25, 2006 at 35.

the high winds recorded in the Bakersfield and Southern SJV area and the high concentrations recorded at the Corcoran and Bakersfield monitors. The State's demonstration of the clear causal relationship between the event and the exceedances on this day is discussed in greater detail in subsection b. below.

ii. Not Reasonably Controllable or Preventable

Section 50.1(j) of the Exceptional Events Rule requires that for an event to qualify as an exceptional event, whether natural or anthropogenic, a state must show that the event was not reasonably preventable or controllable. Here this requirement is met by demonstrating that despite reasonable and appropriate measures in place, the December 8, 2006 wind event caused the exceedances. During this event, there were no other unusual dust-producing activities occurring in the SJV and anthropogenic emissions were approximately constant before, during and after the event. In addition, the State shows that reasonable and appropriate measures were in place, including Regulation VIII (the District's general fugitive dust rules) and Rule 4550 which limits fugitive dust emissions specifically from agricultural operations through Conservation Management Practices.[71] Moreover, EPA has approved the District's BACM demonstration for all significant sources of PM–10 in the SJV as meeting CAA section 189(b)(1)(B).[72]

iii. Was a Natural Event

In the preamble to the Exceptional Events Rule, EPA states that ambient particulate matter concentrations due to dust being raised by unusually high winds will be treated as due to uncontrollable natural events where (1) the dust originated from nonanthropogenic sources, or (2) the dust originated from anthropogenic sources within the State, that are determined to have been reasonably well-controlled at the time that the event occurred, or from anthropogenic sources outside the State. 72 FR at 13576. In the preamble EPA also explains that ''[s]tates must provide appropriate documentation to substantiate why the level of wind speed associated with the event in question should be considered unusual for the affected area during the time of year that the event occurred.'' *Id.* at 13566.

On December 8, 2006, the wind-entrained dust originated from anthropogenic sources within California, i.e., from usual dust-generating activities such as agricultural and industrial operations.[73] We discuss the fugitive dust control measures in place in the SJV on December 8, 2006 above.

With respect to the wind speed, EPA concurs with the State's demonstration that the wind speeds in the southern SJV were unusually high on December 8, 2006. The State includes information on the unusual nature of the wind speeds in the SJV on December 8, 2006, stating that winds of these magnitudes are rare, occurring less than 5% of the time. The NED for December 8, 2006 reports that during the blowing dust event, Bakersfield reported winds up to 25 mph with gusts up to 35 mph. Farther north in the area of Kettleman Hills, located on the west side of the San Joaquin Valley, gusts up to 50 mph were reported. Kettleman Hills also reported a twenty-two hour period with gusts of 20 mph or greater (from 6 a.m. on December 8, 2006 to 4 a.m. on December 9, 2006). Maricopa, located on the southwest side of the San Joaquin Valley approximately 25 miles southwest of Bakersfield, reported a one-minute average wind speed of 56 mph.[74]

iv. Determined by EPA To Be an Exceptional Eevent

Finally, EPA must determine through the process established in the Exceptional Events Rule whether an exceptional event occurred. We believe that the State has met the procedural requirements of the Rule including flagging of the data, submission of demonstration, evidence of the public opportunity to review and comment on the demonstration and mitigation requirements as discussed at section V.C.1. and 3. of this proposed rule. We further believe that the State has also met the technical requirements of the Rule as discussed at section V.C.2. Therefore, we are proposing to concur with the State's determination that an exceptional event, i.e., a wind event, occurred resulting in the exceedances on December 8, 2006.

b. Does the State's documentation show a clear causal connection between the exceedances and the claimed exceptional event?

Under 40 CFR 50.14(c)(3)(iii)(B), a state's demonstration must establish a clear causal relationship between the measured exceedances and the claimed exceptional event. Unlike September 22 and October 25, 2006, the winds on December 8, 2006 were erratic and generally from the east, south, and southwest.[75] Wind speeds at meteorological stations near Bakersfield recorded hourly average wind speeds in excess of 35 mph and wind gusts in excess of 50 mph. Winds at Bakersfield on December 8 were from both the southwest and southeast during the time when peak hourly PM–10 concentrations were recorded. The winds continued to blow from the southeast up the Valley, pushing the dust plume towards the Corcoran monitoring site. The peak hours for hourly PM–10 concentrations were from 1 p.m. to 3 p.m. at both the Corcoran and Bakersfield sites, with a second set of high hourly concentrations at Bakersfield occurring from 5 p.m. to 8 p.m. Winds measured at Alpaugh, located between Bakersfield and Corcoran, were highest from 12 p.m. to 4 p.m. and from the southeast, supporting the State's argument that the dust plume moved from the southeast to northwest.[76]

Table 3 and Figure 2 of the NED for December 8, 2006[77] show the correlation of wind speeds and increasing hourly concentrations of PM–10 recorded by the continuous PM–10 analyzers at Corcoran and Bakersfield.

Figure 7 of the NED for December 8, 2006 includes the results of a basic meteorological model known as Hybrid Single-Particle Lagrangian Integrated Trajectory model (HYSPLIT).[78] It is important to note that while this modeling is not meant to quantify the particle concentration recorded in the Bakersfield and Corcoran areas, it does offer support of the State's demonstration that the winds on December 8, 2006 were of the appropriate intensity and direction to move a plume of dust from the southeastern SJV to the Bakersfield area and northward to Corcoran.

c. Did the State demonstrate that the event is associated with measured concentration in excess of normal historical fluctuations including background?

For EPA to concur with a state's claim that an exceptional event caused an exceedance, one of the requirements that the state must meet is to show that the event is associated with concentrations that are beyond the normal historical fluctuations. See 40 CFR 50.14(c)(3)(iii)(C).

[71] NED for December 8, 2006 at 25.

[72] 69 FR at 30035; 71 FR 7683.

[73] NED for December 8, 2006 at 25.

[74] *Id.* at 17.

[75] *Id.* at 11, Table 3.

[76] *Id.* at 56.

[77] *Id.* at 11–12.

[78] *Id.* at 23.

As with the discussion above on the September 22 and October 25, 2006 exceedances, we can compare data from the continuous analyzers only with the separate manual FRM samplers operated at the sites, since the continuous analyzers have only been in operation since late 2006. Figures 8 and 9 of the NED for December 8, 2006 demonstrate the relative infrequency, over the last 10 years, of the concentrations recorded at Corcoran and Bakersfield on December 8, 2006. When we look at PM–10 FRM concentrations recorded at Corcoran in the month of December from 1997 to 2006, the last non-flagged exceedance of the standard was a 174 recorded on December 17, 1999.[79] Levels exceeding 100 only occurred 10 times in December in the past 10 years, out of 96 FRM days sampled. Even when we include the continuous daily data collected at Corcoran in 2006, there are only the 10 values over 100 described above.

For Bakersfield, the last non-flagged day exceeding the standard in December was 159 recorded on December 30, 1998. Of the 42 December FRM sample days since 1997, 9 days exceed 100. Again, even when we include the continuous daily data from 2006, the result remains 9 days exceeding 100 in the last 10 years.[80]

d. Did the State demonstrate that there would have been no exceedance ''but for'' the event?

As discussed above, to qualify as an exceptional event the state must also demonstrate that there would have been no exceedance ''but for'' the event. 40 CFR 50.14(c)(3)(iii)(D). To meet this ''but for'' requirement, the state must include analyses to demonstrate that an exceedance or violation would not have occurred but for the event. Such analyses do not require a precise estimate of the estimated air quality impact from the even. 72 FR at 13570.

To meet this ''but for'' requirement the State first shows that there were no unusual activities occurring in the affected areas in the Valley that could have resulted in the exceedances. Specifically, based on information from District field staff and discussions with representatives of agricultural and industrial operations in the Valley, activities that generate anthropogenic PM–10 were approximately constant in the Valley immediately before, during and after the event. As on September 22 and October 25, 2006, activity levels in the SJV were typical for the time of year and PM–10 emission control programs were being implemented, not only for fugitive dust-generating activities, but also agricultural burning and residential wood combustion in parts of the SJV.[81]

The State provides frequency distributions of the maximum PM–10 24-hour December concentrations for the past 10 years. These figures indicate that PM–10 concentrations at Corcoran and Bakersfield-Golden State Highway rarely exceeded the level of the 24-hour PM–10 NAAQS.[82] This fact is an indication that December 8, 2006 was unusual in that the normal emission activity levels do not cause exceedances, based on historical data.

Examining the make-up of PM–10 on this day using PM–2.5 data collected at the sites with a continuous PM–2.5 analyzer, we can see that coarse particles, or PM–10–2.5, which are associated with windblown dust, represented 78% of the total PM–10 mass collected at Corcoran and 88% of the total PM–10 mass at Bakersfield. CARB studies indicate that at this time of year, fugitive dust generally contributes less than 20% of the total PM–10 mass.[83] The atypical contribution of fugitive dust to the exceedances recorded on December 8, 2006 indicates that but for the wind event these exceedances would not have occurred.

As discussed above, the State also looked at data from the days immediately preceding and after December 8, 2006.[84] Twenty-four hour PM–10 concentrations on December 4–6 were less than 100 μg/m^3 at both sites and were just over 100 μg/m^3 on December 7. On December 8, the concentration at Corcoran increased by more than 50%, exceeding the NAAQS with a level of 162 μg/m^3, but then fell to 32 μg/m^3 on December 9 and continued dropping for weeks after this event. At Bakersfield, on December 8 there was a greater than 100% increase over the December 7 concentration. Again, concentrations dropped dramatically on December 9 and remained low for weeks after.

Finally, as discussed above, there were reasonable and appropriate measures in place to control PM–10 in the SJV on December 8, 2006, Regulation VIII and Rule 4550.[85] Moreover, EPA has approved the District's BACM demonstration for all significant sources of PM–10 in the SJV as meeting CAA section 189(b)(1)(B).[86] The District's Natural Events Action Plan, discussed in section V.A.3. above, also addresses the reasonable and appropriate measures that the District has implemented to address high wind events in the SJV.

Based on the weight of evidence presented, EPA concludes that the State's documentation demonstrates that the exceedances at Corcoran and Bakersfield on December 8, 2006 would not have occurred but for the wind event on this day.

3. Mitigation Requirements

See section V.A.3.c above.

Conclusion

EPA believes that the high winds in the southeastern SJV on December 8, 2006 were an exceptional event as defined in 40 CFR 50.1(j). EPA also believes that the State has provided a sufficient weight of evidence demonstration to show that these high winds generated and transported PM–10 from the area of Bakersfield to Corcoran causing exceedances of the 24-hour PM–10 NAAQS at the Bakersfield and Corcoran monitors. The NED for December 8, 2006 submitted by the State demonstrates that but for the high winds in the southern SJV, the Corcoran and Bakersfield monitors would not have exceeded the 24-hour PM–10 NAAQS on December 8, 2006. Because EPA believes that the State has satisfied the provisions of the Exceptional Events Rule, EPA proposes to concur with the State's request to flag these exceedances as due to exceptional events and to exclude the data from consideration in determining whether the area has attained the PM–10 standard.

VI. EPA Evaluation of September 14, September 20 and October 26, 2006 Exceedances at the Santa Rosa Rancheria

The 24-hour PM–10 NAAQS was exceeded on September 14, 20 and October 26, 2006 at a monitor on the Santa Rosa Rancheria (SRR), tribal land located in Kings County within the SJV. The 24-hour average PM–10 concentrations were 190 μg/m^3, 158 μg/m^3, and 157 μg/m^3, respectively. The SRR Tribe flagged the exceedances as caused by an exceptional event, i.e., construction activities.

The Santa Rosa Rancheria EPA Department (SRREPA) operates a monitoring site on the SRR, located on the roof of a pumping station at the SRR's water treatment facility. The PM–10 sampler is a high volume size

[79] PM–10 Raw Data Report Corcoran 1997–2006, EPA AQS Database, July 30, 2007.

[80] PM–10 Raw Data Report Bakersfield Golden 1997–2006, EPA AQS Database, July 30, 2007.

[81] NED for December 8, 2006 at 25.

[82] *Id.* at 28–29, Figures 8 and 9.

[83] Magliano Presentation.

[84] NED for December 8, 2006 at Table 1.

[85] *Id.* at 25.

[86] 69 FR at 30035; 71 FR 7683.

selective inlet (SSI) Anderson sampler designated as a FRM by EPA. The monitoring site also measures ozone and meteorological parameters including wind speed and wind direction.

The PM–10 sampler is located near the northeast corner on the roof of the pumping station. The current land cover around the pump station is paved parking. There are no obstructions of any kind and there is unrestricted airflow 360 degrees around the sampler inlet.[87]

To the east of the monitor is a paved parking lot, beginning about 25 feet east of the monitor location and extending approximately 50 feet to the east. Beyond the parking area are trailers and undeveloped land. To the north of the monitor is a larger parking lot, beginning about 100 feet north of the monitor location and extending north approximately 525 feet. Beyond the parking lot are a casino hotel, casino, and additional parking lots. To the immediate south (150 feet) and west (300 feet) are the remaining physical plant facilities (tanks, pumps, etc.) and the area is paved. Further south and west are agricultural fields (currently alfalfa). Agricultural fields also lie to the north beyond the casino and parking lot (approximately 0.5 mile). To the east is the SRR residential area.

PM–10 is measured once-in-every-six days by the SRREPA according to the national sampling schedule. Sampling began on August 3, 2006 and continues to the present time.

In 2006 there was a major construction project at the SRR, which involved construction of a casino hotel and associated parking lots. This construction activity, located near the monitor, was ongoing prior to the time the monitor began operation. The original intention of the SRREPA was to begin operation of the monitor and sampling only after completion of the parking lots and external portion of the hotel. Due to delays, however, the construction was not completed until November 2006. The monitor began operating as scheduled on August 3, 2006.

The SRREPA's environmental technician informed EPA that he believes that many of the samples collected since PM–10 monitoring began on August 3, 2006, through mid-November 2006, were unduly influenced by the grading and paving of parking lots immediately adjacent to the monitoring site on the north and east sides of the pump station building where the PM–10 sampler monitor is located.[88] In addition to the exceedance days, much of the data between August 3 and November 25, 2006 submitted to the AQS database, has been flagged as affected by construction activity.[89]

EPA believes there are two bases for excluding the September 14, September 20 and October 26, 2006 exceedances from consideration in determining whether the SJV has attained the PM–10 standard. First, as explained in more detail below, EPA believes that, during the time period the monitor was operating in such close proximity to the construction, the monitor should be considered to have been improperly sited under the principles established in 40 CFR part 58, appendix E. Second, EPA believes that, under its Exceptional Events Rule, the construction activity that occurred within such close proximity to the monitor constitutes an exceptional event that caused the exceedances. EPA believes that both of these rationales, separately or together, support EPA's proposal not to include the SRR monitor data recorded during the period of parking lot construction in our determination of whether the SJV has attained the PM–10 NAAQS.

A. Evaluation Under Principles Established in 40 CFR Part 58, Appendix E

40 CFR part 58 establishes criteria and requirements for ambient air quality monitoring, and appendix E sets forth the probe and monitoring path siting criteria for ambient air quality monitoring. 71 FR 61236 (October 17, 2006). These include both binding requirements and goals. Section 1(b) of appendix E, the Introduction, provides that ''[t]he probe and monitoring path siting criteria discussed in this appendix must be followed to the maximum extent possible.'' Section 58.20 provides that Special Purpose Monitors, which may include monitors on tribal lands, must meet certain requirements of part 58, including appendix E, if the data they collect are to be used for purposes of comparison to the NAAQS. It is not clear whether the monitor in Santa Rosa Rancheria is intended to be designated a Special Purpose Monitor. It is clear, however, that EPA does not intend data from a monitor to be used for purposes of comparison to the NAAQS unless the data meet the criteria set forth in section 58.20, including appendix E. Under the principles established in part 58, appendix E, EPA believes that it is not a reasonable monitoring practice to locate a PM–10 monitor, intended for purposes of comparison to the NAAQS, so close to an obviously temporary dust source, as was the case at the SRR.

Section 3(a) of appendix E, Spacing from Minor Sources, addresses the siting of monitors, including PM–10 monitors. It states that close spacing between a monitor and a minor source may be proper if the purpose of that monitoring site is to investigate emissions from that source and other local sources. However, if, as is the case with the SRR monitor here, the site is to be used to determine air quality over a larger area, such as a neighborhood or city, it should not be placed near local, minor sources, because the plume from the local minor source would inappropriately impact the air quality data collected at the site. It is plain that this occurred in the SRR situation, where the monitor, when it began operating, was only 25 feet from one parking lot construction zone and 100 feet from another.

We believe that in general it is important to avoid placing a particulate monitor inordinately close to a location where active but temporary construction activity is generating dust emissions. As noted above, the SRREPA originally had not intended to start operating the monitor until after the conclusion of the construction activity. As a consequence of monitoring while this construction was still ongoing, the SRR Tribe was compelled to flag data for 12 of the 19 sampling days that occurred between August 3 and November 25, when the construction concluded. Thus more than 60% of the data collected during this time period was considered to be unusable for regulatory purposes.

The dramatic contrast between concentrations monitored while construction was ongoing and post-construction concentrations also testifies to the impact that the improper siting had on the monitored data. After construction ceased, average monitored PM–10 concentrations declined 50%. See discussion below in section VI.B.2.d. below. EPA believes that after the construction concluded the monitor met the appropriate siting criteria.[90]

EPA has concluded that under the very unusual circumstances presented in the SRR, it was not appropriate, according to the principles established in part 58 appendix E, to deploy a new PM–10 monitor, for purposes of comparison to the NAAQS, so close to temporary construction activity, for the duration of that activity. EPA believes it would be unreasonable for the Agency

[87] July 18, 2007 Memorandum, ''On-Site Visit to Santa Rosa Rancheria,'' from Bob Pallarino, EPA, to Sean Hogan, EPA (Site Visit Memorandum).

[88] Site Visit Memorandum.

[89] AQS Raw Data Report, Santa Rosa Rancheria PM–10 2006 to 2007.

[90] Site Visit Memorandum.

to allow the data from such a monitor to determine the attainment status of the SJV.

Conclusion

EPA is proposing to conclude that the exceedances in the SJV at the SRR monitor that occurred on September 14, 2006, September 20, 2006 and October 26, 2006 should be excluded from consideration in determining whether the SJV has attained the PM–10 standard, because during this time period EPA deems that the monitor was not properly sited, under the principles established in part 58, appendix E.

In proposing to find that, during the period of construction, the monitor was not properly sited for the purpose of comparison to the NAAQS, EPA is addressing only the particular facts and circumstances presented by the SRR monitoring operation. EPA notes that the construction activity at the SRR, which occurred in extremely close proximity to the monitor and on tribal land, predated the start of monitoring operations, and that monitoring was originally intended to begin only after the conclusion of construction activity. Under these circumstances, EPA believes that the September 14, September 20 and October 26, 2006 exceedances should be excluded from consideration in determining whether the SJV has attained the PM–10 standard.

B. Evaluation Under the Exceptional Events Rule

In addition to the rationale regarding the siting of the monitor, set forth above, EPA proposes to concur with the SRR Tribe's flagging of the exceedances at the SRR because EPA believes that the construction activity constitutes an exceptional event under EPA's Exceptional Events Rule. Our application of the requirements of the Rule to the SRR exceedances is set forth below.

1. Procedural Requirements

a. Data Are Flagged in EPA's AQS Database

The three exceedances were flagged by the SRR Tribe by the time the data were submitted to the AQS database in 2006.

b. Public Had an Opportunity To Review and Comment on the Tribe's Documentation

EPA is assisting the SRR Tribe by compiling and evaluating the documentation for the exceedances which have been flagged as being caused by exceptional events. The Exceptional Events Rule recognizes that tribes may not be in a position to address all of the requirements of the Rule and thus states that EPA will ''* * * work with tribes on the implementation of this rule, which may include appropriate implementation by EPA of program elements ensuring that any exclusion * * * of data in Indian country with air quality affected by exceptional events comports with the procedures and requirements of this rule.'' 72 FR at 13563. EPA, through this proposed rule, is providing the public with an opportunity to review and comment on the documentation of these exceptional events.

c. The Documentation Was Submitted to EPA

As discussed above, EPA is assisting the SRR Tribe by compiling and evaluating the documentation of the exceedances which they have flagged as being caused by exceptional events.

d. EPA Concurs With the Tribe's Flagging and Demonstration

EPA is proposing to concur with the SRR Tribe's flagging of these exceedances as affected by exceptional events. As discussed above, EPA is assisting the SRR Tribe by compiling and evaluating the documentation of the exceedances it has flagged as being caused by exceptional events, and by ensuring that the public has an opportunity, through this rulemaking, to review and comment upon it.

2. Technical Criteria

a. Did this event satisfy the criteria in section 50.1(j) of the Rule?

i. Affected Air Quality

For an event to qualify as an exceptional event, the state or tribe must show that the event affected air quality. Here, EPA, on behalf of the SRR Tribe, needs to show that the event, identified as construction activity, affected air quality at the SRREPA PM–10 monitor. This criterion can be met by establishing that the event is associated with a measured exceedance in excess of normal historical fluctuations, including background, and there is a causal connection between the event and the exceedance. This demonstration of a causal connection is necessary to establish that the event affected air quality, and it is also a separate statutory requirement as discussed above.

Because the SRREPA PM–10 monitor has been in operation only since August 2006, it is not possible to compare the data from exceedance days to historical levels. In this case, however, we can look at data that have been collected since the construction and parking lot paving was completed to determine representative concentrations of PM–10 in the absence of a large, earth-disturbing project such as the construction, grading and paving of parking lots. We discuss the range of data and its fluctuation in more detail in subsection c. below.

We also need to show the causal connection between the exceptional event, in this case construction activity, and the exceedances recorded. In addition to other information provided during EPA's on-site visit, the SRREPA has provided EPA with wind speed and wind direction data collected at its site that show the wind was blowing in the appropriate direction and demonstrates that the PM–10 monitor was downwind of the construction activity on the exceedance days. We discuss the causal connection between the construction activity and the exceedances in more detail in subsection b. below.

ii. Not Reasonably Controllable or Preventable

Section 50.1(j) of the Exceptional Events Rule requires that for an event to qualify as an exceptional event, whether natural or anthropogenic, a state, tribe (or, in this case, EPA) must show that the event was not reasonably preventable or controllable.

EPA believes that it would not have been reasonable to prevent the activity, i.e., paving of parking lots that were needed for the SRR Tribe's facilities. Paving a parking lot (which involves grading the ground, applying a base material such as gravel and applying asphalt) is a generally accepted form of control of PM–10.[91] To prevent the paving of a parking lot would not only be unreasonable, but illogical.

With respect to whether the event was reasonably controllable, we note that the SRR Tribe does not have PM–10 control measures in place and is not subject to the fugitive dust control regulations adopted by the SJVAPCD. As discussed in the Exceptional Events Rule, ''Tribes are not required to develop TIPs or otherwise implement relevant programs under the CAA. * * *'' [92] ''EPA recognizes Tribal Governments as sovereign entities with primary authority and responsibility for the reservation populace. Accordingly, EPA will work directly with Tribal Governments as the independent

[91] See, for example, SJV Rule 8051 Open Areas (Adopted November 15, 2001; Amended August 19, 2004) and Rule 8071 Unpaved Vehicle/Equipment Traffic Areas (Adopted November 15, 2001; Amended September 16, 2004).

[92] 63 FR 7254, 7265 (February 12, 1998); 72 FR at 13563.

authority for reservation affairs, and not as political subdivisions of States or other governmental units.'' [93]

While paving itself is a control measure, EPA recognizes that other control measures may be reasonable during a paving process. For example, the SJVAPCD regulations require, among other things, that regulated construction sites apply as appropriate water or chemical/organic stabilizers or construct and maintain wind barriers.[94] In the circumstances of the SRR, however, even if these types of measures had been actively employed, we cannot be certain that they would have prevented exceedances at the PM–10 monitor. This is due in large part to the unusual circumstance presented here of the very close proximity of the construction activity to the monitor. As noted above, one of the parking lots was within 25 feet of the monitor, and the other was within 100 feet.

EPA's evaluation of the parking lot construction activity's impact on the monitor, and whether it was reasonably controllable, during the activity, is informed by EPA's views on what constitutes acceptable monitor siting. As EPA has set forth in detail above, EPA believes that, for the duration of the construction activity, the monitor was not properly sited for the purposes of determining attainment of the SJV, and that as a result it was inordinately impacted by that activity.

The provisions of 40 CFR part 58, appendix E regarding the siting of PM–10 monitors, are instructive with respect to EPA's analysis of the exceedances under the Exceptional Events Rule. We cannot conclude that the activity was reasonably controllable given that the exceedances were measured at a monitor that EPA's rule provides should not be operated at such a time and place, for the purposes of determining attainment. Thus, under the particular set of circumstances presented here, for the purposes of evaluating the ''reasonably controllable'' criterion of the Exceptional Events Rule, we deem this criterion to have been satisfied.

iii. Was an Event Caused by Human Activity That is Unlikely to Recur at a Particular Location

In this case, the event was paving of parking lots in the vicinity of the PM–10 monitor, and is a construction activity that is not expected to recur at that location.

iv. Determined by EPA To Be an Exceptional Event

Finally, EPA must determine through the process established in the Exceptional Events Rule whether an exceptional event occurred. The Exceptional Events Rule has both procedural requirements and technical criteria that we are assisting the SRREPA in meeting. We believe that by the initial flagging of the data, and through the vehicle of this proposed rulemaking we will demonstrate that the procedural requirements and technical criteria of the rule will have been met.

b. Is there a clear causal connection between the exceedances and the claimed exceptional event?

Under 40 CFR 50.14(c)(3)(iii)(B), a clear causal relationship must be established between the measured exceedance and the claimed exceptional event. The information compiled by EPA shows a clear causal connection between the exceedances and the construction activity at the nearby parking lots. The SRREPA environmental technician observed the conditions at the time the monitor was operating and noted on the sample tracking forms, which are completed with each sampling run, that there was construction nearby. Copies of these tracking forms are included in the documentation for this rulemaking.

The SRREPA measures wind speed and wind direction at the SRR monitoring site. These meteorological data indicate that on the three days that exceeded the NAAQS, winds were predominantly from the northwest to northeast. This would indicate that any dust-producing activity north and northeast of the monitor would result in high concentrations of geologic dust being blown towards the monitor.

The meteorological data lend support to the environmental technician's account of the events of that day. EPA also discussed these events with the SRR construction superintendent, who agreed with the environmental technician's account of the construction activity. A private consultant working for the SRREPA also stated that he had witnessed major earth-disturbing activities on these days.[95]

Based on the meteorological data, eyewitness accounts, and an on-site inspection of the monitoring site location and its proximity to the parking lots, we believe that there was a clear causal connection between the construction activity and the recorded PM–10 exceedances.

c. Can it be demonstrated that the event is associated with a measured concentration in excess of normal historical fluctuations including background?

For EPA to concur with the SRREPA's claim that an exceptional event caused an exceedance, one of requirements is to show that the event is associated with concentrations that are beyond the normal historical fluctuations. See 40 CFR 50.14(c)(3)(iii)(C).

Of the 44 samples collected by the SRREPA, nearly 80% of the samples (35 days) were less than 100 $\mu g/m^3$. After completion of the paving projects in mid-November, 2006, average PM–10 concentrations dropped by more than 50%, from an average of 97 $\mu g/m^3$ to an average of 45 $\mu g/m^3$.[96] This would indicate that the construction activity had an obvious effect on the concentrations recorded by the SRR monitor and that the data collected during this construction period, including the exceedances recorded in September and October, 2006, were not representative of typical post-construction PM–10 concentrations at the location of the monitor.

d. Can it be demonstrated that there would have been no exceedance ''but for'' the event?

To qualify as an exceptional event, there must be an analysis which demonstrates that there would have been no exceedance ''but for'' the event. 40 CFR 50.14(c)(3)(iii)(D). Such analyses do not require a precise estimate of the estimated air quality impact from the event. 72 FR at 13570.

To meet this requirement, EPA believes the SRREPA environmental technician, consultant and the SRR construction superintendent have clearly indicated that the exceedances occurred on days where nearby construction was also occurring. As EPA has shown, the proximity of the monitor to the construction activity and the concomitant infeasibility of control measures to prevent the exceedances also demonstrate that there would have been no exceedances but for the construction activity. Given these factors and the fact that the average PM–10 concentrations dropped by more than 50% after the completion of the paving projects, we believe the weight of evidence shows that the exceedances would not have occurred but for the construction activity.

[93] 59 FR 43956 (August 25, 1994).

[94] SJV Rule 8021 Construction, Demolition, Excavation, Extraction, and Other Earthmoving Activities (Adopted November 15, 2001; Amended August 19, 2004).

[95] Site Visit Memorandum.

[96] Santa Rosa Rancheria PM–10 24 hour average concentrations, Excel spreadsheet, Bob Pallarino.

3. Mitigation Requirements

Under 40 CFR 51.930, a state or tribe requesting to exclude air quality data due to exceptional events must take appropriate and reasonable actions, including public notification, public education and implementation of measures, to protect public health from exceedances or violations of the NAAQS. In the case of the SRR, EPA recognizes that tribes may implement only portions of air quality programs and not be in a position to address each of the procedures and requirements associated with excluding or discounting data. In the preamble to the Exceptional Events Rule, EPA cites an example of tribes that ''* * * may operate a monitoring network for purposes of gathering and identifying appropriate data, but may not implement relevant programs for the purpose of mitigating the effects of exceptional events. * * *'' 72 FR at 13563. That is the case with the SRR. Under these circumstances, as indicated in the preamble to the Exceptional Events Rule, EPA intends to work with the SRR on the implementation of the Rule.

Conclusion

EPA believes that the construction activities at the SRR on September 14, 2006, September 20, 2006 and October 26, 2006 were exceptional events as defined under 40 CFR 50.1(j). EPA believes that there is sufficient weight of evidence to conclude that the construction activities caused the exceedances on the exceedance days, and that the exceedances would not have occurred but for the construction activity. The proximity of the construction activities to the monitor and the wind direction recorded at the monitor support this conclusion. Because EPA believes that the provisions of the Exceptional Events Rule have been satisfied, EPA is proposing to concur with the SRR Tribe's flags indicating that these exceedances were due to exceptional events, and to exclude the data from consideration in determining whether the SJV has attained the PM–10 standard.

In proposing to concur with the SRR Tribe's flags that construction activity at SRR constituted exceptional events, EPA is addressing only the particular facts and circumstances presented by the SRR monitoring operation. In general, fugitive dust control measures employed during construction activities are helpful in reducing ambient PM–10 concentrations and avoiding exceedances of the NAAQS. However, in the specific circumstances of the SRR during the days when exceedances were recorded, we are not able to conclude that the event was reasonably controllable due to the very close proximity of the monitor to the construction activity, and the other factors discussed above. Given this singular constellation of factors, EPA is proposing to concur with the Tribe's flagging of the exceedances on September 14, September 20 and October 26, 2006 as caused by exceptional events.

VII. Summary of Exceedances From 2004 Through 2006

The table below provides a summary of exceedances relevant to today's proposed rule that were recorded at monitors located within the boundaries of the SJV. The table indicates, whether in determining attainment, EPA has excluded or proposes to exclude the exceedance, based on a finding that it was due to an exceptional event. The 24-hour standard is attained when the expected number of days per year with levels above 150 $\mu g/m^3$ (averaged over a three-year period) is less than or equal to one. 40 CFR part 50, appendix K. As shown in the table, all of the monitoring locations are meeting the PM–10 standard.

TABLE SUMMARIZING PM–10 24-HOUR EXCEEDANCES IN THE SJV

[From 2004 through 2006]

Monitor	Operating schedule	Recorded (observed) exceedances 2004—2006		Number of estimated exceedances		Average number of annual exceedances 2004—2006
		Date	Conc	Included in attn. deter.	Reason for excluding exceedance	
Corcoran Manual FRM ...	1 in 3 day	9/3/04	217	No	Exceptional Event	0
		9/22/06	215	No	Exceptional Event	.....
Corcoran TEOM	Continuous	9/22/06	261	No	Exceptional Event	0
		10/25/06	304	No	Exceptional Event	.....
		12/8/06	162	No	Exceptional Event	.....
Bakersfield Golden Manual FRM.	1 in 6 day	9/22/06	157	No	Exceptional Event	0
Bakersfield Golden BAM	Continuous	11/22/05	156	Yes	N/A	0.67
		11/23/05	180	Yes	N/A	.....
Bakersfield Golden TEOM.	Continuous	9/22/06	157	No	Exceptional Event	0
		10/25/06	193	No	Exceptional Event	.....
		12/8/06	213	No	Exceptional Event	.....
Tracy BAM	Continuous	9/22/06	161	Yes	N/A	0.33
Oildale Manual FRM	1 in 6 day	9/22/06	162	No	Exceptional Event	0
Santa Rosa Rancheria Manual FRM.	1 in 6 day	9/14/06	190	No	Exceptional Event	0
		9/20/06	158	No	Exceptional Event	.....
		10/26/06	157	No	Exceptional Event	.....

Sources:
EPA Air Quality System Database.
E-mail from Steven Shaw, SJVAPCD to Bob Pallarino, EPA Region 9, April 20, 2006.
E-mail from Steve Shaw, SJVAPCD to Bob Pallarino, EPA Region 9, October 12, 2006.

VIII. Petitions for Reconsideration and Withdrawal

A. Winds and Wildfires on September 22 and October 25, 2006

Earthjustice filed its 2006 Petition for Reconsideration (PFR) before the State provided its exceptional event documentation for the September 22, 2006 exceedances to the public or EPA. At that time CARB and the District had simply informed EPA that, based on preliminary analysis, they believed that these exceedances were due to high wind and wildfire natural events. Similarly, when Earthjustice filed its 2007 Petition for Withdrawal (PFW) and the accompanying Jan Null declaration, the State had not yet submitted the complete documentation for the September and October 2006 exceedances on which EPA is basing this proposed rule. Therefore Earthjustice's conclusion in the petitions that the September 22, 2006 and October 25, 2006 exceedances do not qualify as natural events does not address the technical analysis of the winds and wildfires as ultimately submitted by the State and which EPA has evaluated in section V. above. To the extent that Earthjustice's assessments in the petitions of the nature and effect of the winds and wildfires are currently relevant, we believe our evaluation in section V. addresses the significant points raised in them.

In addition, since EPA, as stated in section V. above, agrees with the petitioners that regional transport from north of the SJV and the northern SJV and wildfires were not the cause of the exceedances on September 22 and October 25, it is unnecessary for EPA to further address the arguments raised by petitioners with respect to these theories.

B. Notice/Comment on September 22 and October 25, 2006 Exceedances

The gravamen of the 2006 petition, which is reiterated in the Petition for Withdrawal, is Earthjustice's claim that EPA did not provide the public with an opportunity to comment on the September 22, 2006 exceedances and thus should not have finalized the attainment determination for the SJV. PFR at 2–4. Petitioners also complained that EPA did not require adequate documentation that these exceedances were caused by exceptional events. PFR at 3–4.

Contrary to Earthjustice's assertions, EPA did not abuse its discretion in addressing the September 22, 2006 exceedances in its October 2006 determination of attainment. EPA noted at the time that the exceedances were based on preliminary data only: ''Because these data, which were collected using manual reference method samplers, are preliminary and have not been quality assured, and because EPA believes that they may qualify as caused by natural events, and thus be excluded from consideration in an attainment determination, EPA is proceeding to finalize its determination that the area is in attainment.'' 71 FR 63642. Thus the data had not been quality assured, and in addition EPA was on notice that CARB and the District intended to flag the data as due to exceptional events and to request EPA's concurrence on excluding the data from consideration in an attainment determination.

EPA went on to note that ''[i]f, after the data is quality assured, and after further evaluating CARB's request with respect to these data, EPA determines that the data do not qualify for exclusion under EPA's natural events policy, and EPA further believes that if included that they would establish that the area is in violation of the NAAQS, EPA will proceed with appropriate rulemaking action to withdraw its determination of attainment.'' *Id.* It was thus clear that EPA's determination was subject to revision based on subsequent quality assurance and evaluation of the data, and EPA outlined its projected procedure for dealing with the data once they were quality assured and EPA had an opportunity to evaluate the documentation of the potential exceptional events.

In this proposed rule, EPA is following through with this procedure, and is now providing for full notice and an opportunity for comment, in the context of a rulemaking, on whether those exceedances qualify as caused by exceptional events. EPA is also providing notice and opportunity for comment on additional claims that exceedances were caused by exceptional events on October 25, 2006, and December 8, 2006, and at the Santa Rosa Rancheria on September 14 and 20 and October 26, 2006.

Contrary to Earthjustice's contention in its Petition for Reconsideration and Petition for Withdrawal, EPA did not reverse the burden of proof required to establish an exceptional event, or relieve the State from the obligation to document its claims. PFR at 4; PFW at 17. In the final determination, it is clear that EPA did not conclusively concur in excluding the data without requiring appropriate documentation and a showing from the State. Rather, EPA deferred its determination on the impact of the preliminary data until the data could be quality assured and the State would have an opportunity to meet its burden of showing that an exceedance qualified as caused by an exceptional event.

Finally EPA notes that Earthjustice alleges in its 2007 petition that the Agency ignored in its final attainment determination the October 25, 2006 exceedances as well as the September 22, 2006 exceedances. PFW at 2. This is not the case. The exceedances in October occurred eight days after EPA promulgated its final determination of attainment, on October 17, 2006. (The notice was published on October 30, but the determination had been signed and disseminated to the public on October 17). Thus, EPA had no information on these exceedances at the time of its final action.

C. Wind Conditions in the Valley

With respect to the existence of high winds in the Valley generally, Earthjustice, in both petitions, characterizes statements in the 2003 PM–10 Plan for the area as concluding that wind erosion is not a significant contributing factor in dust emissions and as suggesting that winds with enough velocity to cause erosion disperse PM–10 concentrations and/or transport PM–10 out of the Valley. PFR at 4; PFW at 8. Earthjustice in its 2007 petition also cites a letter from the District to EPA which states that ''there is no evidence of any significant linkage between high winds and PM–10 federal exceedance events [in the Valley].'' *Id.* at 8–9.

Earthjustice has taken the statements in the 2003 Plan to attain the PM–10 standard out of context. Chapter 2 of the Plan, quoted by Earthjustice, is a 12-page general overview of the San Joaquin Valley Air Basin, the purpose of which is to describe normal or typical meteorological conditions. It is not intended to nor does it address unusual winds such as those under consideration here that may occur in the Valley. Nevertheless, the District did determine that windblown dust is not a significant problem in the SJV for the purposes of attaining the PM–10 standard. For example, the Plan states that ''[w]ind related PM–10 events are rare but possible when conditions are right'' and that ''PM–10 readings in the SJVAB are most severe during the fall and winter periods when wind speed and direction are not conducive to interregional transport.'' 2003 PM–10 Plan, ES–10, 2–6. The District also states that ''winds are effective in dispersing PM–10 concentrations and/or transporting PM–10 out of the Valley'' in explaining why the spring and

summer months, which are the windier months of the year in the SJV, do not yield higher PM–10 levels.

However, the fact that PM–10 pollution from windblown dust is not generally a significant enough problem in the SJV that it needs to be controlled for the purposes of attaining the PM–10 standard, does not mean that windblown dust cannot cause an exceedance of the standard. In addition, even if windblown dust were a significant problem, there could be individual situations where particular conditions make it unreasonable to expect the District and State to be able to control sources in those circumstances. For such situations, EPA has issued the Exceptional Events Rule, and previously its policies, which as discussed above allows exceedances caused by exceptional events to be excluded from regulatory considerations as appropriate if certain conditions are met. Since there are many variables that can cause exceptional event exceedances, EPA believes the analyses for such events should be reviewed on a case by case basis. 72 FR 13560. For example, not all high wind days will lead to exceedances and not all exceedances monitored when high winds are recorded are necessarily due to those high winds. For the exceedances discussed in today's proposal, however, EPA believes the State has made an adequate demonstration that they were caused by exceptional events and have met all of the Exceptional Events Rule requirements, and thus the data for these particular events should be excluded from regulatory consideration.

Earthjustice also cites a letter from the District to EPA responding to a letter from Charles Swanson to EPA commenting on the 2003 PM–10 Plan. April 15, 2004 letter from James Sweet, SJVAPCD, to Doris Lo, EPA (Sweet letter). Mr. Swanson disputes the following passage from Table G–15 in Appendix G entitled ''BACM Comparative Analysis for 'On-Field Activities''' concerning the BACM justification discussion associated with the ''Other'' category of the District's proposed Agricultural Conservation Management Practices:

> The SJV does not have a windblown dust problem to anywhere near the extent of the other nonattainment areas. The SJV has some of the lowest average wind speeds in the country. No wind related exceedances have been recorded in the basin during the last three years. Wind speeds are highest during the spring when PM–10 levels are at their lowest. The majority of the fugitive dust emissions are generated from earth disturbing activities. Certain soil types and crops are more prone to windblown dust problems. The ''Other'' category will give the farmers with the potential to experience wind blown dust emissions the flexibility to address this issue with a CMP.

March 18, 2004 letter from Charles Swanson to Doris Lo, EPA (Swanson letter) at 1.

In responding to Mr. Swanson, the District stated in its April 15, 2004 letter that ''[t]he statements in the Plan provide a general characterization of the San Joaquin Valley (SJV) and, as with all generalizations, are not without exception.'' Sweet letter at 1. Furthermore, while, as Earthjustice points out, the District did also state that an analysis of all wind events since 1990 did not establish a linkage to PM–10 exceedances, the District also enumerated technical limitations that bear directly on this conclusion. For example, the data used did not report wind gusts and the 1 in 6 day sampling for PM–10 will not capture all wind events. Sweet letter at 7–8. Therefore, Earthjustice's attempts to characterize the statements in the Sweet letter regarding windblown dust as absolute is not warranted. Finally, the District also asserts that:

> Evaluation of past events indicates that often the area with the highest PM–10 levels is not where the wind is highest, but rather where the wind begins to slow. To understand the dynamics of this pattern we need only review the mechanisms for entrainment and deposition. When the wind slows, it can no longer keep the larger PM–10 particles aloft and they settle toward the surface. The settling of particulates aloft * * * results in an increased concentration in the deposition area.

Sweet letter at 2. This scenario is precisely what occurred on September 22 and October 25, 2006 as discussed in section V. above.

D. EPA's Natural Events Policy

1. BACM Implementation

In both petitions Earthjustice asserts that EPA's 1996 Natural Events Policy requires that the State demonstrate that BACM were in place and that all sources were in compliance in order for EPA to concur on a high wind natural event request. PFR at 5; PFW at 9. Earthjustice contends that the State cannot demonstrate that agricultural sources were in compliance at the time of the wind event since it is not clear if any compliance inspections had been conducted.

As discussed in sections IV. and V., EPA is evaluating the State's exceptional event documentation under EPA's Exceptional Event Rule and not under its pre-existing policies. The Rule does not require either a showing that BACM was in place at the time of the event or proof that sources were in compliance. Rather, in the preamble to the Rule EPA states that the State must take reasonable and appropriate measures under these circumstances. 72 FR at 13576–13577. That said, EPA has approved the District's BACM demonstration for all significant sources of PM–10 in the Valley, including agricultural sources, as meeting CAA section 189(b)(1)(B). 69 FR at 30035; 71 FR 7683. Moreover the State's documentation for the September 22 and October 25, 2006 events includes information on compliance inspections throughout the SJV. See section V. above.

2. District's Natural Events Action Plan

In its 2007 petition Earthjustice claims that for the September 22, 2006 exceedances the District failed to meet the requirements of its Natural Events Action Plan for ''[a]cceptable documentation for establishing an extraordinary natural event * * *.'' Specifically, Earthjustice contends that acceptable documentation for establishing ''an extraordinary natural event'' includes issuance by the national Weather Service of a high wind or blowing dust advisory, the occurrence of strong winds aloft and surface wind maps showing potential for high winds to occur at the site. According to Earthjustice no adequate documentation of these factors was offered. PFW at 11.

Earthjustice's statements regarding the requirements for documentation under the District's ''Natural Events Action Plan for High Wind Events in the San Joaquin Valley Air Basin,'' February 16, 2006 (NEAP) appear in the portion of its 2007 petition that addresses the causal relationship between high winds and the September 22, 2006 exceedances. *Id.* Section 3 of the NEAP concerns the documentation of high wind events and lists specific sources of documentation suggested by EPA: Filter analysis, meteorological data, modeling and receptor analysis, videos and/or photographs, maps, news accounts and BACM[97] requirements. Section 6 of the NEAP concerns meteorological forecasting criteria. This section states that if certain enumerated criteria are met, the District, in consultation with CARB, will declare a NEAP episode. The items that Earthjustice contends are required to document an exceptional event are among these criteria. Thus Earthjustice has confused forecasting an exceptional event with the documentation of it. EPA believes that

[97] As noted above, BACM implementation is not required under EPA's exceptional events rule.

the State has adequately documented the September 22, 2006 exceedances as being caused by all exceptional events as discussed above in section V.A.

Finally we note again that EPA is proceeding in this rulemaking under its Exceptional Events Rule rather than the 1996 policy it replaces. In the preamble to the Rule, EPA explained that ''following the promulgation of this rule, States will no longer be required to keep NEAPs in place that were not approved as a part of a SIP for an area.'' 72 FR at 13576.

E. Harvest Activities

Earthjustice asserts in its 2006 petition that September is the peak harvest season for cotton and almonds and that EPA should investigate the contribution of these activities to the September 22 exceedances. PFR at 6. In the 2007 petition Earthjustice states that the end of October is generally when two of the dustiest crop harvests, cotton and almonds, take place and that these activities caused the October 25 exceedances. PRW at 13–14. EPA discusses the effect of anthropogenic sources on the 2006 exceedances in section V. above.

F. Exceedances at Corcoran and Stockton in 2004, Bakersfield in 2005 and the Santa Rosa Rancheria in 2006

The 2007 petition raises issues regarding several exceedances that have already been addressed by the October 2006 attainment determination. These exceedances occurred on September 3, 2004 at Corcoran and Stockton and on November 22–23, 2005 at Bakersfield. EPA's position on these exceedances is found in the final rule at 71 FR at 63658–63661.

Regarding the September 3, 2004 exceedance, Earthjustice states that EPA must now evaluate whether the Agency can concur on the State's request to flag the exceedance as a high wind event and cannot continue to rely on the argument that it is irrelevant because ''even if EPA had not concurred with the exclusion of this data, the Corcoran site would still attain the 24-hour NAAQS * * *.'' Earthjustice takes this position because it believes there are now other exceedances at Corcoran that cannot be excluded and that the September 3, 2004 exceedance will thus be important in determining the SJV's PM–10 attainment status. PFW at 9.

EPA disagrees with Earthjustice's contention that there are now other exceedances that cannot be excluded. As discussed above, EPA believes the exceedances on September 22, October 25 and December 8, 2006 are all due to exceptional events and is proposing to concur with the State's request to flag these data as caused by high wind events. Thus our conclusion that the September 3, 2004 exceedance is not significant for the attainment determination is still valid.

Regarding the November 2005 exceedances at Bakersfield, EPA stated in its determination of attainment that ''[e]ven if the Bakersfield-Golden State Highway BAM and TEOM data are considered together (and even if they were quality-assured data not subject to natural events), the exceedances recorded at these monitors would not show that the area is in violation of the standard.'' 71 FR at 63659. As discussed above, EPA believes that the exceedances at Bakersfield in 2006 were due to exceptional events and is proposing to concur with the State's request to flag these data. Thus we still believe that the 2005 Bakersfield-Golden exceedances, when considered for purposes of our 2006 attainment determination, would not contribute to or constitute a violation.

In the 2007 petition Earthjustice also raises questions about exceedances recorded at the Santa Rosa Rancheria on September 14, 20 and October 26, 2006. PFW at 15–16. EPA addresses these exceedances in section VI. above.

IX. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this proposed action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This action merely proposes a determination based on air quality data and does not impose any additional requirements. Accordingly, the Administrator certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.). Because this proposed rule does not impose any additional enforceable duty, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Order 13175 (65 FR 67249, November 9, 2000) requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' Several Indian tribes have reservations located within the boundaries of the SJV. EPA is aware of only one tribe in the SJV that operates a PM–10 monitor, the Santa Rosa Rancheria. EPA has consulted with representatives of the Santa Rosa Rancheria Tribe on the data recorded by their monitor, and the flagging of the data, and will continue to work with the Tribe, as provided for in Executive Order 13175. Accordingly, EPA has addressed Executive Order 13175 to the extent that it applies to this action. This proposed action also does not have Federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This proposed action merely makes a determination based on air quality data and does not alter the relationship or the distribution of power and responsibilities established in the CAA. Executive Order 12898 establishes a Federal policy for incorporating environmental justice into Federal agency actions by directing agencies to identify and address, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority and low-income populations. Today's action involves proposed determinations based on air quality considerations and proposes to affirm that the San Joaquin area has attained the PM–10 NAAQS. It will not have disproportionately high and adverse effects on any communities in the area, including minority and low-income communities.

This proposed rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant. The requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This proposed rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Particulate matter, Reporting and recordkeeping requirements.

40 CFR Part 81

Environmental protection, Air pollution control, National parks, Wilderness areas.

Dated: August 15, 2007.

Wayne Nastri,

Regional Administrator, Region 9.

[FR Doc. E7–16693 Filed 8–24–07; 8:45 am]

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Federal Register

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August 27, 2007

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 347 and 352

Sunscreen Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 347 and 352

[Docket No. 1978N–0038] (formerly Docket No. 78N–0038)

RIN 0910–AF43

Sunscreen Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a proposed rule that would amend the final monograph (FM) for over-the-counter (OTC) sunscreen drug products as part of FDA's ongoing review of OTC drug products. This amendment addresses formulation, labeling, and testing requirements for both ultraviolet B (UVB) and ultraviolet A (UVA) radiation protection. FDA is issuing this proposed rule after considering public comments and new data and information that have come to FDA's attention. This rule proposes to lift the stays of 21 CFR 347.20(d) and 21 CFR Part 352 when FDA publishes a final rule based on this proposed rule.

DATES: Submit written or electronic comments by November 26, 2007. Submit written or electronic comments on FDA's economic impact determination by November 26, 2007. Please see section X of this document for the effective and compliance dates of any final rule that may publish based on this proposal.

ADDRESSES: You may submit comments, identified by Docket No. 1978N–0038 and RIN number 0910–AF43, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name, docket number and regulatory information number (RIN) for this rulemaking. All comments received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For additional information on submitting comments, see the ''Request for Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Matthew R. Holman, Office of Nonprescription Products, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5414, Silver Spring, MD 20993, 301–796–2090.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

In the **Federal Register** of May 12, 1993 (58 FR 28194), FDA published a notice of proposed rulemaking in the form of a tentative final monograph (TFM) for OTC sunscreen drug products. In the TFM, FDA proposed the conditions under which OTC sunscreen drug products would be considered generally recognized as safe and effective (GRASE), under section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(p)), and not misbranded, under section 502 of the act (21 U.S.C. 352).

In the **Federal Register** of April 5, 1994 (59 FR 16042), FDA reopened the administrative record until July 31, 1994, to allow additional submissions on UVA-related issues and announced a public meeting for May 12, 1994, to discuss UVA testing procedures. As explained in that **Federal Register** notice, the TFM included proposed UVB (i.e., 290–320 nm) testing and labeling. The sun protection factor (SPF)

test and corresponding labeling reflects the level of protection against sunburn, which is caused primarily by UVB radiation. The TFM also explained the importance of protection against UVA radiation (i.e., 320–400 nm), the other UV component of sunlight (58 FR 28194 at 28232 and 28233). The TFM referenced published UVA test methods but did not propose a method (58 FR 28194 at 28248 to 28250). Rather, the TFM stated that a product could be labeled as ''broad spectrum'' or a similar claim if it protected against UVA radiation. Thus, FDA held the 1994 public meeting to gather further information about an appropriate UVA test method and labeling.

In the **Federal Register** of June 8, 1994 (59 FR 29706), FDA proposed to amend the TFM (and reopened the comment period until August 22, 1994) to remove five proposed sunscreen ingredients from the TFM because of lack of interest in establishing United States Pharmacopeia—National Formulary (USP–NF) monographs. FDA also reiterated that all sunscreen ingredients must have a USP–NF monograph before being included in the FM for OTC sunscreen drug products.

In the **Federal Register** of August 15, 1996 (61 FR 42398), FDA reopened the administrative record until December 6, 1996, to allow additional submissions on zinc oxide and titanium dioxide as well as sunscreen photostability. FDA also announced a public meeting for September 19 and 20, 1996, to discuss the safety and efficacy of these two ingredients and photostability of sunscreens in general.

In the **Federal Registers** of September 16, 1996 (61 FR 48645) and October 22, 1998 (63 FR 56584), FDA amended the TFM to add the UVA-absorbing sunscreen ingredients avobenzone and zinc oxide to the proposed list of monograph ingredients. FDA also proposed indications for these ingredients. As a result of this amendment to the TFM, in the **Federal Register** of April 30, 1997 (62 FR 23350), FDA announced an enforcement policy allowing interim marketing of OTC sunscreen drug products containing avobenzone.

On November 21, 1997, Congress enacted the Food and Drug Administration Modernization Act of 1997 (FDAMA). Section 129 of FDAMA stated that ''Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services shall issue regulations for over-the-counter sunscreen products for the prevention or treatment of sunburn.'' FDA identified the UVB portions of the monograph (and related provisions on water resistant test methods and cosmetic labeling) as items that could be finalized within the timeframe set by FDAMA. Because of outstanding issues related to the development of testing standards and labeling for UVA radiation protection, FDA deferred final action on these items.

Therefore, in the **Federal Register** of May 21, 1999 (64 FR 27666), FDA published the FM for OTC sunscreen drug products in part 352 (21 CFR part 352) with an effective date of May 21, 2001, but deferred UVA testing and labeling for future regulatory action. FDA stated that more time was required to review comments from interested parties on active ingredients, labeling, and test methods for products intended to provide UVA protection. This proposed amendment to the FM for OTC sunscreen drug products will complete the FM by addressing both UVB and UVA testing and labeling.

In the **Federal Register** of June 8, 2000 (65 FR 36319), FDA reopened the administrative record of the rulemaking for OTC sunscreen drug products to allow for specific comment on high SPF and UVA radiation testing and labeling. FDA also extended the effective date for the FM to December 31, 2002.

In the **Federal Register** of December 31, 2001 (66 FR 67485), FDA stayed the December 31, 2002, effective date of the FM for OTC sunscreen drug products in part 352 until we provided further notice in a future issue of the **Federal Register**. FDA took this action because we planned to amend part 352 to address formulation, labeling, and testing requirements for both UVB and UVA radiation protection. This document proposes such changes. This document also proposes an effective date related to publication of an amended FM (see section X of this document). The existing stay of the effective date for part 352 remains in effect at this time.

In the **Federal Register** of June 20, 2002 (67 FR 41821), FDA published a technical amendment to change the names of four sunscreen active ingredients in § 352.10 of the monograph to be consistent with name changes that appeared in USP 24. The new names, which are simpler and more convenient, are meradimate for menthyl anthranilate, octinoxate for octyl methoxycinnamate, octisalate for octyl salicylate, and ensulizole for phenylbenzimidazole sulfonic acid. Because the names became official on March 1, 2001, manufacturers could begin using them at any time after that date.

In the **Federal Register** of June 4, 2003 (68 FR 33362), FDA issued a final rule establishing conditions under which OTC skin protectant products are generally recognized as safe and effective and not misbranded. This final rule lifted the stay of 21 CFR part 352 to amend the final monograph for OTC sunscreen drug products to include sunscreen-skin protectant combination drug products. This final rule concluded by placing a stay on both part 352 and on § 347.20(d). The proposed rule that is the subject of this document provides UVA testing and labeling that is necessary on sunscreen and sunscreen-skin protectant combination drug products. This proposed rule, therefore, proposes that the stays of both part 352 and § 347.20(d) be lifted when this rule is finalized. These stays will be maintained until a final rule based on this proposed rule becomes effective.

In the **Federal Register** of September 3, 2004 (69 FR 53801), FDA delayed the implementation date for OTC sunscreen drug products subject to the final rule that established standardized format and content requirements for the labeling of OTC drug products (i.e., Drug Facts rule). FDA explained that we postponed the Drug Facts implementation date because we did not expect to complete the final amendment of the sunscreen monograph to include UVA testing and labeling by the Drug Facts implementation date of May 16, 2005 (64 FR 13254 at 13273 and 13274, March 17, 1999). Thus, FDA delayed the implementation date of the Drug Facts rule with respect to OTC sunscreen drug products until further notice to avoid issuing successive relabeling requirements for sunscreen drug products at two closely related time intervals, as required by the Drug Facts rule and the final amendment to the sunscreen monograph.

II. Summary of Major Changes to the FM

In response to the TFM and FM, FDA received substantial data and information regarding UVA and UVB active ingredients, claims, and testing procedures, as well as on other issues addressed in this document. FDA summarizes these issues and proposed changes to the FM in this section.

A. Ingredients

FDA proposes to add combinations of avobenzone with zinc oxide and avobenzone with ensulizole as permitted combinations of active sunscreen ingredients in the FM (see section III.C, comment 7 of this document).

B. UVB (SPF) Labeling

The FM allowed specific labeled SPF values up to, but not exceeding, 30. OTC sunscreen drug products with SPF values greater than 30 could be labeled with the collective term ''30+.'' In this amendment, FDA proposes to increase the specific labeled SPF value to 50 and revise the collective term to ''50+.'' FDA will consider higher specific labeled SPF values upon receipt of adequate, validated data (see section III.F, comment 15 of this document).

In addition, FDA proposes to revise the following FM labeling:

- The phrase ''sun protection'' to ''sunburn protection'' where used in §§ 352.3(b)(1), (b)(2), (b)(3), and (d) and 352.52(e)(1)(i), (e)(1)(ii), and (e)(1)(iii) (see section III.D, comment 10 of this document); and
- Section 352.50(a) to include the term ''UVB'' before the term ''SPF'' on the principal display panel (PDP), along with the product category designation (PCD) (see section III.E, comment 14 of this document).

FDA also proposes to revise the PCD SPF ranges in § 352.3(b)(1), (b)(2), and (b)(3) (proposed § 352.3(c)(1) through (c)(4)) to reflect the following:

- The current standard public health message concerning use of sunscreens,
- The proposed increase of the labeled SPF value to ''50+,'' and
- The proposed addition of the term ''UVB'' before the word ''sunburn.'' Proposed § 352.3(c)(4) contains a new PCD of ''highest UVB sunburn protection product'' for products that provide an SPF value over 50. FDA further proposes to revise current § 352.3(b)(1) and (b)(2) to replace the current category descriptors of ''minimal'' and ''moderate'' with the terms ''low'' and ''medium,'' respectively. FDA considers the new terms to be simpler and uniform with the proposed UVB and UVA ''Uses'' statements. Proposed changes to PCDs and category descriptors also occur in proposed § 352.52(e)(1) (see section III.D, comment 13 and section III.G, comment 16 of this document). In addition, FDA proposes optional UVB radiation protection statements (see proposed § 352.52(e)(2) and (e)(3)).

C. UVA Labeling

FDA proposes new labeling to designate the level of UVA protection on the PDP of OTC sunscreen drug products. FDA proposes the use of symbols (''stars'') in conjunction with a descriptor (i.e., ''low,'' ''medium,'' ''high,'' or ''highest''). FDA also proposes to add new § 352.50(b) specifying the required PDP labeling for OTC sunscreen products tested in accordance with the proposed UVA testing procedures in §§ 352.71 and 352.72 (see section III.E, comment 14 and section III.N, comment 45 of this document).

D. Indications

The FM allowed the following two UVB indications in § 352.52(b)(1):

- ''helps prevent sunburn''
- ''higher SPF gives more sunburn protection''

In this amendment, FDA proposes to revise the first statement to read ''low,'' ''medium,'' ''high,'' or ''highest'' ''UVB sunburn protection'' in proposed § 352.52(b)(1)(i) through (b)(1)(iv). FDA is proposing to revise the additional indications in § 352.52(b)(2) to reflect the new PCD ranges in proposed § 352.3(c) (e.g., SPF of 2 to under 12 becomes SPF of 2 to under 15) and create the new PCD range over SPF 50. These proposed revisions are based upon the revised PCD categories in proposed § 352.3(c) (see section III.G, comment 16 of this document). FDA proposes that the second statement in current § 352.52(b)(1) (''higher SPF gives more sunburn protection'') no longer be required and proposes an additional indication regarding UVA protection (see proposed § 352.52(b)(2)(v)).

In proposed § 352.52(b)(2)(v), FDA includes a new indication for UVA protection that involves selection of the appropriate descriptor (''low,'' ''medium,'' ''high,'' or ''highest'') to describe the level of protection. In proposed § 352.52(b)(2)(vi), FDA includes a modified version of the sunburn ''Uses'' statement required by proposed § 352.52(b)(1)(i) through (b)(1)(iv) when the additional statement in proposed § 352.52(b)(2)(v) is used and bears the same category descriptor as the SPF value (e.g., medium UVA/UVB protection from sunburn) (see section III.G, comment 17 of this document).

E. Warnings

FDA is proposing to shorten the warning in § 352.52(c)(1)(ii) (proposed § 352.52(c)(3)) under the subheading ''Stop use and ask a doctor if'' from ''[bullet] rash or irritation develops and lasts'' to ''[bullet] skin rash occurs.''

FDA proposes removing the optional ''sun alert'' product performance statement (current § 352.52(e)(2)) and requiring a revised ''sun alert'' statement in the ''Warnings'' section (proposed § 352.52(c)(1)). FDA proposes that this revised statement be required on all OTC sunscreen drug products except lip cosmetic-drug and lip protectant-sunscreen products subject to § 352.52(f), which are not required to include this statement under proposed § 352.52(f)(1)(v) and (f)(1)(vi) (see section III.G, comment 19 of this document). The statement in proposed § 352.52(c)(1) reads as follows: ''UV exposure from the sun increases the risk of skin cancer, premature skin aging, and other skin damage. It is important to decrease UV exposure by limiting time in the sun, wearing protective clothing, and using a sunscreen.'' FDA proposes that the statement appear in bold type as the first statement in the ''Warnings'' section.

F. Directions

FDA proposes changes to the directions to reduce the likelihood that OTC sunscreen drug products are underapplied. Section 352.52(d)(1)(i) currently provides manufacturers the option to select one or more of the following terms: ''liberally,'' ''generously,'' ''smoothly,'' or ''evenly.'' FDA is proposing to allow the choice of one of two required terms (i.e., ''liberally'' or ''generously'') and to include ''evenly'' as an additional optional term. FDA is proposing to eliminate the term ''smoothly'' because it is vague.

FDA also proposes to add a new direction ''apply and reapply as directed to avoid lowering protection'' (proposed § 352.52(d)(1)(ii)). Because new information demonstrates the importance of sunscreen reapplication, FDA also proposes to make the optional directions in paragraph (d)(2) a requirement. As a result of this change, FDA is proposing to remove the current language in paragraph (d)(3) because it is no longer necessary. Instead, FDA is proposing, in paragraph (d)(3), required information for products that do not satisfy the water resistant testing procedures in § 352.76. FDA is also proposing a required reapplication statement in § 352.52(d)(1)(ii). The reapplication information in current § 352.52(d)(2) appears in proposed § 352.52(d)(2) and (d)(3) of this document (see section III.H, comment 22 of this document).

G. UVB Testing

FDA is proposing to revise the SPF (UVB) testing procedure (see section III, paragraphs I through L of this document) and to move the SPF testing procedure currently in §§ 352.70 through 352.73 to proposed § 352.70. FDA proposes a padimate O/oxybenzone sunscreen standard in § 352.70 that will be required for testing sunscreen products with SPF values over 15. Manufacturers may use either this padimate O/oxybenzone standard

or the homosalate standard to test products with SPF values of 2 to 15. FDA proposes a high pressure liquid chromatography (HPLC) method to replace the spectrophotometric method used to assay the homosalate and padimate O/oxybenzone standards.

FDA proposes the following modifications to the SPF testing procedure:

- Specifications for the solar simulator in § 352.71 (proposed § 352.70(b)),
- Instructions for the application of test materials and response criteria in § 352.72 (proposed § 352.70(c)), and
- Doses and determination of minimal erythema dose (MED) in § 352.73 (proposed § 352.70(d)).

FDA proposes to continue requiring a finger cot to be used in the application of sunscreen standard and test product as specified in § 352.72(e) (proposed § 352.70(c)(5)). However, FDA now proposes that the finger cot be pretreated. These two proposed UVB testing changes also apply to UVA in vivo testing.

H. UVA Testing

FDA proposes a combination of spectrophotometric (in vitro) and clinical (in vivo) UVA test procedures in proposed §§ 352.71 and 352.72, respectively. To assure UVA protection for ''water resistant'' and ''very water resistant'' sunscreen products, FDA proposes that the in vivo UVA test be conducted after the appropriate water immersion period for OTC sunscreen drug products making a UVA claim. Therefore, FDA proposes modification of § 352.76 to state that the water resistance claim applies to the SPF and, if appropriate, UVA values determined after the appropriate water immersion period as described in proposed § 352.70 and, if appropriate, proposed § 352.72.

III. FDA's Tentative Conclusions on the Comments

A. General Comments on OTC Sunscreen Drug Products

(Comment 1) Several comments asked that FDA provide more time to comply with requirements of the FM in order to avoid an adverse economic impact on the suncare industry and consumers. The comments described the seasonal dynamics of the suncare industry (i.e., products are sold in two marketing cycles over a period of 18 months) and stated that the industry would need more time to develop products that meet the FM requirements and allow for shipment of the previous year's returns. The comments mentioned times from 2 to 3 years after publication of the FM as appropriate or necessary for implementation. Several of these comments added that the date should be in the June/July time period because the shipping season is practically over at that time and manufacturing for the next season is just beginning.

FDA understands the seasonal nature of the sunscreen industry and the time required for product testing and relabeling. FDA is also aware that more than 1 year may be needed for implementation. FDA is proposing an 18- to 24-month implementation date and will try to have it coincide with the June/July time period (see section XI of this document).

(Comment 2) One comment requested that FDA and the Federal Trade Commission (FTC) take steps to make sure that sunscreen manufacturers provide information to the American public to help them understand and use the Ultraviolet Index (UVI) to determine their risk of sunburn.

The National Weather Service, the Environmental Protection Agency (EPA), and the Centers for Disease Control and Prevention (CDC) developed the UVI, which has been in use since 1995. This index is an indication of the amount of UV radiation reaching the surface of the earth as a function of ozone data, atmospheric pressure, temperature, and cloudiness and is generated for 58 cities around the United States.

Usage information required by the OTC sunscreen drug product monograph applies regardless of the UVI value. Therefore, FDA believes that UVI information need not be required in the monograph for the safe and effective use of these products and should not be included in the ''Drug Facts'' labeling. However, manufacturers who wish to do so may voluntarily include such information in their labeling outside the ''Drug Facts'' box.

(Comment 3) One comment requested that FDA make clear, through either the FM for skin protectant or sunscreen drug products, or both, that combination products containing sunscreen and skin protectant ingredients may be lawfully marketed.

Section 347.20(d) of the skin protectant FM (21 CFR 347.20(d)), which published in the **Federal Register** of June 4, 2003 (68 FR 33362), provides for combinations of sunscreen ingredients and specific skin protectant ingredients. The final rule for OTC skin protectant drug products also included an amendment to the sunscreen FM, adding new § 352.20(b), which allows combinations of sunscreen and skin protectant active ingredients. Thus, both monographs now state the same conditions for lawfully marketing these combination products. The existing language in §§ 347.20(d) and 352.20(b) would include the two new combinations that FDA is proposing to add to the sunscreen monograph (see section II.A, comment 7 of this document).

B. Comments on Tanning and Tanning Preparations

(Comment 4) One comment requested that the effective date of § 740.19 (21 CFR 740.19) be extended to December 31, 2002, consistent with the delay of the effective date for § 310.545(a)(29) and (d)(31), part 352, and § 700.35 (65 FR 36319). The comment stated that singling out § 740.19 to become effective earlier might constitute an arbitrary and capricious decision by FDA.

The May 21, 1999, final rule set a 2-year effective date (May 21, 2001) for § 310.545(a)(29) and (d)(31), part 352, and § 700.35. In the **Federal Register** of June 8, 2000 (65 FR 36319), FDA extended the effective date for compliance with § 310.545(a)(29) and (d)(31), part 352, and § 700.35 until December 31, 2002, to provide time for completion of a more comprehensive UVA/UVB FM for OTC sunscreen drug products. On December 31, 2001, FDA then stayed the effective date of part 352 (but not § 310.545(a)(29) and (d)(31), and § 700.35) until further notice (66 FR 67485). FDA took this action because we are amending part 352 to address formulation, labeling, and testing requirements for both UVA and UVB radiation protection. The May 21, 1999, final rule also set a 1-year effective date (May 22, 2000) for new § 740.19, which addresses a warning statement for cosmetic suntanning preparations that do not contain a sunscreen active ingredient. These products are not subject to the monograph for OTC sunscreen drug products in part 352. FDA considered this warning to be sufficiently important for safety reasons when we issued the final rule (64 FR 27666 at 27669) to require a 12-month effective date as opposed to the 24-month effective date for the other sections of the rule. Further, FDA's primary reason for extending the effective date of those other sections to December 31, 2002, and then staying part 352 to address formulation, labeling, and testing requirements for both UVA and UVB protection, was to allow FDA to develop a comprehensive UVB/UVA final monograph. This reason does not apply to § 740.19. Accordingly, FDA did not extend the effective date for § 740.19, and § 740.19 is in effect at this time. FDA concludes that this

decision is not arbitrary and capricious, but is based on valid health concerns related to the products subject to the warning requirement in § 740.19.

(Comment 5) One comment requested that FDA and FTC take steps to ensure sunscreen manufacturers inform consumers that their natural skin pigmentation provides protection from sunlight. The comment stated that these adaptive individuals might not require a daily application of a sunscreen. Another comment submitted a copy of a patent for an electronic sensor device to measure solar radiation. The comment stated that the personal device could alert consumers to their level of UV exposure so they could either come out of the sun or apply a sunscreen to avoid sunburn and skin cancer.

FDA has no objection to sunscreen manufacturers informing consumers that their natural skin pigmentation provides protection from sunlight. However, FDA has no basis to require such information as part of the required labeling for OTC sunscreen drug products. Thus, manufacturers may include this information in labeling outside of the ''Drug Facts'' box, but are not required to include this information. FDA considers the comment regarding the UV measuring device to be outside the scope of this rulemaking, which evaluates the safety, effectiveness, and labeling of OTC drug products.

C. Comments on Specific Sunscreen Active Ingredients

(Comment 6) Several comments requested that dihydroxyacetone (DHA) be added to the monograph as a single active ingredient for UVA protection. The comments claimed that DHA alone provides an SPF of 2 to 4. One comment claimed that a 15 percent topical solution of DHA provided a photoprotective factor of 10 in the UVA region. Other comments contended that the brown color produced by DHA, resembling melanin, should potentiate the action of sunscreens. Another comment stated that DHA alone is not a sunscreen, but forms a sunscreen when combined with lawsone. The comment cited unpublished observations by two independent investigators that the melanoidins of DHA-induced skin pigment resemble melanin in that they absorb UVB strongly, with decreasing absorbance through the UVA region and into visible light. The comment added that, because DHA alters the structure of the skin surface, it is, by definition, a drug.

One comment provided information on the safety and UVA effectiveness of DHA alone (Ref. 1). Safety studies included the following:

- Oral and dermal toxicity studies,
- A chronic skin painting carcinogenicity study in mice,
- Comedogenecity tests in rabbits,
- Repeated insult patch test in humans, and
- Photoallergy tests.

Effectiveness studies consisted of published articles using either humans or photosensitized rats. Another comment discussed investigations with DHA on psoriasis patients sensitized with 8-methoxypsoralen (8–MOP).

FDA is not proposing to include DHA in the monograph as a single active ingredient in OTC sunscreen products. Although there were no product submissions to the Advisory Review Panel on Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products (the Panel) using DHA as a sunscreen ingredient, the Panel discussed available scientific evidence for DHA as a single sunscreen ingredient. The Panel concluded that DHA is not a sunscreen but a cosmetic; it is a sunscreen only when used with lawsone (43 FR 38206 at 38215 to 38216, August 25, 1978). Although one comment stated that DHA alters the structure of the skin, it did not provide data to support this claim. Thus, at this time, FDA agrees with the Panel that DHA is a cosmetic.

FDA acknowledges that DHA is the subject of an approved color additive petition and its safety as a color additive has been established. However, the submitted chronic (life-span) skin painting study in mice does not support the safe use of DHA as a sunscreen because no group of mice was included in the study to determine the possible photocarcinogenic effect of DHA. This effect needs to be studied because DHA is associated with carbonyl compounds known to react with pyrimidine bases in the presence of UV radiation, and it appears to be a potent inducer of thymine dimers, premutagenic deoxyribonucleic acid (DNA) lesions. Therefore, its safety, in terms of the type, extent, and location of photo-induced DNA damage, is of concern and should be determined. Whether DHA contributes or promotes UV carcinogenesis is not known.

The submitted studies on the effectiveness of DHA as a single UVA sunscreen ingredient add only qualitative information. Many of the studies utilized animal models; few included human subjects. One study involved only five subjects, three with erythropoietic protoporphyria and two with polymorphic light eruptions. Another study involved six subjects sensitized with 8–MOP. In both studies, too few subjects were enrolled, and the study subjects were not representative of the average sunscreen user.

Well-controlled clinical trials with DHA alone are lacking. Although some investigations described by the comments suggest that DHA may help protect the normal skin of psoriasis patients, concerns remain about the usefulness of DHA products in the OTC market. For example, one comment stated that photoprotection provided by DHA depends upon the way the product polymerizes in the stratum corneum and that polymerization depends on the skin of each individual. Therefore, the photoprotection provided by DHA varies from person to person and has to be determined for each person by diffuse reflectance spectroscopy. Given these statements, it is not clear how appropriate OTC drug product labeling could be written to aid consumers in proper selection and use of a DHA sunscreen.

FDA concludes that current information is inadequate to include DHA in the monograph as a single sunscreen ingredient. None of the comments provided information to establish the appropriate number of consecutive product applications and the timing of these applications (how far apart or how soon before sun exposure) that are necessary to achieve the desired protection using products containing various concentrations of DHA. In two submitted studies, a preparation containing 3 percent DHA was applied six times prior to sun exposure and a preparation containing 15 percent DHA preparation was applied one time 24 hours prior to sun exposure, respectively (Ref. 1). The comments did not include any information on appropriate regimens for various skin types, which is necessary because the level of photoprotection provided by DHA is dependent on skin type. Therefore, based upon this lack of information, it is not clear how to state appropriate label directions for consumer use. FDA needs additional information from clinical studies to determine the effective concentration of DHA in sunscreen product formulations and the frequency and timing of product application.

(Comment 7) One comment submitted data to support the combination of avobenzone with ensulizole and avobenzone with zinc oxide (Ref. 2). The safety data included the following:

- A repeat insult patch test,
- A phototoxicity study, and
- A photoallergy study.

The effectiveness data involved a clinical study using the in vitro ''critical wavelength'' (CW) method and the in

vivo ''protection factor A'' (PFA) method to support the UVA radiation protection potential of the combination products. The PFA test data were from a double blind clinical study using five sunscreen formulations.

The safety studies demonstrated that the following combinations of active ingredients have a low potential for irritation, allergenic sensitization, and phototoxicity:

- 3 percent or less avobenzone with 2 percent ensulizole
- 3 percent or less avobenzone with 5 percent zinc oxide

The data further suggested that the photoallergenic potential of avobenzone is not augmented by its combination with either ensulizole or zinc oxide.

The clinical study using the PFA in vivo method demonstrated that the following combinations of active ingredients are significantly more effective than 1.5 percent ensulizole or 3 percent zinc oxide alone in protecting against UVA radiation:

- 3 percent avobenzone with 1.5 percent ensulizole
- 3 percent avobenzone with 4 percent zinc oxide

FDA's detailed comments on the safety and effectiveness studies are on file in the Division of Dockets Management (Ref. 3).

FDA considers the data submitted by the comment sufficient to support the safety and effectiveness of avobenzone with ensulizole and avobenzone with zinc oxide when used in the concentrations established for each ingredient in § 352.10 of the sunscreen monograph. Accordingly, FDA is proposing to amend § 352.20(a)(2) by adding ensulizole and zinc oxide.

Marketing of products containing avobenzone with ensulizole and avobenzone with zinc oxide will not be permitted unless and until the following three actions occur:

1. The comment period specific to this proposal closes.

2. FDA has evaluated all comments on these combination products submitted in response to the proposal.

3. FDA publishes a **Federal Register** notice announcing our determination to permit the marketing of OTC sunscreen drug products containing these combinations.

D. General Comments on the Labeling of Sunscreen Drug Products

(Comment 8) One comment agreed that the labeling modifications allowed by the FM in § 352.52 for OTC sunscreen products marketed as a lipstick or labeled for use only on specific small areas of the face (e.g., lips, nose, ears, and/or around eyes) are appropriate for these products. Based on the labeling in § 352.52, the comment proposed eight additional modifications for all other OTC sunscreen products regardless of package size:

1. Delete ''Drug Facts'' title because it is inappropriate and unnecessary for sunscreens.

2. Omit ''Purpose'' because it is repetitive of the statement of identity on the PDP and ''Uses'' information.

3. Revise ''higher SPF gives more sunburn protection'' in ''Uses'' to read ''higher SPF products give more sun protection, but are not intended to extend the time spent in the sun,'' and require this statement only on products with an SPF value over 30.

4. Omit ''For external use only'' warning because it is self-evident for sunscreen products.

5. Revise ''When using this product [bullet] keep out of eyes. Rinse with water to remove'' to read ''Keep out of eyes.''

6. Revise ''Stop use and ask a doctor if [bullet] rash or irritation develops and lasts'' to read ''Stop use if skin rash occurs.''

7. Omit barlines, hairlines, and box enclosure.

8. Allow the option to list inactive ingredients in a different location on the label or in labeling accompanying the product.

The comment stated that these modifications would allow reduced Drug Facts labeling for all OTC sunscreen drug products.

The comment contended that sunscreen products meet all of FDA's criteria for reduced labeling (64 FR 13254 at 13270):

- Packaged in small amounts,
- High therapeutic index,
- Extremely low risk in actual consumer use situations,
- A favorable public health benefit,
- No specified dosage limitation, and
- Few specific warnings and no general warnings (e.g., pregnancy or overdose warnings).

The comment added that OTC sunscreen products are a unique category substantially different from most other types of OTC drug products because they are recommended for use on a daily basis to prevent serious disease. The comment concluded that FDA's rationale for standardized labeling format and content requirements does not necessarily transfer to OTC sunscreen products and specifically not to drug-cosmetic products with a sunscreen.

When FDA created the standardized labeling format and content requirements (i.e., ''Drug Facts'' labeling) for OTC drug products, we recognized that some product packages were too small to accommodate all of the required labeling. Therefore, under § 201.66(d)(10) (21 CFR 201.66(d)(10)), FDA allows labeling format modifications for all OTC drug products sold in small packages. In the final rule establishing ''Drug Facts'' labeling, FDA also stated that we may allow reduced labeling requirements beyond those specified under § 201.66(d)(10) for OTC drug products that meet the criteria listed in the preceding paragraph (see section III.D, comment 9 of this document).

In the final rule for OTC sunscreen drug products (64 FR 27666 at 27681 to 27682), FDA recognized that some OTC sunscreen drug products meet these criteria for reduced labeling. Specifically, FDA identified OTC sunscreen drug products that qualify for the small package specifications in § 201.66(d)(10) and are labeled for use only on specific small areas of the face as meeting the criteria for reduced labeling. Therefore, FDA allows content and format modifications for these products under § 352.52(f). FDA allows further modifications for lip products containing sunscreen because these products for small areas of the face are sold in even smaller packages than the other sunscreen products marketed under § 352.52(f) (68 FR 33362 at 33371; 64 FR 13254 at 13270). FDA believes that sunscreen products labeled for use only on small areas of the face, including lip products containing sunscreen, serve an important public health need and FDA does not want to discourage manufacturers from marketing these products (64 FR 13254 at 13270).

FDA does not find it appropriate to extend the labeling modifications for OTC sunscreen drug products marketed under § 352.52(f) to all OTC sunscreen drug products. FDA disagrees with the comment's argument that all sunscreen products meet the criteria for reduced Drug Facts labeling (64 FR 13254 at 13270), because most sunscreen products are not sold in small packages. Therefore, because sunscreen products do not generally meet all of the criteria for reduced Drug Facts labeling, FDA is not proposing reduced labeling for all OTC sunscreen products.

FDA does not consider sunscreens as a unique category substantially different from other types of OTC drug products because they are recommended for use on a daily basis to prevent serious disease, as argued by the comment. Other OTC drug products are used on a daily basis, some to prevent serious disease and some for other reasons. For example, anticaries drug products are

used daily to prevent dental caries. Antiperspirant drug products can be used daily to reduce underarm wetness. FDA has concluded that these various products should generally be labeled using the standardized content and format in § 201.66. The standardized labeling allows consumers to more easily recognize that these products are, in fact, drug products and to more easily read and understand the labeling information.

The same principle applies when the product is a drug cosmetic product (e.g., sunscreen moisturizer or antiperspirant deodorant). Consumers need to be informed that the product has a drug effect, and the uniform Drug Facts labeling for all OTC drug and drug cosmetic products helps convey this message. FDA applied this rationale when it finalized the requirements in the final rule that established § 201.66.

FDA agrees that some OTC sunscreen drug products meet the criteria for reduced information for safe and effective use (64 FR 13254 at 13270, 64 FR 27666 at 27681 to 27682). However, FDA disagrees with most of the modifications proposed by the comment for all package sizes of OTC sunscreen products. FDA disagrees with deletion of the ''Drug Facts'' title and the ''Purpose'' information because many sunscreen products do not meet the parameters for reduced Drug Facts labeling.

FDA disagrees that the ''Purpose'' information is repetitive and, therefore, disagrees that it may be omitted where there is sufficient labeling space. The ''Purpose'' section is a standard part of Drug Facts labeling and is intended to inform consumers which ingredients are sunscreens in a product. This information is even more important when a sunscreen is marketed in a combination product. For example, in a sunscreen skin protectant drug product, the ''Purpose'' section informs consumers which ingredients are sunscreens and which are skin protectants.

FDA has revised the ''Uses'' section and deleted the statement ''higher SPF gives more sunburn protection'' (see section III.G, comment 16 of this document). FDA disagrees with omitting the ''For external use only'' warning for all OTC sunscreen drug products. FDA finds no basis to exclude all OTC sunscreen products from this requirement. Likewise, FDA finds no reason to omit the two standard subheadings that accompany the warning statements, as proposed by the comment. Further, FDA disagrees with the comment's suggestion to omit the statement ''Rinse with water to remove.'' This is useful information if a sunscreen product gets into the eyes. FDA agrees with part of the proposed shortened warning for OTC sunscreen drug products to ''Stop use if skin rash occurs'' in place of ''Stop use and ask a doctor [bullet] if rash or irritation develops and lasts.'' Therefore, FDA is proposing to amend § 352.52(c)(1)(ii) (proposed § 352.52(c)(3)) to state: ''Stop use and ask a doctor if [bullet] skin rash occurs.''

FDA finds no reason to omit barlines, hairlines, or the box enclosure for all OTC sunscreen drug products regardless of package size. These labeling formats help consumers identify a product as a drug and help make labeling information easier to read and understand. Thus, they should be included when package size allows. The FM already allows horizontal barlines and hairlines and the box enclosure to be omitted if a small package meets the criteria in §§ 352.52(f) and 201.66(d)(10).

Finally, FDA has no basis to provide an option for sunscreen products to list inactive ingredients in labeling that accompanies the products. FDA interprets section 502(e)(1)(A)(iii) of the act (21 U.S.C. 352(e)(1)(A)(iii)) as requiring the inactive ingredients to be listed on the outside container of a retail package or on the immediate container if there is no outside container or wrapper (§ 201.66(c)). Because this information, by law, must appear either on the outside container or immediate container of the product, FDA does not find a basis for allowing an option to list the inactive ingredients in a different location, such as other labeling accompanying the product. In accordance with § 201.66(c)(8), the inactive ingredients must be listed on the product label in the ''Drug Facts'' box.

(Comment 9) Two comments supported extending the labeling in § 352.52(f) for products intended for use only on specific small areas of the face and sold in small packages to all OTC sunscreen products. The comments contended that all OTC sunscreen drug products meet most of FDA's criteria for products that require minimal information for safe and effective use (64 FR 13254 at 13270) (see section III.G, comment 8 of this document).

The first comment added that FDA should permit the labeling modifications in § 352.52(f) for the following products:

- Makeup products (as defined in 21 CFR 720.4(c)(7)) with sunscreen, and
- Lotions and moisturizers for the hands or face with sunscreen in containers of 2 ounces (oz) or less (by weight or liquid measure).

The comment added that most facial makeup products are typically packaged in small containers. The comment stated that to meet any of FDA's concerns that lotions and moisturizers sold in larger packages may be used over the entire body despite labeling that restricts use to the face or hands, FDA could limit the flexible labeling to containers of 2 oz or less. Furthermore, the comment added that containers of 2 oz or less could not feasibly include the full OTC drug labeling.

The second comment contended that the modified labeling in § 352.52(f) is particularly compelling for color cosmetic products for the face that contain sunscreens (i.e., ''facial makeups with sunscreen''). The comment added that these products and OTC sunscreen drug products for use only on specific small areas of the face have the same overall safety profile, and, therefore, FDA should allow these products to be labeled similarly.

A third comment strongly disagreed with a specific labeling exemption for makeup with sunscreen and moisturizer products for use on the face and hands. The comment contended that an exemption would not be in the best interest of consumers. The comment also argued that consumer confusion and subsequent misuse of sunscreen products, particularly failure to apply adequate amounts of sunscreen or to reapply a product after certain activities, will occur if FDA permits reduced labeling for these products. The comment added that many consumers use face and hand cosmetic products with sunscreen as their primary and only source of UV radiation protection for those areas of the body. Moreover, consumers are more likely to use these products properly if they contain full sunscreen drug labeling. The comment concluded that makeup foundations, tints, blushes, rouges, and moisturizers that are intended to be used on a daily or frequent basis to protect against the adverse health and skin aging effects of acute and chronic sun exposure must be labeled as drugs similar to other OTC sunscreen products.

FDA is not proposing to extend the labeling modifications in § 352.52(f), which is specific for products used only on small areas of the face and sold in small packages, to all OTC sunscreen products. FDA has determined that most OTC sunscreen products should have full drug labeling information using the standardized content and format in § 201.66 to ensure the safe and effective use of these products. In establishing the labeling modifications in § 352.52(f),

FDA determined how the labeling information for sunscreen drug products, including drug cosmetic products, could best be presented on products with limited labeling space and still provide consumers with adequate information to use these products safely and effectively. Although any sunscreen products sold in small packages that meet the criteria in § 201.66(d)(10) are allowed the format exemptions under that section, FDA is also proposing content exemptions for sunscreen products marketed under § 352.52(f). FDA is proposing these exemptions under § 352.52(f) because sunscreen products labeled for use only on small areas of the face and sold in small packages are generally sold in packages substantially smaller than other sunscreen products, even those sunscreen products labeled for other uses that meet the criteria in § 201.66(d)(10).

FDA continues to believe that requiring full Drug Facts labeling on sunscreen products used only on specific small areas of the face and sold in small packages (i.e., § 352.52(f)) would discourage manufacturers from marketing some of these products for drug use. Many of these products, such as sunscreen-lip protectant products, are sold in extremely small packages that cannot accommodate the required labeling even with the format exemptions allowed under § 201.66(d)(10). As explained in a number of rulemakings (64 FR 27666 at 27681 to 27682; 68 FR 33362 at 33371; 64 FR 13254 at 13270), these products meet the criteria for additional reduced labeling. Removal of these products from the OTC market would have a negative impact on public health. FDA believes that the benefit of UV radiation protection provided by these products outweighs the need for manufacturers to include all sunscreen labeling information. In contrast, FDA believes manufacturers of sunscreen products that are not within the scope of § 352.52(f) will continue to market their products even though full Drug Facts labeling is required. Unlike sunscreen products that meet § 352.52(f), the package size of products that do not meet § 352.52(f) will accommodate full Drug Facts labeling.

Although FDA is not extending the labeling modifications in § 352.52(f) to all OTC sunscreen products, as requested by the first and second comments, we are allowing these labeling modifications for certain makeup with sunscreen products. Specifically, these labeling modifications would apply to makeup with sunscreen products that are labeled for use only on specific small areas of the face and that meet the criteria in § 201.66(d)(10). However, FDA does not agree that these labeling modifications should apply to all makeup products identified in § 720.4(c) (21 CFR 720.4(c)) that contain sunscreen, because most are not sold in small packages and, therefore, do not meet all of the criteria for reduced labeling (64 FR 13254 at 13270). Thus, most of these products can accommodate full Drug Facts labeling, and FDA finds no reason to extend the labeling modifications in § 352.52(f) to all makeup with sunscreens products.

As explained in the previous paragraph, the labeling modifications in § 352.52(f) apply to makeup with sunscreen products labeled for use only on specific small areas of the face and sold in small packages. FDA also believes that any sunscreen products that are used only on specific small areas of the face and sold in small packages meet FDA's reduced labeling criteria regardless of whether they are drug or drug-cosmetic products. Therefore, FDA is proposing to amend the heading of § 352.52(f) to read as follows: ''Products, including cosmetic-drug products, containing any ingredient identified in § 352.10 labeled for use only on specific small areas of the face (e.g., lips, nose, ears, and/or around the eyes) and that meet the criteria established in § 201.66(d)(10) of this chapter.''

In addition, FDA is proposing to extend the labeling exemptions, with some modifications, currently allowed for lipsticks in § 352.52(f)(1)(vi) to the following lip products with sunscreen, as defined in § 720.4(c):

- Lipsticks,
- Lip products to prolong wear of lipstick,
- Lip gloss, and
- Lip balm.

FDA has identified lip products to prolong wear of lipstick as ''makeup fixatives'' under § 720.4(c)(7)(viii). Lip gloss and lip balm fall under ''other makeup preparations'' in § 720.4(c)(7)(ix). As long as these lip products with sunscreen are used only on specific small areas of the face and are sold in small packages (i.e., meet the criteria in § 201.66(d)(10)), they would meet FDA's reduced labeling criteria. As discussed earlier in this comment, FDA believes not allowing Drug Facts labeling exemptions for these products would discourage manufacturers from marketing some of these products for drug use. In proposed § 352.52(f)(1)(vi), FDA is proposing to extend the labeling modifications for lipsticks to other lip cosmetic products containing sunscreen and clarifying that the labeling modifications in § 352.52(f) apply to both sunscreen and makeup with sunscreen products. Furthermore, because lip products with sunscreen have substantially less labeling space than the nonlip products with sunscreen used only on specific small areas of the face and sold in small packages, proposed § 352.52(f)(1)(vi) allows more labeling exemptions for lip products with sunscreen than other products that are within the scope of § 352.52(f).

(Comment 10) Several comments recommended changing the acronym ''SPF'' from ''sun protection factor'' to ''sunburn protection factor'' because the latter definition is more descriptive of the use of OTC sunscreen drug products and avoids giving consumers the impression of solar invincibility and a false sense of security.

FDA agrees. In § 352.52(b) of the sunscreen FM, FDA included only indications for sunburn protection (e.g., ''helps prevent sunburn'') (64 FR 27666 at 27691). In this document, FDA is proposing to change the word ''sun'' to ''sunburn'' in § 352.3(b)(1), (b)(2), (b)(3), and (d) and § 352.52(e)(1)(i), (e)(1)(ii), and (e)(1)(iii).

Manufacturers can continue to use existing labeling until the compliance dates of a final rule based on this proposal. However, FDA encourages manufacturers to revise any labeling that states ''sun protection'' attributed to sunscreen active ingredient(s) to the new term ''sunburn protection'' as early as possible.

(Comment 11) Some comments questioned the constitutionality of the FM's labeling provisions. Specifically, the comments contended that the FM's prohibition on the labeling of SPF products over 30, its restrictions on skin aging claims, and its limitation of the indications for use for OTC sunscreen drug products all violate the first amendment to the U.S. Constitution. The comments asserted that these bans on allegedly truthful labeling in the FM go well beyond constitutionally permissible restrictions on commercial free speech.

One comment contended that FDA had failed to meet its burden to demonstrate that the claims at issue are misleading or that the restrictions on speech directly advance any substantial governmental purpose. In addition, the comment claimed that any interest FDA has asserted in restricting the speech at issue is served equally well, if not better, by regulations that do not restrict speech to the same extent as FDA's regulations.

FDA disagrees with the comments for the following reasons. OTC drug monographs establish conditions under which ingredients for certain OTC uses are generally recognized as safe and effective (GRASE) and are not misbranded. General recognition of safety and effectiveness in an OTC drug monograph means that experts qualified by scientific training and experience recognize the conditions as safe and effective for OTC marketing for the use recommended or suggested in the product's labeling. An OTC drug monograph establishes, among other things, specific indications that are appropriate for the safe and effective use of a drug. An OTC drug product with labeled indications different than those set forth in an applicable OTC drug monograph would not be considered GRASE.

OTC drug monographs allow manufacturers to market those products satisfying the monograph standard without requiring the specific approval of the product by means of a new drug application (NDA) under section 505 of the act. FDA has issued numerous OTC drug monographs for certain categories of OTC drug products. If an OTC drug product subject to a final monograph is labeled for indications that differ from those set forth in the monograph, then it would be a ''new drug'' under section 201(p) of the act. In order to be legally marketed and distributed in interstate commerce, the drug manufacturer would be required to obtain approval from FDA for that product, and those conditions varying from the monograph, in an NDA under section 505 of the act.

All OTC drug monographs place limits on the conditions that have been found acceptable for inclusion in the monograph by an administrative rulemaking process based on scientific data. Here, FDA set certain limits on the labeling of sunscreen drug products in the final rule, such as the prohibition on specific SPF values over 30, certain skin aging claims, and other indications for use. FDA is maintaining similar labeling restrictions in this proposed rule with respect to skin aging claims and other indications proposed by the comments. Also, as described elsewhere in this document, the revised ''sun alert'' in the ''Warnings'' section does not include any skin aging claims (see section III.G, comment 19 of this document). However, FDA is proposing to increase the SPF labeling limit from 30 to 50, based on additional data that was submitted subsequent to the issuance of the FM. FDA is also proposing that the term ''SPF 50+'' can be used, rather than the term ''SPF 30+'' allowed in the FM. This increase in the SPF labeling limit addresses, in part, the comments' request that FDA allow specific labeled SPF values over 30.

Elsewhere in this document, FDA explains the reasons for the specific labeling proposals, such as the required SPF labeling, revised ''sun alert'' in the ''Warnings'' section of the Drug Facts box, and indications for use (see section III.F, comment 15 and section III.G, comments 16, 17, and 19 of this document). FDA also explains our denial of specific labeling claims suggested by the comments, including the prohibition on specific SPF values over a certain threshold (SPF 50), skin aging claims, and additional indications for use (see section III.F, comments 15 and 17 of this document). As noted earlier in this comment, any variation from these labeling conditions in the monograph, if finalized, would cause an OTC sunscreen drug product to be a new drug requiring an approved NDA before it could be legally marketed in the United States.

The labeling requirements in this proposed rule would not violate the first amendment. FDA's requirements for the disclosure of information in the labeling of OTC sunscreen drug products are constitutionally permissible because they are reasonably related to the Government's interest in promoting the health, safety, and welfare of consumers and because they are not an ''unjustified or unduly burdensome'' disclosure requirement that offends the first amendment (see *Zauderer* v. *Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985); see also *Ibanez* v. *Florida Dep't of Bus. and Prof'l Regulation*, 512 U.S. 136, 146 (1994)). The reasonable relationship between the required labeling disclosures proposed herein and the Government's interest is plain here.

The proposed labeling disclosures addressed by the comments, such as the SPF value, indications for use, and revised ''sun alert,'' would contribute directly to the safe and effective use of OTC sunscreen drug products. The SPF value and indications for use are critical components of labeling that allow consumers to understand more clearly a sunscreen product's use in preventing sunburn and relative level of UVA/UVB protection. As explained elsewhere in this document, the revised ''sun alert'' we propose to require in the ''Warnings'' section would help consumers understand more clearly the role of sunscreens as part of a comprehensive sun protection program (see section III.F, comment 19 of this document). The greater consumer understanding resulting from all of these labeling conditions would promote directly the proper use of sunscreens, which, in turn, would better ensure the protection of public health.

In addition, it would not be ''unduly burdensome'' to sunscreen manufacturers to require these labeling disclosures. Finally, it is important to note that a sunscreen manufacturer could pursue alternative labeling conditions for its product by filing an NDA with the appropriate evidence demonstrating the product's safety and effectiveness under the proposed conditions.

In any event, FDA believes that the labeling requirements outlined in this proposed rule would pass muster when analyzed under the four-part test for restrictions on commercial speech set fourth by the Supreme Court in *Central Hudson Gas & Electric Corporation* v. *Public Service Commission*, 447 U.S. 557 (1980). Under the test, the first question is whether the commercial speech at issue is false, misleading, or concerns unlawful activity, because such speech is beyond the first amendment's protection and may be prohibited. If the speech is truthful, nonmisleading, and concerns lawful activity, the Government may nonetheless regulate it if the government interest asserted to justify the regulation is substantial, the regulation directly advances the asserted governmental interest, and the regulation is no more extensive than necessary to serve the government interest (Id. at 566). The Supreme Court has explained that the last element of the test is not a ''least restrictive means'' requirement but, rather, requires narrow tailoring (i.e., ''a fit that is not necessarily perfect, but reasonable'' between means and ends) (*Board of Trustees of the State Univ. of N.Y.* v. *Fox*, 109 S.Ct. 3028, 3032–35 (1989)). In subsequent decisions, the Court has also clarified that ''misleading'' in the first element of the test refers to speech that is inherently or actually misleading. Thus, if the speech to be regulated concerns lawful activity and is not inherently or actually misleading, the remainder of the test applies (see *In re R.M.J.*, 455 U.S. 191, 203 (1982)).

Based on the data currently available, FDA believes that the labeling statements proposed by the comments (i.e., specific SPF values above FDA's established threshold, skin aging claims, and certain other indications) would not be protected speech and may be prohibited under the first prong of the *Central Hudson* test. FDA has tentatively determined that these proposed labeling statements would be inherently misleading on OTC sunscreen products sold and, thus,

misbrand the products under section 502(a) and 201(n) of the act. Because FDA believes these labeling statements are inherently misleading, they would not be subject to protection under the first prong of the Central Hudson test.

With respect to the labeling limitations for SPF values, based on current data, FDA believes that the labeling of sunscreens with specific SPF values greater than 50 would be inherently misleading. As discussed elsewhere in this document, FDA is concerned with the accuracy and reproducibility of test results showing protection greater than SPF 50 due to the lack of adequate validation data (see section III.F, comment 15 of this document). FDA had the same concern with SPF values above 30 when we published the FM in 1999. At that time, FDA had only received data demonstrating that the SPF test produces accurate results for products with SPF values of 30 or less. Since publication of the FM, FDA has received additional SPF testing data for sunscreen products with SPF values between 30 and 50 (Ref. 13). However, FDA has not received any data for sunscreen products with SPF values greater than 50. The data submitted to FDA indicate that the SPF test is accurate and reproducible for sunscreen products with SPF values up to 50 (Ref. 13). However, these data cannot be extrapolated to SPF values above 50. Thus, FDA is proposing to allow specific labeled SPF values only up to 50.

Increasing variability in test results is likely with increasing SPF values. If there is large variability in test results, then the SPF value determined from the test is not accurate (i.e., an SPF 60 product may not actually be an SPF 60 product). The submitted data demonstrated that variability is not an issue for sunscreen products with SPF values up to 50. However, FDA is concerned that variability will become an issue for sunscreen products with SPF values over 50.

For those sunscreens with SPF values above 50, FDA is proposing that the labeling can denote such values by a ''50+'' designation. As discussed elsewhere in this document, FDA has sufficient assurance that a result over 50 from the required SPF test is, in fact, greater than 50 and can be labeled ''50+'' (see section III. F, comment 15 of this document). Thus, FDA believes that the term ''50+'' is truthful and nonmisleading on the label of OTC sunscreen drug products for which the SPF test in the monograph has indicated an SPF value greater than 50. However, without proper validation of specific SPF values above 50, there is no assurance that the specific values themselves are in fact truthful and not misleading. Thus, labeling of specific values above SPF 50 without appropriate validation (which FDA currently lacks) would be inherently misleading. As noted elsewhere, FDA invited any interested parties to submit such validation data for consideration by FDA and possible inclusion of specific values above SPF 50 in the FM.

With respect to anti-aging, skin cancer, and sun damage claims proposed by the comments, as discussed elsewhere in this proposed rule, FDA is concerned that these statements would be false or misleading due to lack of sufficient data in support of these claims (see section III.F, comment 17 of this document). FDA has reviewed the submitted articles concerning UV-induced skin damage (i.e., premature aging and cancer) along with the articles obtained from a search of scientific literature (Refs. 26 through 34). As discussed elsewhere, although FDA has concluded that the studies support the conclusion that exposure to UV rays increase the risk of premature skin aging, the study data fails to show that sunscreen use alone helps prevent premature skin aging and skin cancer for several reasons (see section III. F., comment 17 of this document).

First, with respect to premature skin aging, the studies have not completely defined the action spectrum for the majority of UV radiation-induced effects on human skin. Second, the inability to identify the exact UVB and UVA wavelengths that induce each histological change in skin derives from the study designs. Without knowing which UVB and UVA wavelengths induce each histological change in the skin, FDA is unable to determine which wavelengths are most important to causing skin aging and cannot determine the action spectrum for aging. Third, the studies did not examine the chronic, long-term consequences of UV radiation exposure in human skin. Fourth, although the studies that examined the ability of sunscreens to protect against UV radiation-induced histological changes in the skin provide useful data, it is difficult for FDA to conclude that sunscreen use alone helps prevent skin aging based on these studies.

Likewise, FDA is not aware of data demonstrating that sunscreen use alone helps prevent skin cancer. Like skin aging, these are studies examining the effects of sunscreen drug products on short-term factors for skin cancer, such as sunburn and other cellular damage. However, it is difficult to extrapolate these short-term adverse effects of UV radiation to a long-term, chronic effect such as skin cancer. In addition, like skin aging, the complete action spectrum for skin cancer is not known at this time.

For all these reasons, FDA has tentatively concluded that the available evidence fails to show that sunscreen use alone helps prevents skin cancer or premature skin aging. Thus, the anti-aging, skin cancer, and sun damage claims proposed by the comments would be false or misleading due to lack of sufficient data in support of these claims. For example, the statement proposed by one comment that sunscreen use ''may help prevent sun-induced skin damage, such as premature skin aging'' would be inherently misleading to consumers by suggesting that sunscreen use alone may help prevent premature skin aging. As explained in this response, the available data fail to show that sunscreen use alone helps prevent premature skin aging and skin cancer.

As described elsewhere, FDA is proposing a revised ''sun alert'' so that the labeling of OTC sunscreen drug products include the most accurate information, based on the available scientific evidence, concerning the relationship of sunscreen use to the prevention of sunburn, skin cancer, and premature skin aging caused by UV exposure (see section III.F, comment 19 of this document). The revised ''sun alert'' also includes a statement about limiting sun exposure and wearing protective clothing because FDA has tentatively determined that it is critical for consumers to understand the role of sunscreen use in a comprehensive sun protection program. As FDA has explained, the available evidence strongly suggests that consumers rely more heavily on sunscreens alone without taking other protective measures against sunlight, particularly when the labeling of products indicates the potential for greater protection (see section III.F, comment 19 of this document). By indicating the potential for greater protection than is supported by the available evidence, the proposed anti-aging, skin cancer, and other related claims would mislead consumers into relying more heavily on sunscreens alone. Such excessive reliance would undermine consumers' protection from the sun and, thus, FDA's public health mission.

FDA has also preliminarily determined that the proposed labeling statements would concern unlawful activity which are not protected speech under the first prong of the Central Hudson test.

FDA is proposing specific conditions in the monograph under which OTC sunscreen drug products would be GRASE. Elsewhere, FDA explains how the labeling statements proposed by the comments would not be appropriate monograph indications for these sunscreen products (see section III.G, comment 17 of this document). Thus, the proposed labeling statements outside the proposed indications of the final monograph, as FDA proposes to revise it, would promote a sunscreen drug product for use as an unapproved new drug, which is illegal. In addition, any variation in the statements in a ''Warnings'' section of a final monograph, such as the revised ''sun alert'' statement in this proposed rule, would be outside the monograph conditions and, thus, would promote the product as an unapproved new drug. The marketing and distribution in interstate commerce of an OTC sunscreen drug product with such labeling variations would be prohibited under sections 301(d) and 505(a) of the act. Speech promoting such an illegal activity may be restricted without violating the first amendment (*Central Hudson*, 447 U.S. at 563–564).

If a manufacturer could circumvent the requirements and restrictions imposed by a final monograph by including nonmonograph labeling statements, or excluding required monograph statements, based on its own assertions of the alleged appropriateness and truthfulness of the statements, then such activity would significantly undermine the monograph system and FDA's assurance that OTC drugs are safe and effective for their labeled conditions. FDA has assessed the labeling statements proposed by the comments and preliminarily determined that they are not justified by the available scientific evidence as GRASE conditions for the monograph. Instead, in order to legally market a sunscreen drug product with such labeling statements, an interested manufacturer would have to submit an NDA to FDA with the appropriate evidence to show the safety and effectiveness of the drug under the proposed nonmonograph labeling conditions. Requiring premarket FDA review and authorization of such nonmonograph drug claims ensures that such claims will be evaluated by a public health agency that has scientific and medical expertise so that only products that are safe and effective will be permitted to be sold for therapeutic purposes.

Although this preliminary-determination that the labeling statements at issue would be inherently misleading and would concern unlawful activity would obviate the need for FDA to address the other three prongs of the *Central Hudson* test, we believe that the labeling requirements proposed in this document would satisfy each of the parts of this test. With respect to the second prong, FDA's interest in the required labeling disclosures and prohibitions addressed by the comments would contribute directly to the safe and effective use of these OTC sunscreen drug products, which is critical for the protection of public health. FDA's interest in protecting the public health has been previously upheld as a substantial government interest under *Central Hudson* (see *Pearson* v. *Shalala*, 164 F.3d 650, 656 (D.C. Cir. 1999) (citing *Rubin* v. *Coors Brewing Co.*, 514 U.S. 476, 484–485 (1995)).

The proposed labeling requirements would directly advance this interest, thereby satisfying the third prong of the *Central Hudson* test. By requiring labeling disclosure of the SPF value, the proposed revised ''sun alert,'' and indications for use, FDA can better assure that consumers understand more clearly the use of sunscreens in preventing sunburn, their relative UVA/UVB protection, and their role as part of a comprehensive sun protection program. The greater consumer understanding resulting from all of these labeling conditions would promote directly the proper use of sunscreens, which, in turn, would better ensure the protection of the public health.

Likewise, this proposed rule's exclusion from the monograph of the labeling statements proposed by the comments also directly advances FDA's public health interest. FDA has preliminarily determined from the available evidence that these statements would not be appropriate conditions for OTC use under the monograph. Thus, the statements would directly undermine the protection of public health. In addition, it is important to note that the *Pearson* court, in assessing whether the specific dietary supplement regulations at issue directly advanced FDA's stated public health goals under the third prong of the *Central Hudson* test, explained that its findings under this prong did not apply to drugs, where ''the potential harm is presumably much greater'' than other products (*Pearson*, 164 F. 3d at 656, n 13).

Finally, under the fourth prong of the *Central Hudson* test, there are not numerous and obvious (*Cincinnati* v. *Discovery Network*, 507 U.S. 410, 418 n. 13 (1993)) alternatives to the required labeling statements or labeling prohibitions proposed herein. Consumers are accustomed to using the label as their primary source of information about a drug product's contents and use. Neither a public education campaign, nor encouraging OTC drug product manufacturers to provide information, such as that in the proposed revised ''sun alert,'' to consumers by other means, would ensure that people have the information they need about sunscreen products at the point of sale or use. Likewise, with respect to the alternative labeling statements proposed by the comments, FDA's proposed indications and revised ''sun alert'' present the relevant public health information to consumers in the clearest and most direct manner. Thus, FDA's proposed indications and prohibition of other labeling statements are not more extensive than necessary. In this way, the required labeling disclosures and prohibitions proposed in this document would meet the fourth prong of the test.

Furthermore, the proposed prohibition of claims in a final monograph does not prevent such claims from being approved in an NDA. As explained previously, a final monograph sets forth those conditions, including labeling, under which an OTC drug product would be considered GRASE and not misbranded. In issuing monographs, FDA considers whether the available scientific evidence demonstrates that OTC drug products within a therapeutic category are GRASE. A final monograph does not constitute an FDA decision regarding an NDA for an OTC drug proposing variations in these conditions. Thus, FDA's proposals in this document would not prohibit any interested manufacturer from filing an NDA, with the appropriate evidence, for any variations from the monograph labeling conditions. Because of this significant available option to manufacturers for proposing alternative labeling statements, FDA's proposed labeling requirements and prohibitions are not more extensive than necessary.

In conclusion, FDA believes it has complied with its burdens under the first amendment to support the labeling requirements of this proposed rule.

(Comment 12) One comment stated that voluntary professional labeling can be provided to physicians that will allow them to select or recommend sunscreen products for their patients' needs, based on more detailed information describing the quantity (protection factor) and the range of UV protection (e.g., UVB, UVA, or UVB/UVA protection). Another comment stated that FDA should not require professional labeling because complete

and accurate product labeling should be available to all consumers, not just to their health care providers.

FDA defines professional labeling in OTC drug monographs as labeling that is provided to health professionals but not to the general public (i.e., not directly to consumers) (for example, see § 331.80 (21 CFR 331.80)). In the final rule, FDA stated that it would consider professional labeling, such as protection against photosensitization reactions, if data were received (64 FR 22666 at 27674). FDA has not received any data to date. Therefore, FDA is not proposing any professional labeling in this document. FDA will consider professional labeling for OTC sunscreen drug products in the future if specific supportive data are provided.

(Comment 13) Some comments objected to the ranges of SPF values that define the product category designations (PCDs) in § 352.3(b). Stating that standard public health messages recommend use of a sunscreen with at least an SPF of 15, the comments contended that the ''moderate'' PCD (SPF values of 12 to under 30) may cause consumers to believe that SPF values of less than 15 provide adequate protection. One comment further stated that if the PCD range is from SPF 12 to 29, manufacturers will only produce the minimum SPF value as they can use less active ingredients and get the same PCD classification.

As discussed in the final rule (64 FR 27666 at 27681), the PCD ranges in § 352.3(b) and § 352.52(e) reflect a modified, simpler, combined version of the previously proposed five PCDs and the ''Recommended Product Guide.'' However, FDA agrees with the comments that the current standard public health message from public health organizations generally recommends use of a sunscreen with an SPF value of at least 15 (see section III.G, comment 19 of this document). We also agree that allowing SPF values below 15 in any but the lowest PCD range may appear to contradict this message. Therefore, FDA is proposing to modify the PCD SPF value range in proposed § 352.3(c)(1) from ''2 to under 12'' to ''2 to under 15'' and in proposed § 352.3(c)(2) from ''12 to under 30'' to ''15 to under 30.'' FDA is also proposing to replace the PCD terms ''minimal'' and ''moderate'' with the simpler terms ''low'' and ''medium,'' respectively, and to use these simpler terms for the UVA radiation protection categories (see section III.E, comment 14 of this document). These labeling changes will provide consumers with familiar and consistent terms describing both UVA and UVB radiation protection.

FDA disagrees with the comment contending that manufacturers will only produce the minimum SPF value in a given PCD range because they can use less active ingredients and get the same PCD classification. Section 352.50 of the current FM requires the SPF value to appear on a sunscreen product's PDP. This proposed rule would not change that requirement. Thus, while the PCD provides additional information about the SPF value, consumers seeking higher SPF values can readily identify such products by the SPF value stated on a sunscreen product's PDP.

E. Comments on the Labeling of Sunscreen Drug Products With UVA Protection

(Comment 14) Many comments discussed ways to categorize, phrase, and display UVA/UVB radiation protection on an OTC sunscreen drug product label. All of the comments stated that the SPF value should retain preeminence on the label's PDP and be the consumers' criteria for choosing an OTC sunscreen product. Some comments recommended that UVA radiation protection be stated on the PDP in descriptive words or simple phrases, rather than numbers or symbols, for the following reasons:

- Simplicity,
- Clarity,
- To avoid confusion with SPF, and
- To maximize consumer comprehension.

Some comments referenced consumer research, discussed in subsequent paragraphs, to support this recommendation (Refs. 4 and 5).

One comment suggested the following labeling statements:

- ''Protects against UVA rays''
- ''screens out UVA rays''
- ''shields from UVA rays''
- ''broad spectrum sunscreen''
- ''UVA/UVB protection''
- ''provides protection against both UVB and UVA rays''
- other truthful and nonmisleading statements describing a quantification of the product's UVA radiation protection

The comment stated that quantification of the UVA radiation protection should be allowed in labeling, but not required, so that consumers can have additional product performance information to help them select appropriate products.

Another comment stated that UVA radiation protection should be labeled only as grades of effectiveness (multiple levels) for the following reasons:

- UVA radiation irritation induces various skin reactions (e.g., erythema, pigment darkening, skin cancer, and photodermatitis), and
- Some action spectra of damages have not been determined.

This comment referred to The Japan Cosmetic Industry Association (JCIA) Measurement Standards for UVA Protection Efficacy (Ref. 6), which recommend labeling UVA protection as three grades: (1) PA+, (2) PA++, or (3) PA+++.

Several comments recommended two categories of UV protection labeling based on the ratio of UVA radiation protection factor to SPF value:

- ''with UV protection'' if ratio equals 0.20
- ''with extra UV protection'' if ratio equals 0.25

The proposed ratio is based on the UVA radiation protection factor as determined by the persistent pigment darkening (PPD) test method (see section III.N, comment 46 of this document). These comments stated that, because the ratio of damage from solar UVB radiation to that of solar UVA radiation is 80:20 over a day, a sunscreen must protect against an 80:20 ratio of UVB to UVA radiation. The comments also recommended that products labeled ''with UV protection'' or ''with extra UV protection'' exhibit absorbance of 360 nanometers (nm) and longer wavelengths.

Another comment suggested two categories to state overall UV radiation protection: ''regular'' and ''broad spectrum.'' The comment proposed that the ratio of a sunscreen product's SPF value to its UVA protection factor be the single criterion for the ''broad spectrum'' designation, with the maximum ratio no greater than 4:1. For example, an SPF 16 product would need to provide a UVA protection factor of at least 4 to be designated ''broad spectrum.''

One comment disagreed with the previous comment, stating that there is no supportable scientific basis for the relevance of the 4:1 ratio. The comment argued that the ratio inappropriately combines, in the same equation, SPF values obtained with a solar simulator and solar irradiance values at low sun angles.

Another comment suggested that sunscreen products with an SPF value of 2 or greater must have a UVA protection factor of at least 2 to be labeled ''UVA/UVB'' or ''broad spectrum protection.'' The comment stated that products with SPF values of at least 15 and UVA protection factors of at least 4 may be labeled ''extra (or extended or enhanced) UVA protection.'' The comment stated that these criteria are independent of test method and should apply to any of the proposed UVA radiation test methods.

Another comment proposed establishing PCDs based on the UVA

radiation protection value obtained by the PPD test method. The comment suggested four PCDs that would enable consumers to choose the desired levels of protection:

- ''moderate''
- ''high''
- ''very high''
- ''extra''

Another comment recommended three PCDs:

- ''low UVA protection''
- ''moderate UVA protection''
- ''maximum UVA protection''

Another comment suggested using the five PCDs proposed in the TFM (58 FR 28194 at 28295) and added a UVA protection factor number for each PCD based on the immediate pigment darkening (IPD) test method.

Two comments recommended a four-star rating system to describe UVA radiation protection. The comments stated that this system, based on the ratio of UVA to UVB radiation absorbance, would provide a simple method for consumers to determine the protective nature of an OTC sunscreen drug product. The absorbance ratio would range from 0 for products exhibiting no protection against UVA radiation to 1 for products exhibiting equal absorption at all wavelengths throughout the UVA/UVB radiation spectrum. Using this ratio, products would be classified in one of the following five categories:

- 0 to < 0.2 = no UVA radiation protection claim
- 0.2 to < 0.4 = Moderate (★)
- 0.4 to < 0.6 = Good (★★)
- 0.6 to < 0.8 = Superior (★★★)
- 0.8 plus = Maximum (★★★★)

Another comment recommended a five point rating system using the ''critical wavelength'' (CW) (λ_c) test method. This system uses a scale analogous to the star rating system to assign products a ''broad spectrum'' rating as follows:

- $\lambda_c < 325$ = ''0''
- $325 < \lambda_c < 335$ = ''1''
- $335 < \lambda_c < 350$ = ''2''
- $350 < \lambda_c < 370$ = ''3''
- $370 < \lambda_c$ = ''4''

Several comments supported a single claim, such as ''provides broad spectrum protection against UVB and UVA radiation,'' based on determining a sunscreen pass/fail CW (λ_c). Comments that supported this ''broad spectrum protection'' claim stated that, in combination with SPF, it provides simple and accurate labeling that is easily understood by consumers. The comments referred to a research study that suggested this approach to UVA radiation protection labeling was superior for consumer comprehension and ease of product selection (Ref. 7). Other comments provided consumer research data, discussed elsewhere in this comment, suggesting this approach was least preferred by consumers (Refs. 4 and 8).

One comment stated that UVA radiation protection claims should be allowed for sunscreen products with SPF values of 4 and higher. The comment added that, for products claiming to protect against UVA and UVB radiation, a minimum UVA protection factor of 2 should be required if the SPF value is less than or equal to 12.

Several comments stated that sunscreen drug products labeled as ''full spectrum'' or ''broad spectrum'' should protect consumers from substantially all of the harmful effects of the sun, including sunburn associated with UVA radiation. According to one comment, sunscreen drug products labeled ''full spectrum'' or ''broad spectrum'' that do not protect against nearly all UVB and UVA radiation wavelengths seriously risk misleading consumers into believing they are fully and completely protected from the dangers of the sun. One comment recommended using the claim ''full spectrum'' rather than ''broad spectrum'' to describe products that attenuate more than 90 percent of UVA radiation and are at least SPF 15. The comment suggested no UVA radiation protection claims be allowed if the product is below SPF 15.

In support of their proposed UVA labeling, a number of comments provided results from consumer research studies that assessed consumer labeling preferences for stating UVA radiation protection. One comment described a 1996 survey (Ref. 4) in which 275 subjects compared two labeling systems:

- 3-level descriptive (''light,'' ''intermediate,'' or ''extended'' ''UVA protection'') and
- Grapho/numerical (a bar graph indicating a level, 0, 4, 8, or 12, with the corresponding number appearing alongside the graph).

The comment stated that the survey data suggested that, while equally able to understand both types of labels, the panelists preferred the grapho/numerical system over the descriptive system.

Another comment described two consumer research studies, conducted in 1994 and 1995 (Ref. 9), in which 235 subjects compared three potential UVA radiation labeling options:

- Numerical (2, 3, or 5),
- Symbolic (4 stars with 1, 2, 3, or 4 stars filled), and
- 3-level descriptive (labeled blank if no UVA radiation protection provided or labeled ''UVA and UVB Protection'' or ''UVB Plus Extended UVA Protection,'' depending on the level of UVA radiation protection provided).

The studies included focus group discussions and indepth interviews. The comment stated that the data suggested that a numeric designation for UVA radiation protection (in addition to the SPF value) created confusion for consumers and that symbols (i.e., stars) misled consumers into giving equal or greater importance to the UVA radiation rating compared to the SPF value. The comment concluded that a descriptive approach better conveyed to consumers the added benefit of UVA protection without detracting from the SPF value.

Another comment described two consumer research studies conducted in 1999 (Ref. 7) in which 2,238 consumers assessed three sunscreen product labeling systems:

- A pass/fail descriptive (labeled blank if no UVA protection provided (i.e., fails) or labeled ''Broad Spectrum UVA and UVB Protection'' if UVA radiation protection provided (i.e., passes)),
- A 3-level descriptive (labeled blank if no UVA radiation protection provided or labeled ''UVA and UVB Protection'' or ''UVB Plus Extended UVA Protection,'' depending on the level of UVA radiation protection provided), and
- A 3-level grapho/numerical (a bar graph indicating a level, 4, 8, or 12, with the corresponding number appearing alongside the graph).

The comment stated that the data suggested the pass/fail descriptor, ''broad spectrum,'' was significantly superior to the other labels and recommended that FDA use this labeling to designate UVA radiation protection.

Another comment described a consumer research study conducted in 2000 (Ref. 8) at 20 urban and suburban shopping malls in which 1,921 subjects ranked four labeling systems:

- 4-level numerical,
- 4-level symbolic,
- 4-level descriptive, and
- Pass/fail descriptive (''with/without broad spectrum UVA/UVB protection'').

The numerical labeling system was shown as Arabic numerals ''1, 2, 3, 4'' with the number ''2'' highlighted. The descriptor labeling system was shown as the words ''Minimum, Moderate, High, Maximum'' with the word ''Moderate'' highlighted. The symbolic labeling system was shown as a picture of four stars with two stars highlighted.

The comment concluded that the subjects had a significant preference for a labeling system based on descriptive words or numbers because of clarity, specificity, and ease of comprehension. Subjects least preferred the pass/fail system because they found it unclear, nonspecific, and lacking sufficient information to compare sunscreen products. This study also revealed that the numerical labeling system was one of the top two choices because numbers were ''clearer, more specific, and easier to understand.'' Age, gender, and educational or ethnic background were reported as not affecting the study results.

In the TFM for OTC sunscreen drug products (58 FR 28194 at 28233), FDA proposed to allow claims relating to ''broad spectrum protection'' or ''UVA radiation protection'' for OTC sunscreen products that meet the following two criteria:

1. Contain sunscreen active ingredients with absorption spectra extending to 360 nm or above, and

2. Demonstrate meaningful UVA radiation protection using appropriate testing procedures to be developed.

In the FM for OTC sunscreen drug products (64 FR 27666 at 27672), FDA stated that UVA radiation labeling of OTC sunscreen drug products could continue in accordance with the TFM and its amendments until addressed in a future issue of the **Federal Register**. Elsewhere in this document, FDA is proposing test methods for determining the UVA radiation protection potential of an OTC sunscreen drug product (see section III.N, comment 46).

FDA believes that the existing data do not clearly define the relationship between UVA radiation and skin damage. The principal reason for not better understanding this relationship is that the action spectra for specific types of UVA radiation-induced skin damage (i.e., which wavelengths of UVA cause which types of skin damage) have not been established. However, most scientific data demonstrate that UVA radiation is harmful to the skin. Thus, until these action spectra are known, FDA believes that more protection against UVA radiation damage is better for consumers' health. Therefore, FDA believes it is important, as with the SPF value, to designate UVA radiation protection in a straightforward manner that consumers clearly understand.

FDA proposes that the UVA radiation protection of an OTC sunscreen drug product determined from these UVA test methods be designated on the PDP using a combination of category descriptors (i.e., ''low,'' ''medium,'' ''high,'' or ''highest'') and stars (i.e., symbols) similar to those described by some of the comments. The category descriptors and stars will designate relative levels of UVA radiation protection as measured by the UVA radiation test methods. The level of UVA radiation protection identified on the label reflects the following:

- A numerical ''UVA protection factor'' (from the clinical test), and
- A numerical ratio of UVA I (340 to 400 nm) radiation absorption to UVB/UVA (290 to 400 nm) radiation absorption (from the in vitro test).

The test that indicates the lowest level of UVA radiation protection determines the level identified on the label. For example, if the clinical test indicates ''low'' protection and the in vitro test indicates ''medium'' protection for a product, the product is labeled as providing ''low'' UVA radiation protection. This system comprises four categories of UVA radiation protection as described in table 1 of this document.

TABLE 1.—OVERALL UVA PROTECTION OF A SUNSCREEN DRUG PRODUCT

Star category	Category descriptor
★☆☆☆	Low
★★☆☆	Medium
★★★☆	High
★★★★	Highest

Some of the comments argued that the UVB radiation protection labeling is more important than UVA radiation protection and should be emphasized in the labeling over UVA radiation protection. FDA disagrees with the comments and proposes that the UVA radiation protection designation appear on the PDP along with the SPF value in an equally prominent manner that does not conflict with the SPF value. Because action spectra for UV-induced skin damage have not been clearly defined, FDA is unable to specify labeling for OTC sunscreen drug products that indicates what ranges of UV radiation are most harmful to consumers. In other words, FDA cannot conclude whether UVB or UVA radiation is more harmful to humans based on the scientific data collected to date. Therefore, FDA considers both UVB and UVA radiation protection equally important at this time because scientific data demonstrates that both have harmful effects on the skin.

So that consumers consider UVB and UVA radiation protection equally in selecting an OTC sunscreen drug product, FDA is proposing a number of labeling requirements. Under this proposal, the font size of the stars and category descriptors for UVA radiation protection must be the same size as the SPF value and its descriptors. All four stars must appear and be preceded by the term ''UVA'' and followed by the appropriate category descriptor (e.g., UVA ★★★☆ High). All star borders and the color inside a solid star must be the same while the color of ''empty'' stars must be lighter and distinctively different than solid stars. The color inside a solid star must be distinctively different than the background color. The stars must be filled in starting with the first star on the left and must appear in a straight horizontal line.

As requested by some comments, an OTC sunscreen drug product that does not provide the minimum UVA protection, as determined by the proposed UVA test methods, may only display an SPF value on the PDP. An OTC sunscreen drug product is not required to provide UVA protection and may bear only a sunburn (UVB/SPF) protection claim. However, FDA is proposing that a sunscreen product that does not provide at least a ''low'' level of UVA protection include the following statement on the PDP: ''no UVA protection.'' This statement must be the same font size as the SPF value and its descriptor. FDA is not proposing four empty stars because we are concerned that consumers may confuse products providing no UVA protection (i.e., four empty stars) with those providing the highest UVA protection (i.e., four filled stars).

In developing this UVA radiation protection labeling, FDA has particularly considered the label comprehension studies (Refs. 4, 7, 8, and 9). These studies used multiple methodologies and report a diverse range of preferences for each labeling system:

- Category descriptors,
- Graphics,
- Symbols,
- Numerics, and
- ''Pass/fail'' descriptors.

The diverse results and varying methodology make it difficult to identify a clear preference for one labeling system. However, the studies indicate an overall preference for category descriptors.

In agreement with the studies, FDA is proposing category descriptors to indicate the relative level of UVA radiation protection. As discussed in preceding paragraphs, FDA believes consumers should consider UVB and UVA radiation protection equally when selecting an OTC sunscreen drug product. For this reason, FDA is proposing that stars be used with category descriptors. FDA believes that

the category descriptor and star labeling for UVA radiation protection will give it equal prominence with UVB radiation protection (i.e., category descriptor and SPF) on the PDP.

FDA is not proposing grapho/numeric labeling because we are concerned that consumers may be confused by a second number on the PDP (i.e., in addition to the SPF value). FDA is also not proposing any of the simple two-category designations suggested by the comments:

- With/without UVA protection,
- With UVA protection/with extra UVA protection, or
- Regular/broad spectrum protection.

FDA agrees with one of the comments, which argued that these types of statements are misleading. FDA does not consider this labeling as providing consumers with enough information about the magnitude of UVA protection offered by an OTC sunscreen product. However, FDA does not object to the use of the following four statements for OTC sunscreen drug products that satisfy the requirements of proposed § 352.73 for a labeled UVA protection value:

- ''broad spectrum sunscreen'',
- ''provides [select one of the following: 'UVB and UVA,' or 'broad spectrum'] protection'',
- ''protects from UVB and UVA [select one of the following: 'rays' or 'radiation']'', and
- [select one of the following: ''absorbs'' or ''protects''] ''within the UVA spectrum''.

These statements may appear elsewhere in product labeling outside the ''Drug Facts'' box or enclosure but not intermixed with the information required on the PDP under § 352.50. FDA agrees with some comments that these statements, by themselves, may be misleading by implying that a sunscreen protects against nearly all UVB and UVA radiation. However, FDA does not believe these optional statements will be misleading in the context of the entire label, because the relative level of UVB and UVA protection must be stated on sunscreen product labels (alongside these more general statements).

Although none of the studies combined labeling systems as proposed in this document, FDA believes the studies support use of category descriptors and symbols together. One study suggested that symbols may imply importance over SPF values (Ref. 9). However, FDA believes consumers will not place greater importance on UVA protection because we are proposing a required statement to inform consumers about the importance of both UVB and UVA protection. We are proposing to require one of the following statements on the PDP of all OTC sunscreen drug products:

- ''UV rays from the sun are made of UVB and UVA. It is important to protect against both UVB & UVA rays.''
- ''UV rays from the sun are made of UVB and UVA. It is important to protect against both UVB & UVA rays to prevent sunburn and other skin damage.''

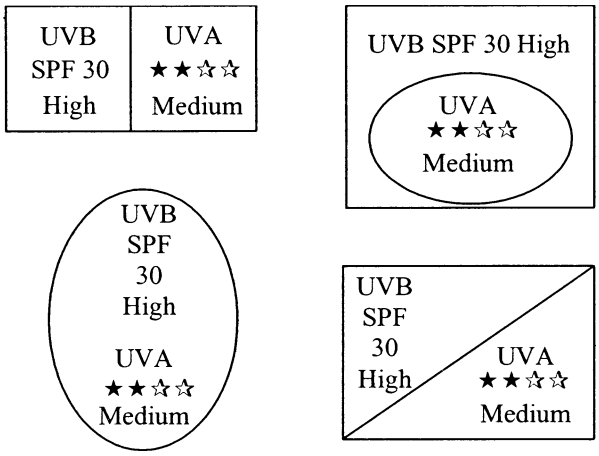
FDA believes that the use of one of these statements, along with the proposed UVB and UVA radiation protection labeling, including the format requirements described in preceding paragraphs, will lead consumers to view UVB and UVA radiation protection as equally important.

In addition, this statement will educate consumers about UVA radiation, which will be a new term and concept to many consumers. The proposed statement should help consumers better understand the new UVB and UVA labeling when it is initially introduced to the OTC market. Thus, FDA believes that the consumer label comprehension studies, along with the proposed educational statement about UVB and UVA radiation, support the stars and descriptor UVA radiation protection labeling proposed in this document. Moreover, a similar ''star rating system'' for UVA radiation protection (i.e., the Boots Star System) has been used to label sunscreen products throughout Europe for over 10 years.

To prevent consumer confusion about UV radiation protection, FDA is proposing changes to UVB radiation protection labeling (i.e., the SPF value). SPF values indicate how effective a sunscreen product is in protecting against sunburn. By displaying the relative level of sunburn protection on the sunscreen drug product PDP in terms of an SPF value, consumers can choose their desired level of UVB radiation protection. To further improve consumers' understanding of the sunburn protection level provided by a certain sunscreen product, FDA is proposing to require descriptive terms of relative sunburn protection (i.e., ''low,'' ''medium,'' ''high,'' and ''highest'') to accompany the SPF value on the PDP. FDA is further proposing that the SPF value must be preceded by the term ''UVB'' to further differentiate the SPF value from the UVA symbol/descriptor on the PDP. FDA believes that numerical labeling for UVB protection, symbolic labeling for UVA protection, and the same descriptive labeling for UVB and UVA protection will allow consumers to easily understand and choose from relative levels of UVB and UVA radiation protection.

FDA is aware that consumers have used and become accustomed to choosing OTC sunscreen drug products based on the SPF value for many years. Likewise, FDA believes that, over a period of time, consumers will similarly become accustomed to the proposed labeling using symbols and descriptors to designate relative UVA radiation protection. Furthermore, FDA believes consumer familiarity with similar star rating systems (e.g., movies, hotels, and restaurants) used for many years in the United States provide a basis for consumers' understanding of this proposed labeling for OTC sunscreen drug products.

FDA is providing a number of examples of how the UVA/UVB protection designations could appear on the PDP.



FDA believes that, as with SPF values, identifying the relative level of UVA radiation protection provides the most useful information for consumers. Consumers who desire more protection from the sun will be able to identify products with higher UVB (SPF) and UVA radiation protection. FDA agrees with the comments that a product must provide at least some minimum level of UVA radiation protection (as with SPF values) to be labeled as providing UVA radiation protection. Therefore, FDA is proposing minimum criteria for the lowest UVA category in its proposed test procedures (see section III.N, comment 46 of this document).

F. Comments on the Labeling of Sunscreen Drug Products With High SPF Values

(Comment 15) Several comments objected to FDA limiting specific labeled SPF values ''up to but not above 30.'' The comments stated that data and information supplied to FDA since publication of the sunscreen FM demonstrate that SPF values over 30 can be safely tested with accuracy. The comments also argued that removing the limit will not lead to consumers spending more time in the sun when using high SPF sunscreens in comparison to low SPF sunscreens. To address that point, one comment proposed labeling to help reduce potential consumer misuse of sunscreens with SPF values over 30: ''higher SPF products give more sun protection, but are not intended to extend the time spent in the sun.'' Another comment noted that the SPF value, in addition to proper sunscreen application and reapplication, is only part of a comprehensive sun protection program.

Other comments explained the need for high SPF sunscreen products. The comments contended that consumers and physicians are familiar with and want the many currently marketed sunscreens that are labeled as ''SPF 45, SPF 50, etc.'' Thus, the comments argued that U.S. consumers will be at a disadvantage within the international community, because products providing SPF values over 30 are available in other countries. In addition, the comments stated that many prominent medical authorities maintain the need for high SPF sunscreens for individuals at ''high risk'' based on medical and/or occupational concerns and individuals who desire increased protection from photoaging and lengthy/intensive sun exposure situations. The comments argued that the need for high SPF sunscreens is supported by findings that UV exposures in several cities are considerably higher than previously recognized and because high SPF products can reduce cumulative UV exposure. The comments stated that consumer desire for high SPF products is demonstrated by sales data showing that products with an SPF value of 45 are one of the fastest growing segments of the total sunscreen market.

The remaining comments discussed the consequences of limiting the specific labeled SPF value. For example, one comment noted that if manufacturers cannot state the SPF level above 30, they will no longer have an incentive to fund research for better sunscreens. In addition, manufacturers may reformulate products to reduce active ingredients and, thus, reduce the level of UV protection. A comment argued that another adverse consequence results from most consumers failing to achieve the labeled SPF value because they do not apply enough sunscreen and/or reapply it too infrequently. Because high SPF products can help make up for such improper use, limiting the specific labeled SPF value to 30 has a negative impact on UV protection.

A foreign industry organization suggested an upper limit for labeled SPF values of 50+ and provided three reasons:

- Unreasonably high SPF values will lead consumers to expect ''too much effectiveness'' from sunscreen products.
- Higher concentrations of sunscreen active ingredients are not ''in the interest of safety.''
- Higher SPF values will invite excessive, meaningless competition in the industry.

The comment explained that competition would be meaningless because the amount of UV protection provided by products with SPF values above 50 is not significantly greater than products with an SPF of 50.

Another comment from a sunscreen manufacturer agreed with FDA's concern about the possibility of increasing variability when testing high SPF sunscreens. The comment suggested a modified ''binomial'' test method and labeling requirements for SPF values over 20 that would allow for high SPF products.

Another comment submitted a published survey of 208 sunbathers on Miami's South Beach during July 2001 with the goal of measuring UV radiation exposure and probable injury (Ref. 10). The ''worst case'' scenario identified by the survey was based on sunbathers with Type I skin (persons most sensitive to sunlight who burn easily and never tan) exposed to UV radiation near the longest day and highest sun angle of the year at the ''southern-most major beach'' in the United States. The survey was a followup to one conducted in 1993 with 62 sunbathers and evaluated by FDA in the FM (64 FR 27666 at 27674). The 2001 survey determined MEDs absorbed by the following three steps:

1. Measuring incident UV radiation (using three dosimeters),

2. Multiplying by an adjusting factor for skin type (using a 30 percent

increase in sensitivity between skin types), and

3. Dividing by the SPF worn by the sunbather.

The survey suggests that sunbathers with Type I skin might receive a cumulative dose of 49.5 MEDs with 8 hours of exposure. The comment concluded that, while SPF values up to, and including, 50 are warranted, values over 50 are unwarranted in any condition for sunburn protection.

Two comments submitted testing data for sunscreens with SPF values between 30 and 50 using the test method in the FM. The comments concluded that the test method was valid for these high SPF values. In addition, one comment indicated that a very water resistant test for an SPF 45 to 50 sunscreen would take nearly 4.5 hours using the skin types of subjects in the SPF testing procedures in the FM (i.e., skin types I, II, and III) (Ref. 13). The comment concluded that it is beyond the practical endurance capabilities of many people in the test to spend more than 5 to 6 hours in front of a UV radiation lamp and that fatigue can lead to errors in test results. The comment also noted that the potential for intra and interlaboratory variability in test results increases as sunscreen SPF values increase.

FDA concluded in the FM (64 FR 27666 at 27675) that test methods supported specific SPF label values up to 30. FDA invited interested persons to submit data in support of high SPF test methods and to consider proposed methods for communicating the level of protection in labeling. Data and information on high SPF testing and labeling were submitted to FDA at, and following, public meetings on July 22, 1999, and October 26, 1999, and after reopening of the administrative record (65 FR 36319) (see section III.I, comment 24 of this document) (Refs. 11 and 12).

FDA continues to be aware that many OTC sunscreen products with specific labeled SPF values over 30 are currently marketed, both nationally and internationally, and are increasingly used by consumers and recommended by health professionals (64 FR 27666 at 27675). FDA agrees that these products should be available for those sun-sensitive consumers who require such products based upon personal knowledge, planned sun exposure, geographical location, or advice of a health professional. FDA previously noted the lack of any known safety problems for sunscreen products with SPF values greater than 30 (64 FR 27666 at 27675). The comment that argued higher concentrations of sunscreen active ingredients are not ''in the interest of safety'' did not supply any new data to support its contention. FDA will continue to monitor adverse drug experience reports for sunscreen drug products reported to its Medwatch program and in the medical literature.

As noted by one comment, some researchers have raised the concern that sunscreen use may lead to increased sun exposure. The ''compensation hypothesis'' states that consumers who use high SPF sunscreens spend more time in the sun and/or use less protective clothing. The only double blind, randomized trial that addressed this issue showed a significant increase in sun exposure time when comparing use of SPF 30 to SPF 10 (Ref. 14). In addition, two retrospective survey studies showed that sun exposure time is longer when using sunscreen compared to not using sunscreen (Refs. 15 and 16). Other studies cited by the comment to support the premise that the ''compensation hypothesis'' is incorrect and either did not provide data about the length of sun exposure or the study method did not allow for data interpretation (Refs. 17 through 20). Based on all of this data, FDA believes that some consumers may increase total UV exposure through over-reliance on sunscreens. The apparent divergent results on the validity of the ''compensation hypothesis'' between studies may indicate that sun protection behaviors vary greatly for each person. More specifically, there is a spectrum of attitudes about the sun, from those individuals who seek dark suntans to those who seek to avoid the sun and consequent UV skin damage (Ref. 21). Such evidence underscores the need for adequate labeling so consumers can make informed decisions regarding their use of OTC sunscreen drug products.

FDA agrees that the SPF value is one factor in a comprehensive sun protection program. However, the SPF is only a measure of protection from erythema (i.e., UVB radiation-induced sunburn) and does not measure protection from other UV skin damage, such as that induced by UVA radiation. While increased short wavelength UVA radiation protection generally increases with increasing SPF values, studies using in vivo or in vitro UVA radiation testing methods demonstrate that sunscreen products with the same SPF values can have markedly different levels of UVA protection, especially for long wavelength UVA radiation (Refs. 22 and 23). These studies also indicate that a specific high SPF product can provide much less UVA radiation protection than a product with a much lower SPF value. Elsewhere in this document, FDA is proposing UVA radiation testing methods and labeling that will categorize the relative levels of protection provided by the SPF and UVA values of the sunscreen product (see section III.E, comment 14 and section III.N, comment 45 of this document), allowing consumers to compare products and choose the levels of UVB and UVA radiation protection desired.

An SPF 30 sunscreen product may provide adequate sunburn protection for many consumers. However, FDA believes that appropriately tested and labeled high SPF value sunscreen products should be available for consumers who desire or need high levels of UV protection, in particular, those who burn easily. Such products would do the following:

- Help compensate for inadequate application and/or reapplication,
- Provide additional sunburn protection during intense UV radiation conditions,
- Help reduce cumulative UV radiation exposure (when used in conjunction with other measures to reduce overall sun exposure), and
- Generally provide consumers incremental increases in sunburn protection.

FDA agrees that SPF values should be supported by scientific evidence. In the FM, FDA limited the specific labeled SPF value to 30. At that time, FDA had only received data demonstrating that the SPF test produces accurate results for products with SPF values of 30 or less. Since publication of the FM, FDA has received additional SPF testing data for sunscreen products with SPF values between 30 and 50 (Ref. 13). However, FDA has not received any data for sunscreen products with SPF values greater than 50. The data submitted to FDA indicate that the SPF test is accurate and reproducible for sunscreen products with SPF values up to 50 (Ref. 13). However, these data cannot be extrapolated to SPF values above 50. Thus, FDA proposes to allow specific labeled SPF values up to 50.

FDA agrees with the sunscreen manufacturer that increasing variability in test results is likely with increasing SPF values. If there is large variability in test results, then the SPF value determined from the test is not accurate (i.e., an SPF 50 product may not actually be an SPF 50 product). The submitted data demonstrate that variability is not an issue for sunscreen products with SPF values up to 50. However, FDA is concerned that variability will become an issue for sunscreen products with SPF values over 50.

FDA recognizes that future data may demonstrate that variability may not be a problem for sunscreen products with SPF values over 50. Therefore, FDA will consider specific SPF values greater than 50 upon receipt of data demonstrating that accurate and reproducible results can be obtained from the SPF test for sunscreen products with SPF values over 50. Generally, such data should include results from multiple laboratories using the same sunscreen formulations and using the SPF test proposed in this document, along with a statistical analysis of the overall results. In addition, FDA believes that the modified ''binomial'' test method submitted by one comment has merit for high SPF sunscreens and is requesting others' views on this method during the comment period for this rulemaking (see section III.I, comment 24 of this document).

In the FM (64 FR 27666 at 27675), FDA disagreed with the comment that manufacturers would have no incentive to fund research for better sunscreens and may reformulate to less protective products if there is an upper limit to specific labeled SPF values. Although FDA would not want to decrease research incentive, FDA is more concerned about valid scientific data demonstrating the ability of multiple laboratories to accurately and reproducibly determine SPF values. However, FDA does not believe it is necessary to arbitrarily limit specific labeled SPF values. To the contrary, both in the FM and in this proposal, FDA has specifically stated that high SPF sunscreens should be available for those individuals desiring such products. The maximum allowable specific labeled SPF value, both in the FM and in this proposal, is based upon the review of data and information submitted to FDA. FDA purposely did not limit labeled SPF values at 30 in the FM. Instead, FDA used the value of ''30+,'' pending the receipt of adequate data to support any higher specific label values.

Similarly, in this document, FDA is proposing the collective value ''50+.'' FDA has sufficient assurance that a result over 50 from the required SPF test is, in fact, greater than 50 and can be labeled ''50+.'' Thus, FDA believes that the term ''SPF 50+'' is truthful and nonmisleading on the label of OTC sunscreen drug products for which the SPF test in the monograph has indicated an SPF value greater than 50. FDA believes that allowing manufacturers to label sunscreens as ''SPF 50+'' may encourage further research in human skin photobiology and the development of safe and effective sunscreen drug products with specific SPF values over 50. As explained earlier in this comment, FDA is not proposing that the specific value over 50 be stated in the labeling because there is no data, at this time, demonstrating the accuracy and reproducibility of the specific value over 50. Based upon the proposed labeling, improvements to SPF testing methods, and specific high SPF test data, FDA is proposing to modify the labeled SPF values in current § 352.50(a)(1) and (a)(2) by changing the SPF values from ''30'' to ''50.''

G. Comments on Indications for Sunscreen Drug Products

(Comment 16) One comment requested that the ''Uses'' statement, ''higher SPF gives more sunburn protection,'' be omitted except for products with an SPF over 30. This and other comments suggested that FDA's labeling concerns regarding high SPF sunscreens could be alleviated if the following statement was required on sunscreens over SPF 30: ''Higher SPF products give more sun protection, but are not intended to extend the time spent in the sun.''

FDA is proposing to revise the sunscreen FM ''Uses'' statement ''helps prevent sunburn'' and delete the ''Uses'' statement ''higher SPF gives more sunburn protection'' in current § 352.52(b). The first indication, ''helps prevent sunburn,'' is being revised to one of the following, which would be required on all sunscreens:

- ''low UVB sunburn protection''
- ''medium UVB sunburn protection''
- ''high UVB sunburn protection''
- ''highest UVB sunburn protection''

The relative level of sunburn protection is determined from the SPF value:

- low = SPF 2 to under 15
- medium = SPF 15 to under 30
- high = SPF 30 to 50
- highest = SPF over 50

Thus, relative descriptors (low, medium, high, and highest) describe SPF values, which are relative and not absolute levels of sunburn protection intended to help consumers determine differences in sunburn protection offered by different sunscreen products (see section III.I, comment 23 of this document).

FDA considers it important that consumers be made aware of the relative level of sunburn protection provided by a product in addition to its indication for sunburn protection. Individuals may select a low, medium, high, or highest sunburn protection product to meet their specific needs. The descriptor ''UVB'' is included to describe the predominant rays that are screened. The phrase ''helps prevent'' is being deleted because it is duplicative and no longer necessary. This phrase would only lengthen the ''Uses'' statement. Furthermore, consumers will now be able to equate a product's UVB radiation protection rating (i.e., SPF value) directly to the relative level of sunburn protection.

The second indication ''higher SPF gives more sunburn protection'' is no longer needed because the relative level of sunburn protection is provided in the new ''Uses'' statements. In addition, without clarification, the statement may encourage consumers to spend more time in the sun. Clarification is necessary because, as discussed in comment 19 of this document, surveys reveal that consumers spend more time in the sun with increasingly higher SPF sunscreen products (Refs. 14, 15, and 16). Therefore, FDA is not allowing this statement in the ''Uses'' section. However, under proposed § 352.52(e)(2), FDA is proposing the following optional statement under ''Other information'' or anywhere outside of the ''Drug Facts'' box or enclosure: ''higher SPF products give more sun protection, but are not intended to extend the time spent in the sun.'' The phrase ''but are not intended to extend the time spent in the sun'' is additional information not included in the FM indication. FDA believes this revised indication statement will discourage consumers from spending more time in the sun when using a higher SPF product.

FDA is proposing additional revisions in ''Uses'' in § 352.52(b)(1) to include UVA claims and other information (see section III.G, comments 17 and 18 of this document). The proposed revisions will help consumers to more fully understand the uses and expected results for individual sunscreen products. These changes are necessary because the PDP for a sunscreen product will now include two performance ratings (see section III.E, comment 14 of this document):

- The well-accepted SPF value and new descriptor rating for UVB radiation protection, and
- A new star/descriptor rating for UVA radiation protection.

Consequently, FDA considers it important that the ''Uses'' statements in the ''Drug Facts'' box accurately reflect product claims related to specific indications, UVA and UVB radiation, and the level of anticipated protection (low, medium, high, or highest) determined by the UVA and UVB product ratings. As with the introduction of SPF labeling years ago, it will take the combined efforts of government, manufacturers, consumer organizations, and the health care

community to educate consumers to fully understand these labeling initiatives to enhance their safe and effective use of sunscreen products.

(Comment 17) One comment stated that FDA's ''sun alert'' statement in the FM recognized that sun-induced skin damage can contribute to photoaging and increase the risk of skin cancer. This statement reads: ''Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.'' The comment urged FDA to allow other truthful use statements, such as the following:

- ''helps protect against skin damage caused by the sun''
- ''helps protect against skin aging caused by the sun''
- ''regular use helps protect against certain forms of skin cancer caused by the sun''
- ''helps protect against fine lines and wrinkles caused by the sun''
- ''helps protect against pigmentary changes due to sun exposure''

Another comment urged FDA to include the first three use statements suggested by the first comment, as well as ''helps protect against the harmful effects of the sun'' and ''helps protect against (select one: 'casual,' 'incidental,' 'intermittent,' or 'daily') sun exposure.'' The comment contended that, when used effectively as part of a sun protection program, sunscreens may prevent very serious disease conditions.

Another comment provided citations from the medical literature to support its contention that claims of sunscreens preventing skin cancer induction may be false, deceptive, misleading, and unsubstantiated. The comment mentioned an article by Garland (Ref. 25) that states the following: ''No epidemiological studies were identified that showed a protective effect of use of chemical sunscreen on risk of melanoma or other cutaneous malignancies in humans.'' The comment also mentioned an article by Gasparro (Ref. 24) that states the following: ''Although some have promoted daily use (of sunscreen) for the prevention of premature aging of the skin and the prevention of skin cancer, actual data are lacking to support these recommendations.''

FDA has reviewed the submitted articles concerning UV-induced skin damage (i.e., premature aging and cancer) along with articles obtained from a search of the scientific literature (Refs. 26 through 34). Many of the articles involved preclinical data, which can be difficult to extrapolate to consumer (human) actual use conditions. FDA believes that the articles with clinical data provide more meaningful results, as they can be easily extrapolated to consumer actual use conditions. Therefore, FDA is focusing discussion in this document on the clinical studies. In agreement with Garland (Ref. 25) and Gasparro (Ref. 24), FDA does not believe, as a whole, that the studies demonstrate that sunscreens alone help prevent skin aging or skin cancer.

Some of the clinical studies examined the role of UVB and UVA radiation in producing histological changes indicative of skin aging due to the sun. Lowe et al. demonstrated that high doses of UVA radiation (320 to 400 nm) increased melanization of human skin more than lower doses of UVA or solar simulating UV radiation at 290 to 400 nm (Ref. 26). Seite et al. demonstrated that melanization of human skin increased with exposure to UVB/UVA radiation at 290 to 400 nm (Ref. 32) and UVA radiation at 330 to 440 nm (Ref. 27). Seite et al. also showed that human skin hydration decreased after chronic exposure to UV radiation at the wavelengths studied.

Five studies revealed stratum corneum thickening produced by both UVB and UVA radiation (Refs. 26 through 29 and 32). Stratum granulosum thickening was transiently induced after 6 weeks of exposure to UV radiation (UVB/UVA) at 290 to 400 nm (Ref. 32). The same effects were seen with solar simulated radiation and high and low doses of UVA radiation after 12 weeks of exposure (Ref. 26). Viable epidermal thickening was seen after 6 weeks of exposure to UV radiation at 290 to 400 nm in one study (Ref. 32) and after 9 days of exposure to UVA radiation at 335 to 345 nm in another study (Ref. 31).

Inflammation and lysozyme deposition along the dermal elastic fibers were increased more in human skin exposed to UVA than UVB radiation (Refs. 26, 28, 29, and 31). Sunburn cell appearance, a typical response to UVB radiation, was also found to be present after exposure to different UVA radiation regimens in two studies (Refs. 28 and 31) but not found in a third study (Ref. 27). Thus, FDA concludes that these studies demonstrated that both UVB and UVA radiation induce histological changes associated with skin aging.

Four of these studies focused on the histological changes within the skin induced by UVB and UVA radiation and explored the ability of sunscreens to protect human skin against these changes (Refs. 29, 30, 32, and 33). The first study suggested that an SPF 29 sunscreen prevented the development of solar elastosis, a condition in which skin loses its elasticity after chronic exposure to the sun (Ref. 33). However, these method and data analyses raise questions about the validity of the reported conclusion:

- Discrepancies were noted concerning demographic characteristics of subjects, sunscreen application, and compliance rates.
- Skin biopsy data at all three time points in the study were available from only 10 of the 35 subjects.
- The only statistically significant difference between the sunscreen and placebo treatment groups was achieved in a computerized evaluation of solar elastosis at baseline and 24 months.

The second study demonstrated significant contribution of a sunscreen in preventing UV radiation-induced skin damage (Ref. 32). The use of sunscreens with absorption spectra covering the 290 to 400 nm range prevented all of the effects of chronic exposure (6 weeks) to UV radiation evaluated in the study. The third study showed a photoprotective effect of an SPF 15 sunscreen product from damage induced by short term exposure to UVB radiation (Ref. 30). The fourth study showed that a UVB only sunscreen did not provide protection against chronic exposure to UVA radiation (Ref. 29).

The studies provide evidence that both UVB and UVA radiation induce histological changes in the skin consistent with skin aging. Thus, the studies support the conclusion that exposure to UV rays increases the risk of premature skin aging. However, the study data fails to show that sunscreen use alone helps prevent premature skin aging for several reasons. First, the studies have not completely defined the action spectrum for the majority of UV radiation-induced effects on human skin. While studies demonstrate that a given histological change, such as thickening of the stratum corneum, is induced by certain wavelengths within the UVB and UVA region, studies have not examined the ability of the remaining UVB and UVA regions outside of these wavelengths to induce the same change. For example, studies may have shown that 290 nm to 310 nm and 360 nm to 400 nm radiation induce stratum corneum thickening, but it is not known whether 311 nm to 359 nm radiation induces the same histological change.

Second, the inability to identify the exact UVB and UVA wavelengths that induce each histological change in the skin derives from the study designs. Each study differed in the following parameters:

- UV radiation wavelengths,
- UV exposure regimens,
- Sunscreen doses,
- Sunscreen application techniques, and
- Endpoints.

Therefore, FDA cannot combine all of the data from these studies to define a complete action spectrum for each histological change in the skin. Furthermore, the action spectrum for each histological change would need to be combined to define a single action spectrum for skin aging, which is a cumulation of these histological changes. Without knowing which UVB and UVA wavelengths induce each histological change in the skin, FDA is unable to determine which wavelengths are most important in causing skin aging and cannot determine the action spectrum for aging.

Third, the studies did not examine the chronic, long-term consequences of UV radiation exposure in human skin. Thus, it is not possible for FDA to extrapolate the data to longer time points at which the short-term histological changes may cumulate to produce visible signs of skin aging.

Fourth, although the studies that examined the ability of sunscreens to protect against UV radiation-induced histological changes in the skin provide useful data, it is difficult for FDA to conclude that sunscreens alone help prevent skin aging based on these studies. The number of participants in each study was relatively small, with only 10 to 35 subjects per study. Different sunscreen formulations, with differing absorption spectra, were used in each study. As explained previously, these studies do not identify exactly which UVB and UVA wavelengths contribute the most to skin aging (i.e., the studies do not define the skin aging action spectrum). For all of these reasons, the studies do not prove that sunscreens alone help prevent premature skin aging.

Likewise, FDA is not aware of data demonstrating that sunscreens alone help prevent skin cancer. It has been known for many years that UV radiation increases the risk of skin cancer. It has also been known for many years that a higher incidence of sunburn earlier in life corresponds to a higher incidence of skin cancer later in life. However, FDA is not aware of any studies demonstrating that the use of sunscreens alone decreases the risk of skin cancer. Like skin aging, there are studies examining the effects of sunscreens on short-term factors for skin cancer, such as sunburn and other cellular damage. However, it is difficult to extrapolate these short-term adverse effects of UV radiation to a long-term, chronic effect such as skin cancer. In addition, like skin aging, the complete action spectrum for skin cancer is not known at this time.

Unlike skin cancer and premature skin aging, FDA has evidence that sunscreens alone help prevent sunburn. The SPF test measures the effectiveness of sunscreens with sunburn (erythema) as the endpoint. Thus, the impact of sunscreens on sunburn can be measured directly. In contrast, it is difficult to measure directly the impact of sunscreens on skin cancer or premature skin aging because these are long-term, cumulative adverse effects of UV exposure.

Thus, for all of the reasons discussed in this comment, FDA concludes that the available evidence fails to show that sunscreens alone help prevent skin cancer or premature skin aging. Based on this conclusion, FDA is not proposing the indication statements proposed by the first and second comments, because these claims are for protection from premature skin aging, skin cancer, and related factors (e.g., ''helps protect against skin aging caused by the sun''). FDA also is not proposing claims that sunscreens protect against ''casual, incidental, intermittent, or daily'' sun exposure, as proposed by the second comment, because the studies do not support these claims. Furthermore, FDA considers these terms as lacking sufficient meaning to be useful to consumers.

As described elsewhere in this document (see section III.G, comment 19), FDA is proposing to require a revised ''sun alert'' statement in the form of a new warning. The new warning statement is based on FDA's review of the available evidence concerning UV exposure and skin cancer, premature skin aging, and other skin damage. The new warning statement clarifies that UV exposure from the sun increases the risk of skin cancer, premature skin aging, and other skin damage. In addition, the new warning statement specifies that consumers should use complementary sun protection measures along with sunscreen (i.e., limit sun exposure and wear protective clothing). FDA has concluded from the available evidence that it is important to adopt a complete sun protection program (sunscreen, sun avoidance, and protective clothing) to decrease UV exposure. In fact, the second comment argued for new indication statements by considering the sunscreen use as part of such a sun protection program (i.e., in conjunction with limiting time in sun and wearing protective clothing). Thus, the second comment, along with the third comment, seemed to agree with FDA's conclusions in this proposed rule concerning the need for consumers to use sunscreens in conjunction with other sun protection measures.

In addition, the reference in the new warning statement to sunscreen use combined with limiting sun exposure and wearing protective clothing is consistent with recommendations by other public health organizations. For example, the World Health Organization's International Agency for Research on Cancer (IARC) (Ref. 21) makes the following assessments and recommendations:

- There is inadequate evidence in humans for a cancer preventative effect of sunscreens against basal cell or malignant melanoma cancers.
- There is only limited evidence for a preventive effect of sunscreens against squamous cell cancer.
- Sunscreens should not be the first choice for skin cancer prevention or used as the sole agent for protection against UV radiation.

Likewise, the CDC recommends that sunscreens be used as a complementary measure in an overall sun protection program (Ref. 35).

FDA believes that additional information from controlled clinical studies is needed to better understand the role of sunscreens in preventing premature skin aging and skin cancer. Studies examining premature skin aging (using solar radiation or simulated solar radiation) are needed to determine the following in humans:

- Measurable skin properties such as elasticity, collagen/elastin ratios and properties, wrinkling, pigmentation changes and visual grades, leading to accepted quantitative definitions of chronological and sun-induced skin aging;
- The relationship between sunlight exposure and skin aging, stratified by skin type;
- An action spectrum for photoaging of skin;
- A dose response for UV radiation-induced skin aging;
- Quantitative estimates of realistic ''worst case,'' long-term exposures to sunlight in relevant UVA and UVB radiation spectral ranges (i.e., the level of UVB and UVA protection needed); and
- How UV radiation-induced processes that occur at a given wavelength affect UV radiation-induced processes that occur at other wavelengths.

Similar information is needed for skin cancer, except that studies should examine the different types of skin

cancer, rather than examining different skin properties. In addition, IARC has provided recommendations for research on skin cancer prevention and sunscreens. These recommendations can also be used as a guide in designing studies to examine the role of sunscreens in preventing premature skin aging due to the sun (Ref. 21). FDA encourages interested parties to submit study protocols to FDA for review to ensure that studies are as informative as possible. FDA also invites comments by interested parties on the feasibility and validity of surrogate endpoints for studies to determine whether the use of sunscreens alone help prevent skin cancer, premature skin aging, or other skin damage.

(Comment 18) As discussed in section III.E of this document, FDA received several comments discussing ways to categorize, phrase, and display UVA/UVB radiation protection on an OTC sunscreen drug product label. In the amendment to include avobenzone in the monograph (61 FR 48645 at 48655), FDA proposed the following indications for UVB and UVA radiation protection by sunscreen drug products containing avobenzone:

1. ''Broad spectrum sunscreen'';
2. ''Provides'' (select one of the following: ''UVB and UVA,'' or ''broad spectrum'') ''protection'';
3. ''Protects from UVB and UVA'' (select one of the following: ''Rays'' or ''radiation'');
4. (Select one of the following: ''Absorbs,'' ''Protects,'' ''Screens,'' or ''Shields'') ''throughout the UVA spectrum''; and
5. ''Provides protection from the UVA rays that may contribute to skin damage and premature aging of the skin''.

Likewise, in the amendment to include zinc oxide in the monograph (63 FR 56584 at 56588), FDA proposed similar labeling for UVA and UVB radiation protection for products containing zinc oxide (substituting the word ''within'' for the word ''throughout'' in the fourth statement). FDA did not include these indications in the FM but has allowed their use until the UVA portion of the monograph is established.

FDA has reconsidered these UVA protection indications. FDA is proposing to allow all of them except the fifth statement. In proposed § 352.52(e), the first four statements are optional statements allowed for products that demonstrate UVA protection according to the proposed testing (see section III.N, comment 45 of this document). The statements can only be included in labeling outside of the ''Drug Facts'' box. Within the ''Drug Facts'' box, FDA is proposing one of the following UVA indication statements, depending on the level of UVA protection provided by a product:

- ''low UVA protection''
- ''medium UVA protection''
- ''high UVA protection''
- ''highest UVA protection''

The level of protection (i.e., low, medium, high, or highest) is determined from the UVA rating obtained from product testing (see section III.N, comment 45 of this document). Manufacturers who wish to combine the ''Uses'' statements about UVA protection and UVB sunburn protection may do so if the descriptors (i.e., levels of protection) are the same. For example, if the levels of UVA and UVB protection are medium, the ''Use'' may read: ''medium UVA/UVB sunburn protection''.

FDA is not including the fifth indication because FDA does not consider ''skin aging'' or ''skin damage'' claims adequately supported at this time. As discussed elsewhere in this document (see section III.G, comment 19), FDA is proposing a statement in the ''Drug Facts'' box that informs consumers that sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects from the sun when used in a regular program that relies upon limiting sun exposure and wearing protective clothing. Therefore, FDA believes the fifth indication statement would mislead consumers by not discussing sun exposure and protective clothing.

(Comment 19) As discussed in section III.G of this document, FDA received several comments concerning the ''sun'' alert statement. In § 352.52(e)(2) of the FM, FDA included the optional statement: ''Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.'' This statement's emphasis of the need for a comprehensive sun protection program (64 FR 27666 at 27679) was based on the findings of numerous groups, including the following:

- The American Academy of Dermatology (AAD),
- The CDC,
- The Australian Government; and
- The New Zealand Government.

These groups have recommended that sunscreens be considered an adjunct to other UV protection strategies, such as avoiding the sun near midday, seeking shade, and wearing protective clothing and hats.

The FM provided that the ''sun alert'' appear under the heading ''Other information'' or anywhere outside of the ''Drug Facts'' box or enclosure. At that time, FDA encouraged manufacturers to voluntarily include this statement in labeling, make it available at the point of purchase, and/or make it available through consumer education programs.

FDA is now proposing a revised ''sun alert'' statement be required in the ''Warnings'' section of the ''Drug Facts'' box. FDA is proposing the statement to read as follows: ''UV exposure from the sun increases the risk of skin cancer, premature skin aging, and other skin damage. It is important to decrease UV exposure by limiting time in the sun, wearing protective clothing, and using a sunscreen. FDA is proposing that the statement appear in bold type as the first statement in the ''Warnings'' section. FDA believes the statement is most appropriate in the ''Warnings'' section because it warns consumers that effective protection from the sun does not involve only the application of sunscreens, as many consumers believe. In addition, it warns consumers that UV radiation not only increases the risk of sunburn but also increases the risk of skin cancer and premature skin aging, which many consumers may not know. FDA believes the new warning will encourage consumers to use sunscreen, limit time in the sun, and wear protective clothing to reduce UV exposure. Because of the importance of warning statements and the need for consumers to receive a uniform message concerning such warnings, no variations in wording are allowed under § 330.1(c)(2).

FDA acknowledges that the new warning statement differs from the wording of the voluntary ''sun alert'' in the FM. These differences are based on FDA's assessment of the additional evidence available since publication of the FM in 1999. As explained in comment 17 of this document, FDA does not believe that the available data support a claim concerning the use of sunscreen and a reduction in the risk of premature skin aging and skin cancer. The revised wording of the statement more accurately reflects the scientific conclusions that can be drawn from this evidence.

FDA is proposing the warning because we continue to be concerned about adequate consumer understanding of a sun protection program that includes sun avoidance and wearing protective clothes along with sunscreen use. This proposed rule provides for even higher SPF values and a new rating system for UVA protection. Consumers may believe that sunscreens with higher SPF values (especially with UVA protection) provide complete UV radiation protection. Subsequently, consumers may prolong sun exposure

because they think higher SPF values equate to longer times in the sun without burning. FDA is aware of a double-blind, randomized clinical study that showed a significant increase in sun exposure time of persons using high SPF sunscreens compared to persons using low SPF sunscreens (Ref. 14). In addition, two questionnaire-based surveys showed that sun exposure time is prolonged for persons using sunscreens compared to persons not using sunscreens (Refs. 15 and 16). By educating consumers about a sun protection program, we believe requiring this new proposed warning will decrease the likelihood of consumers spending more time in the sun when using a sunscreen.

The new proposed warning also informs consumers that use of sunscreens alone is not the sole measure of protection from UV exposure, even with the use of high SPF products that provide UVA protection. Although it is well established that sunscreens protect against UV radiation, the following factors affect the level of protection provided by a sunscreen for each individual:

- Variations between individuals,
- UV radiation absorption,
- Ability of sunscreens to adhere to and be absorbed by the skin,
- Exposure conditions, and
- Conditions of use (e.g., inadequate application amount or reapplication frequency).

Therefore, FDA agrees with the numerous groups that promote sunscreen use as part of a total sun protection program.

FDA reviewed the relationship between sunscreen use and skin cancer incidence in the scientific literature and did not find confirmatory evidence that sunscreens alone protect against the development of skin cancer. The incidence of skin cancer continues to rise in the United States. The incidence of the most serious form of skin cancer, malignant melanoma, grew 6.1 percent per year during the 1970s (Refs. 14 and 36). The rate is still rising an average 2.8 percent annually, with a rate of 14.3 percent per 100,000 persons in 1997. Melanoma is one of the top 10 cancers, by incidence, for persons with white skin. The American Cancer Society (ACS) estimated the following statistics concerning skin cancer in 2007 (Ref. 37):

- More than 1 million new cases of curable basal cell and squamous cell carcinomas would be detected,
- Approximately 59,940 new cases of malignant melanoma would be diagnosed, and
- An estimated 8,110 persons would die from melanoma and 2,000 persons would die from other skin cancers.

Skin cancer affects roughly the same number of people as all other cancers combined. In view of the continuing increase in the incidence of all types of skin cancer and the lack of data demonstrating that sunscreens alone prevent skin cancer, FDA considers the new warning important for the protection of the public health.

FDA is proposing that the new warning be required on all OTC sunscreen drug products except lip cosmetic-drug and lip protectant-sunscreen products subject to § 352.52(f). FDA continues to believe that all sunscreen products should have labeling to ensure that consumers are adequately protected against overexposure to UV radiation (64 FR 27666 at 27673). Thus, sunscreen products labeled for use only on specific small areas of the face and sold in small packages (i.e., sunscreen products subject to § 352.52(f)) must include the new warning. The only sunscreen products not required to include the new warning are those lip cosmetic-drug and lip protectant-sunscreen products subject to § 352.52(f), as proposed in § 352.52(f)(1)(ii). FDA is making this proposal because lip cosmetic and lip protectant products are often sold in packages that are substantially smaller than those of other products that fall under § 352.52(f). FDA believes requiring the new warning on lip cosmetic-sunscreen and lip protectant-sunscreen products may discourage manufacturers from marketing these products because it requires a significant amount of labeling space.

FDA has limited labeling requirements as much as possible for sunscreen products subject to § 352.52(f). However, FDA believes consumers are at great risk for UV-induced skin damage, including cancer, on the face. Therefore, consumers who purchase products specifically for use on the face need to be informed about the information contained in the new warning. Although these products are marketed in small package sizes, FDA has determined that the products' labeling needs to include this important information in order to protect consumers.

(Comment 20) One comment stated that consumers who use color cosmetics or facial moisturizers with sunscreens make the informed decision to purchase them as an additional benefit to their cosmetic use. The comment contended that a significant number of people with dark skin types, who do not burn easily, purchase sunscreens to provide protection from the sun damage that is not immediately recognizable. For these reasons, the comment requested claims such as the following:

- ''helps protect against casual or incidental or intermittent daily sun exposure''
- ''helps protect against the harmful effects of the sun''

Another comment acknowledged that facial makeups with sunscreen provide protection from sunburn, but that is not the primary reason why consumers use these products. The comment contended that requiring the ''sunburn'' indication would be inappropriate and misleading labeling for most facial makeups with sunscreen. The comment, instead, requested a claim such as ''protects against the harmful rays of the sun.''

FDA notes that the second comment acknowledged that facial makeups with sunscreen provide protection from sunburn. Not every consumer who uses color cosmetics or facial makeups with sunscreen meets the following criteria:

- Has a dark skin type, or
- Uses these products solely to provide protection from sun damage that is not immediately recognizable.

As noted in section III.D, comment 9 of this document, many consumers use facial products with sunscreen as their primary and only source of sunscreen protection for that area of the body. As discussed in section III.G, comment 16 of this document, sunscreen products will be required to bear a claim of low, medium, high, or highest UVB sunburn protection. FDA does not consider it inappropriate or misleading for color cosmetic or facial makeup products containing sunscreens to have this sunburn protection claim of low, medium, high, or highest.

Sunscreen products that provide UVA radiation protection may also bear a claim about the level of protection. In addition, all OTC sunscreen products, except lip cosmetic-drug and lip protectant-sunscreen products subject to § 352.52(f), will be required to bear the revised ''sun alert'' statement, which is now included in the ''Warnings'' section of the ''Drug Facts'' box. FDA considers the information in this new ''Warnings'' statement much more beneficial to consumers than the statements proposed by the comments. FDA rejected the terms ''casual, incidental, and intermittent,'' as explained in section III.G, comment 17 of this document.

H. Comments on Directions for Sunscreen Drug Products

(Comment 21) Several comments requested alternative directions for makeup with sunscreen products. One comment requested ''apply smoothly or evenly before sun exposure and/or as needed.'' The comment added that ''before sun exposure'' may not always be appropriate as these makeup products are not exclusively or even primarily used for protection against sun exposure. A second comment requested ''apply smoothly or evenly before sun exposure and reapply as needed.'' A third comment did not suggest any specific language, but requested flexibility to recognize the product's primary use as a makeup, while providing adequate information about the sunscreen component. This comment added that the direction to consult a doctor for children under 6 months of age was clearly unnecessary for facial makeup with sunscreen because these products cannot reasonably be expected to be used on children that age.

FDA agrees that flexibility is appropriate for the directions for makeup with sunscreen products. Elsewhere in this document, FDA is proposing to allow labeling modifications for makeup with sunscreen products used only on specific small areas of the face and sold in small packages (see section III.D, comment 9 of this document). Those modifications include modified directions for cosmetic lip products containing sunscreen that are within the scope of proposed § 352.52(f). FDA is not extending the proposed modifications to all makeup with sunscreen products. Makeup with sunscreen products not labeled only for specific small areas of the face may be applied to a large area of the face or other areas of the body. As explained later in this comment, FDA would have concerns with the modifications being applied to these products.

Whether intentional or not, makeup with sunscreen products may be the primary sunscreen for many consumers. A recent study examined sunscreen use patterns (Ref. 48). Participants were instructed to apply sunscreen every day. Of those who used sunscreen infrequently, the majority spent some time outdoors with 11 percent spending the majority of their time outdoors. These same participants explained that they did not believe sunscreen was necessary because of their planned activities. The authors cited this finding in advocating educating consumers on the need for sunscreen for frequent incidental sun exposure in addition to intentional sun exposure, such as sunbathing.

For these reasons, FDA considers it important that consumers using makeup with sunscreen products not labeled for use only on specific small areas of the face recognize that these products are sunscreens and use them appropriately to maximize UV protection. Therefore, FDA is not proposing modified directions for these makeup with sunscreen products.

(Comment 22) One comment requested that FDA require sunscreen manufacturers to provide accurate and appropriate instructions about how much sunscreen should be applied to the body. The comment also suggested that a warning about the dangers of sunburn from applying suboptimal amounts be included in sunscreen product labeling. A second comment stated that it was not aware of any study indicating that consumers use adequate amounts of sunscreen. The comment supplied data and other information concerning the dependency of the SPF value on the total quantity of sunscreen applied (Ref. 49).

Section 352.52(d)(1) currently provides manufacturers the option to select one or more of the following application terms for a sunscreen product: ''liberally, generously, smoothly, or evenly.'' Manufacturers may also include optional directions that state ''[bullet] reapply as needed or after towel drying, swimming, or (select one of the following: 'sweating' or 'perspiring').'' In the final rule, FDA had concluded that the directions in § 352.52(d)(1) to apply ''liberally'' or ''generously'' convey the appropriate message to ensure that consumers adequately apply the sunscreen (64 FR 27666 at 27679).

Several studies suggest that, in practice, consumers may apply amounts of sunscreen below the density of 2 milligrams/square centimeter (mg/cm^2), which is the amount of product required for the SPF determination in § 352.72(e) (proposed § 352.71(e)). These data suggest that consumers may apply as little as 0.5 to 1.0 mg/cm^2 (Refs. 50 through 54). One comment reported that, to achieve the rated protection over the whole body, a typical adult with a surface area of 1.73 square meters (m^2) would need to apply 35 milliliters (mL) of sunscreen, roughly one-third of a 4 oz bottle per application (Ref. 55). Studies indicate that SPF values determined at an application rate of 1 mg/cm^2 are approximately 50 percent of those determined at 2 mg/cm^2, and when applied at 0.65 mg/cm^2, the SPF values are 20 to 30 percent of those determined at 2 mg/cm^2 (Refs. 49, 50, and 51). Gasparro notes that statements such as ''apply liberally and frequently'' are too vague to be informative (Ref. 24).

FDA is concerned that, in practice, consumers may be getting less protection than the labeled SPF value and believes that further information should be included in the labeling for sunscreen drug products to reduce the likelihood of underapplication. FDA believes that this information is better communicated as revised product directions rather than a warning. FDA is, therefore, proposing to revise § 352.52(d)(1). The directions will continue to state that OTC sunscreen drug products should be applied ''liberally'' or ''generously'' because it would be cumbersome to specify quantitative amounts for all possible body areas and the various uses on the label. However, FDA is proposing to make optional the directions in § 352.52(d)(1)(i) to apply ''evenly.'' FDA believes that this term, if used alone, may not convey the appropriate message to ensure that consumers apply sufficient sunscreen. In addition, FDA is proposing to remove the term ''smoothly'' from § 352.52(d)(1)(i) because FDA considers that term to be vague and it may have different meanings to different consumers. FDA also believes this term is more likely to result in product underapplication.

In addition to labeling directing consumers to apply sufficient amounts of sunscreen, FDA is also proposing to revise the labeling requirements concerning reapplication of the sunscreen product. In § 352.52(d) of the FM, the general reapplication statement ''and as needed'' was the only required information. FDA made specific reapplication directions in § 352.52(d)(2) of the FM optional in an effort to equalize requirements between sunscreens with and without water resistant claims (64 FR 27666 at 27681). FDA now believes that more detailed reapplication directions must be included on all OTC sunscreen products, because sunscreens may be underapplied as suggested by the comments.

FDA came to this conclusion after reviewing studies concerning sunscreen reapplication as well as recommendations of public health organizations. Wright, et al. suggests that inadvertent sunburn may be due to the failure to use and reapply sunscreen appropriately (Ref. 56). Study subjects who reapplied sunscreen every 1 to 2 hours and after swimming did not report sunburn. Rigel et al. reported that, even under intense solar conditions, those reapplying an SPF 15

sunscreen every 2 hours or sooner were five times less likely to sunburn compared to those who reapplied every 2.5 or more hours (Ref. 57). The AAD (Refs. 38, 58, and 59), the ACS (Ref. 60), and the EPA (Ref. 40) recommend reapplying sunscreens every 2 hours or sooner and also recommend application to all exposed areas of the body (Refs. 60, 61, and 62).

Because the frequency of application appears to be critical for proper protection, FDA is proposing to add the statement ''apply and reapply as directed to avoid lowering protection.'' In addition, FDA is proposing to further revise the directions in § 352.52(d) to include the following reapplication statement: ''reapply at least every 2 hours.'' Likewise, for those products making a water resistant claim, FDA is proposing to include the number of minutes (i.e., 40 or 80) that the product maintains its water resistance before the ''swimming/sweating'' term. FDA believes these additional proposed directions will alert consumers about the hazards of using insufficient amounts of sunscreen product and encourage reapplication after the appropriate time. FDA considers these specific, informative reapplication statements, instead of ''and as needed,'' to be necessary on all OTC sunscreen products. FDA is also proposing the optional direction ''apply to all skin exposed to the sun.'' FDA is proposing that this direction be optional because we believe most consumers know to apply sunscreen to all exposed skin. However, if a sunscreen product can accommodate this direction, it will serve to remind consumers that all exposed skin is susceptible to UV damage. These proposed directions, as a whole, should serve to better protect consumers, particularly those who tend to underapply sunscreen, from overexposure to the sun.

Accordingly, FDA is proposing to change § 352.52(d) to read as follows:

(d) *Directions.* * * *

(1) *For products containing any ingredient in § 352.10.* (i) The labeling states ''[bullet] apply [select one of the following: 'liberally' or 'generously'] [and, as an option: 'and evenly'] [insert appropriate time interval, if a waiting period is needed] before sun exposure''.

(ii) The labeling states ''[bullet] apply and reapply as directed to avoid lowering protection''.

(iii) As an option, the labeling may state ''[bullet] apply to all skin exposed to the sun''.

(iv) The labeling states ''[bullet] children under 6 months of age: ask a doctor''.

(2) *For products that satisfy the water resistant or very water resistant testing procedures identified in § 352.76.* The labeling states ''[bullet] reapply after [select one of the following: '40 minutes of' or '80 minutes of' for products that satisfy either the water resistant or very water resistant test procedures in § 352.76, respectively] swimming or [select one of the following: 'sweating' or 'perspiring'] and after towel drying. Otherwise, reapply at least every 2 hours''.

(3) *For products that do not satisfy the water resistant or very water resistant testing procedures identified in § 352.76.* The labeling states ''[bullet] reapply at least every 2 hours and after towel drying, swimming, or [select one of the following: 'sweating' or 'perspiring']''.

As discussed in the FM (64 FR 27666 at 27679), manufacturers who have data to support different reapplication directions based on specific substantiation information may submit the information for approval of those directions via an NDA deviation as provided in § 330.11 (21 CFR 330.11).

I. General Comments on SPF Testing Procedure

(Comment 23) One comment suggested that the SPF test incorporate an amount of product that more closely reflects the amount applied by consumers. More specifically, the comment requested that FDA replace the 2 mg/cm^2 required in § 352.72(e) (proposed § 352.70(c)(5)) to a value between 0.5 and 1.0 mg/cm^2. The comment argued that the protection afforded during actual usage may be only one-quarter to one-half the labeled SPF value (see section III.H, comment 22 of this document). The comment also suggested that SPF could be stated using descriptive terms, such as ''light,'' ''moderate,'' or ''heavy'' protection, instead of a numerical value.

FDA is not proposing the suggested change in test method at this time. This issue was discussed in detail in the TFM (58 FR 28194 at 28264 to 28266). The majority of comments advocated continuing the use of an application density of 2 mg/cm^2. The current comment did not provide data demonstrating the suitability of a smaller test amount. FDA is concerned that a uniform distribution of sunscreen over the test area might be difficult using a smaller amount of sunscreen. Further, the standard application density used worldwide in the SPF test is 2 mg/cm^2 (Ref. 63).

FDA agrees that SPF values do not reflect exact levels of sunburn protection that consumers receive under actual use conditions. The required SPF test is a clinical test conducted with strict control over factors such as product application density. However, under actual use conditions, these factors are not controlled and vary greatly. The actual level of sunburn protection under consumer use conditions is affected by a number of factors. Some of the key factors are

- Application density,
- Reapplication frequency,
- Skin type (e.g., burns easily versus never burns),
- Time of day during sun exposure, and
- Geographical location during sun exposure.

Thus, SPF values reflect relative and not absolute levels of sunburn protection.

Although SPF values do not convey actual levels of sunburn protection, when comparing multiple sunscreen products, SPF values enable consumers to determine which products provide the most sunburn protection. For example, FDA believes most consumers would correctly identify an SPF 20 product as providing more sunburn protection than an SPF 10 product. Thus, lowering the sunscreen application density would not be necessary to more accurately reflect the degree of relative sunburn protection.

FDA agrees that, in addition to bringing SPF values closer to representing absolute levels of protection, lowering the sunscreen application density might also reduce some of the inaccuracies and limitations encountered when testing high SPF sunscreen products. Thus, FDA invites interested parties to submit data supporting a smaller application density for SPF testing of all sunscreen dosage forms in accordance with § 352.77. However, developing a single global method and labeling would require a coordinated effort between the regulatory agencies in many countries around the world. Because FDA does not have data to validate the SPF test using a lowering sunscreen density, FDA is proposing directions that we believe will encourage consumers to apply greater densities of sunscreen (i.e., closer to 2 mg/cm^2) (see section III.H, comment 22 of this document).

FDA does not find that there are sufficient benefits for using descriptors instead of numerical values for SPF on the PDP. Consumers are familiar with numerical SPF values from over 20 years of usage. As described in section III.G, comment 16 of this document, FDA believes that the use of descriptors in combination with numerical values on the PDP may be beneficial to consumer understanding of the level of sunburn protection provided by a product. Thus, as explained in comment 16, FDA is proposing to include a descriptive term of relative sunburn protection (i.e., low, medium, high, or highest) with the proposed sunburn protection statement in the ''Uses''

section and on the PDP. The intent of this dual descriptive and numerical sunburn protection measure is to allow consumers to more easily differentiate the level of sunburn protection provided by different sunscreen products. In addition, this proposed labeling for sunburn protection is similar to the proposed UVA protection labeling (see section III.G, comment 14 of this document).

FDA is also aware of sunscreen drug products marketed in dosage forms that may not be addressed by current SPF testing procedures. The SPF testing procedure described in § 352.72 (proposed § 352.70) references oils, lotions, creams, gels, butters, pastes, and ointments. FDA invites interested parties to submit SPF testing modifications for new dosage forms (e.g., mousses, foams, and towelettes) in accordance with § 352.77.

(Comment 24) One comment recommended a pass/fail (binomial) test to determine SPF values (Ref. 49). The test would demonstrate that subjects have no reaction to a quantity of UV energy equivalent to an expected SPF value (for products passing the test). For example, subjects being tested with a product with an expected SPF value of 30 would be dosed only at the SPF 30 level, and the product would either pass or fail. A product passing this test would actually have an SPF value of 30 or over, whereas a product failing this test would have an SPF value below 30. The comment argued that while the monograph SPF test is probably adequate for products with low SPF values, it is not adequate for testing high SPF products because differences in solar simulators can provide as much as a 200 percent variation in results depending on the formulation. The comment further argued that an impossibly high number of subjects would be required for the current SPF method to obtain a 95 percent confidence level and that the test exposes subjects to a potentially dangerous condition, sunburn.

According to the comment, the average MED for each skin type can be predicted from existing solar simulator calibration data. During the pass/fail test, each test subject is screened for skin type and then given a first day range of energy that does not exceed the expected MED. The comment proposed using a panel of five subjects. Using the MED information obtained on the first day, each subject is given four UV radiation exposures corresponding to the expected SPF value. Each subsite is then evaluated for erythema. If six or more of the 20 subsites show perceptible erythema, the product fails, as there would be less than a 95 percent probability the actual SPF value was higher than the expected SPF value. If less than six subsites show perceptible erythema, the product passes, as there would be greater than a 95 percent probability that the actual SPF value was more than the expected SPF value. The comment proposed the following:

TABLE 2.—PROBABILITY TABLE

No. of subjects	Maximum no. of failures	Probability
1 (n=4)	0	0.0625[1]
2 (n=8)	2	0.0352
3 (n=12)	3	0.0200
4 (n=16)	5	0.0383
5 (n=20)	5	0.0207

[1] n is not sufficient to make a 95 percent prediction

The comment further proposed that if all eight subsites of the first two subjects pass, then the product passes and the remaining three subjects would not be evaluated. The probability of this happening would be 1/256 unless the product is over the expected SPF value.

FDA agrees that, currently, there may not be enough experience and test data for products with SPF values of 30 and over on which to determine the sample size needed to obtain an acceptable 95 percent confidence interval. As discussed in section III.L, comment 37 of this document, to account for increased variability in SPF values for sunscreens with SPF values over 30, FDA proposes to increase the sample size to at least 25 subjects. Therefore, the comment may be correct in arguing that large numbers of subjects may be required for testing products with high SPF values. FDA believes that the pass/fail test has merit and could provide a reasonable substitute for the current SPF method for products with expected SPF value of 30 or higher. However, before the method can be accepted, method validation data are required that demonstrate the method can be performed satisfactorily by multiple laboratories using the same sunscreen formulation(s). FDA invites such data.

If the pass/fail method is accepted, FDA may stipulate that the method be used only for products with SPF values of 30 and higher because of the large number of subjects that would be required for high SPF products under the current test method. A pass/fail method would require fewer test subjects. Low SPF products can be adequately tested under the current method without large numbers of subjects. In addition, FDA would likely require that all 20 subsites be evaluated even if the first 2 subjects pass. Further, using standard probability computer software, FDA calculates that the values for the maximum number of failures in table 2 of this document for subjects one through five should be 0, 1, 2, 4, and 5, respectively, rather than the values provided by the comment.

FDA would also consider three modifications to the method described by the comment and invites comment. First, each subject may have test successes and failures due to multiple subsites on each subject. Statistically, these will not be independent observations, which is a condition needed for a binomial probability calculation. Therefore, FDA is considering that a test panel should consist of 20 to 25 subjects and that only one site be tested on each subject. A pass/fail determination would be made for each individual.

Second, as an alternate, a double sampling plan based on Taylor's *Guide to Acceptance Sampling* may replace the five-layered plan proposed by the comment (Ref. 64). With the double sampling plan, two subjects are tested simultaneously with up to a maximum of four subjects, each having four subsites tested. If no more than one of the first eight subsites has perceptible erythema, the product passes. If three to eight subsites have perceptible erythema, the product fails. If exactly two of the eight subsites have perceptible erythema, then the second group of two subjects is tested. If two to four subsites from four subjects have perceptible erythema, the product passes. Otherwise, the product fails. According to this scheme, if probability $p = 0.10$ that the product tested would produce any recognizable erythema, then the probability = 0.95 that the product will pass. If probability $p = 0.5$ that the product tested would produce any recognizable erythema, then the probability = 0.05 that the product will pass.

Third, an alternative to the probability calculation is a margin of error approach. With this method, a margin of error for the expected SPF value is defined before testing. The margin of error is used to determine the tolerability interval around the expected SPF value. The 90 percent confidence interval for the product's test result (one result per subject) must fall within the tolerability interval to be labeled with that SPF value. For example, if a 10 percent margin of error is claimed for a product with an expected SPF value of 40, then the tolerability interval would be 40 ± 4, or 36 to 44. If the related 90 percent confidence interval is from 37 to 43, an SPF value of 40 is assigned to the product. If the related 90 percent

confidence interval is from 35 to 45, an SPF value of 40 could not be assigned to the product and the product may be retested at an expected SPF of 30.

FDA invites discussion of these suggested modifications to the comment's pass/fail method for testing sunscreen drug products having an SPF value of 30 or higher.

(Comment 25) One comment described an in vitro method it developed for simultaneously predicting SPF and assessing photostability. The method utilizes a 150 watt xenon arc lamp to irradiate sunscreen applied at a level of 1 to 2 mg/cm^2 to a flat collagen membrane substrate placed in the opening of an integrating sphere attached to a spectroradiometer. The spectral irradiance of the source and the spectral irradiance of the substrate alone are measured from 290 to 400 nm, at 1 nm intervals. The spectral irradiance transmitted by the sunscreen/substrate combination is measured at 1 minute intervals until the total erythemal-effective dose transmitted by the sunscreen exceeds 1 MED, where 1 MED equals 0.02 erythema-effective Joules (J)/cm^2. Each 1 minute interval represents two to three MEDs. The time course of the sunscreen's SPF is then computed (Ref. 65). This information reveals the photostability of a sunscreen. If a sunscreen is photostable, it will not decompose when exposed to UV radiation, and the SPF will not change with increasing UV exposure. If a sunscreen is not photostable, it will decompose when exposed to UV radiation, and the SPF will decrease with increasing UV exposure. Another comment asked FDA to consider replacing the human SPF test with equivalent in vitro technology and chemical engineering, but did not suggest a suitable method.

FDA does not agree that an in vitro method is adequate to replace the in vivo SPF test. In vitro tests are generally inadequate as the sole measure of SPF because substrates cannot mimic sweating, skin absorption, or certain interactions with skin that influence SPF. Some sunscreen ingredients do not behave similarly in vitro and in vivo. At this time, the comment's method has not been validated, and the chosen substrate has not been demonstrated to possess penetration characteristics and surface chemistry similar to human skin.

The described in vitro method does have potential utility for measuring photostability of a sunscreen product. Measuring the erythemal-effective dose transmitted through the sunscreen in vitro over time seems like a reasonable approach. However, portions of the method require further exploration. Items such as the cut-off to define photostability need further explanation and validation. It should also be pointed out that the current SPF test method does not directly measure photostability, but it accounts for photostability. More specifically, the SPF value is determined after a sunscreen is exposed to UV radiation, so the SPF represents UVB protection provided by whatever fraction of the sunscreen has not decomposed.

FDA agrees that in vitro tests are generally rapid and less expensive than in vivo tests and, for SPF measurements, would reduce exposure of human subjects to UV radiation. FDA is willing to consider alternate methods for SPF testing if they are adequately supported with data and are shown to be equivalent to established in vivo methods by collaborative studies. If the methods are equivalent, then the same SPF values should be determined for each sunscreen tested according to the SPF method and the alternate method. The comments have not provided data from such studies. Therefore, FDA is not proposing to include the described in vitro method in the monograph at this time.

(Comment 26) Several comments urged FDA to revise § 352.72(h) and reinstate the requirement for determining MED at 16 to 24 hours after exposure, rather than 22 to 24 hours. The comments submitted data showing that, for an SPF 30 product and for the 8 percent homosalate standard, determining the MED at 16 or 24 hours does not result in any clinical or statistical difference in the SPF (Refs. 66 and 67). Comments argued that immediate pigmentation fades rapidly and does not interfere with MED readings. One comment further argued that the 16 to 24 hour time is universally accepted by the European Union, Australia, and Japan and FDA should adopt this time in the interest of international harmonization.

The Panel recommended that the MED be evaluated 16 to 24 hours after exposure (43 FR 38206 at 38262). FDA proposed a post exposure time of 22 to 24 hours based upon information provided by comments to the Panel's report that immediate pigmentation may persist with higher doses of UV radiation up to 24 hours or, in some cases, for 36 to 48 hours after prolonged exposure (58 FR 28194 at 28268 to 28269). Comments had indicated that immediate pigmentation might interfere with an investigator's perception of minimally perceptible erythema.

FDA agrees that these new data show no significant difference in MED readings at 16 and 24 hours. Thus, FDA is proposing to revise the MED determination time in §§ 352.72(h) and 352.73(c) (proposed §§ 352.70(c)(8) and 352.70(d)(3), respectively) from ''22 to 24 hours'' to ''16 to 24 hours.''

J. Comments on the Sunscreen Standard for SPF Testing Procedure

(Comment 27) Several comments suggested that standard controls with SPF values of 15 or higher be developed to test high SPF sunscreen products. One comment stated that such standards would improve test accuracy and provide a consistent and adequate benchmark for compliance. One comment mentioned use of a control SPF 15 formula routinely in SPF evaluation and considered it a more valuable control than the 8-percent homosalate SPF 4 standard. Another comment supplied ''round-robin,'' collaborative SPF testing data from 7 laboratories on a total of 153 subjects with 2 potential SPF 15 sunscreen standard preparations, ''Formulation A'' on 147 subjects and ''Formulation B'' on 146 subjects (Refs. 13, 68, and 69). The comment concluded that differences between the two preparations were not significant (p=0.653) but ''Formulation B'' was preferred due to its less complex formula and slightly more consistent results. The comment added that the data showed that different laboratories can obtain valid, reproducible results when testing high SPF sunscreens. Another comment stated that it provided test results on 20 subjects using an SPF 25 product as the control (Ref. 70). Three comments suggested that the European Cosmetic, Toiletry, and Perfumery Association (COLIPA) ''European low SPF Standard Code Number COL492/1 (formerly the DIN standard)'' be included in the OTC sunscreen drug product monograph as a permissible standard sunscreen preparation, in addition to the 8-percent homosalate standard, and that either standard should be allowed in the SPF testing procedures. The comments contended that this approach will serve to permit international marketing and eliminate duplicative testing. Another comment asked FDA to adopt the JCIA SPF 15 ''P3'' standard, but did not provide supporting data.

The comment concerning the SPF 25 control provided data from comparative tests on 20 subjects, using the 8-percent homosalate standard, an SPF 15 sunscreen drug product, and an SPF 25 sunscreen drug product (Ref. 70). FDA finds that this study is inadequate to support the comment's request because the study did not do the following:

- Include sufficient numbers of subjects,
- Address suitability of the standard across different laboratories, and
- Document some properties required in a sunscreen standard to test high SPF sunscreen products.

The following properties of a sunscreen standard were not addressed but need to be addressed:

- Low level of interlaboratory variation,
- Sensitivity to experimental error, and
- Ease of preparation with a reasonable degree of accuracy.

These data are also needed for the JCIA standard.

Although comments provided data on 20 subjects in each of 4 laboratories using the COLIPA COL492/1 standard, FDA is not proposing to include this standard as an alternate to the 8-percent homosalate standard because we do not believe that using the COL492/1 standard will make the monograph method comparable to the European method, as other differences exist between the two methods. For example, the monograph method requires 20 evaluable subjects, while the European method requires only 10 evaluable subjects. Therefore, the COL492/1 standard is a valid standard under the European method but may not be a valid standard under the monograph method. Finally, FDA finds that the 8-percent homosalate standard is a suitable control for testing sunscreen drug products with SPF 15 or below (see section III.J, comment 28 of this document).

FDA agrees with the comment that the submitted collaborative data from seven laboratories support ''Formulation B'' as an appropriate SPF 15 sunscreen standard. The mean SPF for ''Formulation B'' was 16.3 in 146 subjects tested, with 1.7 percent standard error of the mean, and laboratory means ranging from SPF 15.6 to 18.5. Therefore, FDA is proposing to include the ''Formulation B'' SPF 15 standard in the FM to be used for sunscreen drug products with an SPF value over 15 (optional for SPF values of 2 to 15).

(Comment 28) One comment noted that there are two recognized standard control formulations:

1. An 8-percent homosalate preparation with an SPF value of 4 (§ 352.70(b) of the FM), and

2. Formulation B (padimate O/oxybenzone) with an SPF value of 15.

The comment stated that the function of the standard formulation is quality assurance for method control and not as a calibration standard to bracket specific SPF ranges. The comment claimed that the 8-percent homosalate SPF 4 standard is appropriate to test products at any SPF level and that the choice of whether to use the SPF 4 or SPF 15 control formulation should rest with the manufacturer. Several other comments agreed with this comment.

Another comment provided data using the 8-percent homosalate standard to test product formulations with estimated SPF values of 15, 30, and 45 on 20 subjects (Ref. 67). The comment concluded that the data showed testing procedures in the FM can differentiate high SPF sunscreens using the homosalate SPF 4 standard. The comment requested that the homosalate SPF 4 standard be allowed to be used for products with an SPF value over or below 15.

FDA does not consider the data adequate to support the suggestion that the 8-percent homosalate standard currently used to evaluate sunscreen drug products with SPF values up to 15 is equally applicable to products with SPF values over 15 (Ref. 67). The study had the following deficiencies:

- Did not include sufficient numbers of subjects,
- Did not address suitability of the standard across different laboratories, and
- Did not document certain properties required in a sunscreen standard to test high SPF sunscreen products.

The following sunscreen standard properties were not addressed but need to be addressed:

- Low level of interlaboratory variation, and
- Sensitivity to experimental error.

FDA agrees that the two standards are method controls rather than calibration tools. As such, the standard used should approximate the expected SPF of the product being tested to better verify that all aspects of the testing method are performing properly at the expected SPF level.

Using the SPF 4 standard to measure SPF values over 15 is more likely to produce erroneous results than using a standard with an SPF of 15. In measuring SPF values over 15, much higher light energies (J/cm^2) are used in comparison to measuring SPF values below 15. Problems in the accurate quantitation of high light intensities may not be detected if the SPF 4 standard is used for SPF values over 15. While the SPF 4 standard may give acceptable results for products with SPF values over 15 in some studies, the extrapolation of these results to approximately 4 to 13 fold higher light energies used to test products with SPF values over 15 may be erroneous in other studies. Better assurance of an accurate SPF value is obtained by using a standard that is closer in SPF value to the sunscreen product being tested.

The use of an SPF 15 standard would be reasonable to test products with SPF values below 15. SPF 15 is in the middle (geometrically) of the 4 to 50 range. The ratio of SPF 15 to SPF 4 is 3.75, and the ratio of SPF 50 to SPF 15 is 3.33. Thus, there would be equal coverage of all ranges. Therefore, FDA is proposing that Formulation B may be used to test sunscreen drug products with SPF 2 and over, and is required for testing sunscreen drug products with SPF over 15 (proposed § 352.70(a)(1)(ii)). The 8-percent homosalate standard may be used for testing sunscreen drug products with SPF of 2 to 15.

(Comment 29) Several comments suggested that a modern, HPLC method is superior to the older spectrophotometric assay in § 352.70(c) of the FM. One comment provided technical information about the HPLC method and stated that it is now commonly used by analytical laboratories to assay sunscreen formulations (Ref. 71). Although this HPLC assay method was used in the study of two SPF 15 sunscreen standard preparations (see section III.J, comment 27 of this document), one comment noted that there are limited data on this method with the SPF 15 control formulation because FDA has not yet published this formula as an accepted standard.

FDA agrees that an HPLC method is superior to the spectrophotometric method, which was originally published by FDA in 1978, in specificity and precision. Validation data provided by the comment documented the following:

- Specificity,
- Accuracy,
- Limit of detection,
- Linearity,
- Precision, and
- Reproducibility of the method.

The validation data included chromatograms and demonstrated that the HPLC method is suitable for both the SPF 4 and SPF 15 standards. Further, FDA validated the method in its laboratories and concludes that the method is acceptable for quality control and regulatory purposes (Ref. 72). Finally, the spectrophotometric method has not been validated for the SPF 15 standard, and the HPLC method has been validated for both the SPF 4 and SPF 15 standards. Therefore, FDA is proposing to revise § 352.70 to replace the outdated spectrophotometric method with the HPLC method and to

use the HPLC method to assay both the SPF 4 and SPF 15 standards.

(Comment 30) Two comments disagreed with the requirement in § 352.70(a) for concomitant use of a standard sunscreen for each SPF test. One comment suggested that a standard could be run twice yearly. Another comment suggested that data to evaluate proper laboratory test procedures could be obtained from panels of a standard run as part of ''the ongoing laboratory operation.'' A third comment stated that a standard preparation should be run each time an SPF determination is made.

FDA discussed this issue in comment 78 of the TFM (58 FR 28194 at 28253 to 28254). FDA disagreed with one comment that the standard could be run once or twice a year and reaffirmed the Panel's recommendation that concomitant testing is necessary in SPF determinations to ensure uniform evaluation of OTC sunscreen drug products and to serve as an internal indicator of experimental errors. The comments requesting a change did not provide any supporting data. In the absence of supporting data, FDA is not persuaded to change the concomitant use requirement in § 352.70(a).

(Comment 31) One comment suggested that there is a need for a specific source to maintain and supply sunscreen standards. The comment contended that a few testing laboratories are reporting differences in the tested SPF of the 8-percent homosalate standard preparation depending on whether the standard is prepared by the laboratory or purchased from one company that manufactured this standard. The comment stated that either the testing procedures or the standard itself have changed since the original formula was published (earlier standard SPF values were 3.7/3.8 to 4.2/4.3 with an average of 4.1, while current values are 4.3 to 4.9/5.0).

Data supporting the reliability and wide acceptance of the 8-percent homosalate standard preparation were previously discussed in the TFM (58 FR 28194 at 28250 through 28252). The comment did not provide any data to support its contention concerning discrepancies in the SPF of 8-percent homosalate standard preparations and FDA is not aware of any new data that support the need for a specific source to maintain and supply this standard. The standard is a control to validate the testing procedure, equipment, and facilities rather than a calibration tool for setting SPF values of sunscreen products. FDA considers the parameters established in § 352.70 of the FM adequate to assure a uniform standard and is not requiring that a specific source maintain and supply the sunscreen standard at this time.

K. Comments on Artificial Light Sources for SPF Testing Procedure

(Comment 32) Several comments suggested that FDA replace the specifications in § 352.71 that state ''sun at a zenith angle of 10°'' and ''less than 1 percent of its total energy output contributed by nonsolar wavelengths shorter than 290 nm'' with the COLIPA table of ''percent erythemal contribution'' as the spectral power distribution standard for the light source used in the SPF test procedures (Ref. 73). The comments suggested that the spectra of currently used solar simulators (especially around 290 nm and above 350 nm) could cause overestimation of SPF values for high SPF sunscreens. Because shorter wavelengths can make a very large contribution to erythema, the comments stated that small errors in the 290 nm region of solar simulator spectra could have considerable effects. The comments noted that spectral power deficiencies above 350 nm may give artificially high SPF values for sunscreen drug products that absorb poorly in the long wavelength UVA region.

The comments added that there is general agreement in the industry that § 352.71 should be revised to permit compliance with the COLIPA standard for solar simulators. The comments further recommended one modification to the COLIPA standard: The energy for wavelengths below 290 nm should be limited to ''less than 0.1 percent'' rather than ''less than 1.0 percent,'' as stated in the COLIPA standard. The comments stated that a more restrictive specification of ''0.01 percent,'' as mentioned by FDA (65 FR 36319 at 36321), would result more in testing the limits of the measurement spectroradiometer rather than the true output of the solar simulator. One comment that supported the COLIPA standard subsequently suggested that the spectral limits be further narrowed to prevent excessive variability of SPF values for certain sunscreen products (Ref. 74).

One comment discussed the calculations to obtain the source spectral specification according to COLIPA (Ref. 73). In the COLIPA table, the source spectral specification is described in terms of cumulative erythemal effectiveness by successive wavebands. The erythemal effectiveness of each waveband is expressed as a percentage of the total erythemal effectiveness from 250 nm to 400 nm, or as the Percentage Relative Cumulative Erythemal Effectiveness (%RCEE). According to the COLIPA specifications and consistent with § 352.71, wavelengths below 290 nm should be excluded from any source by appropriate filters. Likewise, wavelengths above 400 nm should be limited as much as possible and are not included in the calculation of %RCEE. Because RCEE values are calculated as relative percentages, measuring the spectral irradiance in absolute energy units is not necessary. Relative units are sufficient. The spectral irradiance of the source is multiplied by the Commission International de L'Eclairage (CIE) (1998) standard skin erythemal action spectrum to obtain the erythemal effectiveness of the source. The spectral erythemal effectiveness values of the source spectrum are then integrated from 250 nm to the various successive reference wavelength values shown in the COLIPA table in order to produce the cumulative erythemal effectiveness for each spectral waveband, and the total erythemal effectiveness is calculated up to 400 nm. Finally, the %RCEE is calculated at the reference waveband as the percentage ratio of the cumulative erythemal effectiveness in each of these wavebands to the total integrated value from 250 nm to 400 nm.

Based on these calculations, the COLIPA table includes limits up to 400 nm. In contrast, when FDA requested comments on this issue, we included a modified COLIPA table that includes limits up to 350 nm (65 FR 36319 at 36321). However, the modified COLIPA table published by FDA was erroneous. FDA agrees with the comment (and COLIPA) that it is necessary to include all UV erythemal wavelengths (i.e., up to 400 nm) when standardizing solar simulator output. As argued by the comment, the erythemal contribution from long-wavelength UVA radiation (i.e., 350 nm to 400 nm) can become important when a high SPF product is tested. However, FDA believes that the limits for the 290 to 350 waveband should be changed from 93.5 to 99.0 percent to 93.5 to 98.5 percent. This modification will address some of the errors in SPF that are attributed to the lack of match between the solar simulator and actual solar spectra. FDA invites comments on these proposed changes.

FDA does not agree, at this time, with the comment's suggestion to further narrow the COLIPA standard to the spectral limits that it proposed. The comment based its suggestion on a theoretical argument and did not supply the complete emission spectra of the

four solar simulators used in its two referenced studies. There may be significant differences in the 290 to 350 nm range in these studies that can account for the reported differences in SPF test results. Further, FDA has concerns about the ability of currently used solar simulators to meet the comment's suggested spectral standard and invites comments on the changes suggested by the comment.

FDA agrees with the comments that the COLIPA approach provides a more appropriate description for solar simulators. FDA's original proposal that solar simulators have a spectral power distribution ''similar to sunlight at a zenith angle of 10°'' is nonquantitative and may not be practical, considering the types of solar simulators that are generally available. Accordingly, FDA is proposing to revise the first part of § 352.71 (proposed § 352.70(b)) as follows:

(b) *Light source (solar simulator)*—(1) *Emission spectrum.* A solar simulator used for determining the SPF of a sunscreen drug product should be filtered so that it provides a continuous emission spectrum from 290 to 400 nanometers (nm) with * * * the following percentage of erythema-effective radiation in each specified range of wavelengths:

SOLAR SIMULATOR EMISSION SPECTRUM

Wavelength range (nm)	Percent erythemal contribution
< 290	< 0.1
290–310	46.0–67.0
290–320	80.0–91.0
290–330	86.5–95.0
290–340	90.5–97.0
290–350	93.5–98.5
290–400	93.5–100.0

(Comment 33) Several comments suggested the following revisions to the light source (solar simulator) requirements in § 352.71:

- Delete the ''out of band'' specification that not more than 5 percent of a solar simulator's total energy output can be contributed by wavelengths longer than 400 nm.
- In place of this 5 percent ''out of band'' limitation, allow a limit such as 1,250 to 1,500 watts/square meter (W/m^2) on the total solar simulator irradiance delivered to the skin for all wavelengths.

One comment provided data comparing solar simulators with and without a 50 percent neutral density filter to demonstrate that there is no measurable impact of heat load on the outcome of SPF testing (Ref. 13). The comment stated that thermal overload does not occur for COLIPA-compliant solar simulators operated at or below a total irradiance limit of 1,500 W/m^2. The comments added that the ''out of band'' specification is not possible with existing solar simulators and new systems would need to be designed, tested, manufactured, and distributed to provide equipment capable of meeting this specification. The comments concluded that replacing the ''out of band'' specification with a limit would improve the testing of all products, including high SPF products.

FDA believes that it is important to limit total energy delivered to the skin during the SPF test so that skin temperature does not reach a point that may compromise dose reciprocity. FDA concurs with the comments and is proposing to replace the ''out of band'' specification in § 352.71 (proposed § 352.70(b)) with a limit of 1,500 W/m^2 on total solar simulator irradiance between 250 and 1,400 nm.

(Comment 34) Two comments recommended that FDA change the solar simulator specification in § 352.71 from ''good beam uniformity (within 10 percent) in the exposure plane'' to ''the delivered dose to the UV exposure sites be within 10 percent of the prescribed dose with good beam uniformity'' (without defining ''good beam uniformity''). The comments contended that although ''reasonable'' or ''good'' beam uniformity is desirable, beam uniformity within 10 percent is virtually impossible to measure or achieve for the vast majority of solar simulators.

FDA agrees that ''dose'' accuracy is a critical variable and the delivered dose to the UV exposure sites should be within 10 percent of the prescribed dose. Because FDA considers quantification of ''good beam uniformity'' to be an important issue, it is keeping a specification for this parameter. However, FDA believes that a specification of 20 percent is more achievable than the proposed 10 percent. Beam uniformity can be measured with broadband UV detectors that have been modified to provide a small input aperture to the detector. For example, for a single beam simulator with a subsite exposure area of approximately 1 cm^2, an appropriate input aperture would be 0.25 cm^2. Beam uniformity can then be checked by making a measurement in the center of each of the four quadrants of the exposure field. These readings should be within 20 percent of the peak reading. The same principle can be applied to larger exposure fields. Additionally, the average of these four readings should be within 10 percent of the prescribed dose for a given exposure site. In addition, FDA is proposing a requirement that places a quantifiable limit of 20 percent on time related fluctuations of the radiation emissions of the solar simulator.

Accordingly, FDA is proposing to revise portions of § 352.71 (proposed § 352.70(b)(2)) to read as follows:

(2) *Operation.* A solar simulator should have no significant time related fluctuations (within 20 percent) in radiation emissions after an appropriate warmup time and good beam uniformity (within 20 percent) in the exposure plane. The average delivered dose to the UV exposure site must be within 10 percent of the prescribed dose.

(Comment 35) Several comments recommended that the last sentence of § 352.71 be modified to include additional requirements for the periodic testing of solar simulators. The comments suggested that periodic measurements be made twice a year and that measurements be done after changes in the optical filtering components.

FDA agrees with the comments and is proposing to revise the last part of § 352.71 (proposed § 352.70(b)(3)) to read as follows:

(3) *Periodic measurement.* To ensure that the solar simulator delivers the appropriate spectrum of UV radiation, the emission spectrum of the solar simulator must be measured every 6 months with an appropriate and accurately calibrated spectroradiometer system (results should be traceable to the National Institute for Standards and Technology). In addition, the solar simulator must be recalibrated if there is any change in the lamp bulb or the optical filtering components (i.e., filters, mirrors, lenses, collimating devices, or focusing devices). Daily solar simulator radiation intensity should be monitored with a broadband radiometric device that is sensitive primarily to UV radiation. The broadband radiometric device should be calibrated using side by side comparison with the spectroradiometer at the time of the semiannual spectroradiometric measurement of the solar simulator. If a lamp must be replaced due to failure or aging during a phototest, broadband device readings consistent with those obtained for the original calibrated lamp will suffice until measurements can be performed with the spectroradiometer at the earliest possible opportunity.

L. Comments on the Design/Analysis of SPF Testing Procedure

(Comment 36) Several comments contended that the series of seven exposure doses in § 352.73(c) should be modified to eliminate the two doses placed symmetrically around the middle exposure. One comment provided data comparing the seven-exposure series against the five-exposure series and concluded that the seven-exposure series did not increase the precision of the test (Ref. 66).

Comments also argued that the seven-exposure series would require longer testing times, thus increasing exposure risk and discomfort to subjects, and that the five-exposure series is as accurate as the seven-exposure series even at high SPF values.

FDA discussed its rationale for seven versus five exposure doses in the TFM (58 FR 28194 at 28269 to 28272). FDA sought an exposure format that would provide better accuracy and precision to SPF measurements, particularly at higher SPF values. FDA reasoned that the seven-exposure series in § 352.73(c), with two additional exposures symmetrically placed around the middle exposure of the geometric series, would increase precision and eliminate possible overestimation of the true SPF value of a product with a high SPF.

FDA has evaluated the data and other information submitted by the comments and agrees they demonstrate that the additional two exposure doses do not make the test more precise. Therefore, FDA is proposing to modify § 352.73(c) (proposed § 352.70(d)(3)) as follows:

* * * Administer a series of five UV radiation doses expressed as J/m²-eff (adjusted to the erythema action spectrum calculated according to paragraph (d)(1) of this section) to the subsites within each test site on a subject using an accurately calibrated solar simulator. The five UV doses will be a geometric series as described in paragraph (d)(2) of this section, where the middle exposure represents the expected SPF. For products with an expected SPF less than 8, use exposures that are the product of the initial unprotected MED times 0.64X, 0.80X, 1.00X, 1.25X, and 1.56X, where X equals the expected SPF of the test product. For products with an expected SPF between 8 and 15, use exposures that are the initial unprotected MED times 0.69X, 0.83X, 1.00X, 1.20X, and 1.44X, where X equals the expected SPF of the test product. For products with an expected SPF greater that 15, use exposures that are the initial unprotected MED times 0.76X, 0.87X, 1.00X, 1.15X, and 1.32X, where X equals the expected SPF of the test product. * * *

(Comment 37) Several comments suggested changes to the number of subjects per test panel in § 352.72(g). One comment suggested deletion of the phrase ''with the number fixed in advance by the investigator.'' The comment reasoned that if the first 20 subjects provided data that can be evaluated, risk to human subjects could be curtailed by not impaneling another 5 subjects. Other comments recommended using 10 to 20 subjects, arguing that the criterion for accuracy should not be the number of subjects, but the relative deviation of individual SPF measurements. One comment used absorbance instead of the SPF value to calculate the number of subjects required for high SPF products and proposed a binomial test method to reduce the number of subjects (see section III.I, comment 24 of this document). Another comment stated that the 20 of 25 subject limitation may be an issue for products with high SPF values due to the high variability in the responses obtained and suggested that the number of subjects be increased when evaluating sunscreen products with high SPF values.

As discussed in section III.I, comment 24 of this document, the binomial test method deserves further investigation and may prove to be a reasonable approach as additional data and experience become available. In addition, based on the current SPF test method, FDA agrees with the comment recommending deletion of the requirement to fix the number of subjects per panel in advance. This requirement is unnecessary because the panel is limited to a range of 20 to 25 subjects (under current § 352.72(g)). Thus, if 20 subjects produce valid data in accordance with proposed § 352.70(c)(9), then it would be unnecessary to test additional subjects. In addition, some subjects may not produce valid data in accordance with proposed § 352.70(c)(9) (e.g., no erythema produced), requiring testing of additional subjects (not exceeding 25 subjects). FDA agrees that the number of subjects should be based on error about the mean SPF, but disagrees that the minimum number of subjects can be lowered to 10. As described later in this comment, FDA has reevaluated the proposed minimum number of subjects based on error about the mean SPF.

FDA agrees with one comment that more subjects are needed when testing products with high SPF values. FDA believes that a minimum sample size of 20 subjects is adequate for products with an expected SPF value of 30 or less. However, current data and experience with products having SPF values over 30 are not sufficient to determine an appropriate sample size. Therefore, to account for increased variability in SPF values for sunscreens with SPF values over 30, FDA proposes to increase the sample size to at least 25 subjects. FDA invites data demonstrating an appropriate panel size for sunscreens with SPF values over 30. At this time, FDA is proposing to revise § 352.72(g) (proposed § 352.70(c)(7)) as follows:

(7) *Number of subjects*—(i) *For products with an expected SPF value under 30.* A test panel shall consist of 20 to 25 subjects with at least 20 subjects who produce valid data for analysis. Data are valid unless rejected in accordance with paragraph (c)(9) of this section. If more than 5 subjects are rejected based on paragraph (c)(9) of this section, the panel is disqualified, and a new panel must be created.

(ii) *For products with an expected SPF of 30 or over.* A test panel shall consist of 25 to 30 subjects with at least 25 subjects who produce valid data for analysis. Data are valid unless rejected in accordance with paragraph (c)(9) of this section. If more than 5 subjects are rejected based on paragraph (c)(9) of this section, the panel is disqualified, and a new panel must be created.

In the 1978 advance notice of proposed rulemaking (ANPRM), the Panel recommended that studies enroll at least 20 subjects, adding that ''the standard error shall not exceed ± 5 percent of the mean'' (43 FR 38206 at 38261). Following publication of the ANPRM, FDA held a public meeting on January 26, 1988 (52 FR 33598 at 33600 to 33601). During that meeting, attendees argued the following four points related to the number of subjects:

1. Test panels should consist of at least 20 subjects.

2. The size of the test panel should be fixed in advance.

3. The limitation that the standard error should be less than ± 5 percent should not apply.

4. The testing procedures should make it clear that the addition of subjects to the test panel to achieve the desired minimum is acceptable under specific conditions (58 FR 28194 at 28267).

In the 1993 TFM, FDA based § 352.72(g) on these comments and the Panel's recommendation.

The calculations of the sample size and confidence interval in § 352.72(g) are based on the assumption that there is a normal distribution about the mean (i.e., a bell curve). Based on this assumption, the t-test is used for statistical analysis. Based on the t-test, FDA calculated that a panel of 20 subjects should result in an acceptable error about the mean. However, in some cases, a panel of 10 subjects would probably result in an error about the mean that is unacceptably large. There is inherently higher variability in testing and, consequently, larger error about the mean for products with high SPF values. Therefore, FDA believes a greater number of subjects is necessary when testing products with high SPF values. FDA believes a panel of 25 to 30 subjects should result in an acceptable error about the mean for products with high SPF values. FDA invites additional data demonstrating adequate numbers of subjects, especially for products with high SPF values.

(Comment 38) One comment stated that one factor affecting the SPF of a

product is the erythemal threshold of the skin, or MED(US). The comment argued that SPF decreases with increasing erythemal threshold. The comment maintained that, because MED(US) varies only with skin type, the MED(US) of each subject in a test group should be within reasonably similar limits. The comment suggested that the MED(US) of each subject should be 50 to 150 percent of the median MED(US). The comment also suggested that subjects with an MED(US) that is twice the median should be excluded regardless of skin type.

FDA is not proposing the revisions suggested by the comment. FDA based § 352.73(b), which describes determination of an MED(US), on the Panel recommendation in the ANPRM. The procedure for determining MED(US) requires irradiation of subjects with a geometric series of UV doses. When developing this procedure, the Panel explained that the geometric series provides the same relative level of uncertainty independent of the subject's sensitivity to UV light (i.e., independent of skin type) (43 FR 38206 at 38266). Thus, the Panel disagreed that skin type affects MED(US). The comment did not provide any data or other information demonstrating that skin type, in fact, affects MED(US). FDA is not aware of any data demonstrating this phenomenon. FDA will revise the proposed test criteria if we receive data or information demonstrating that the criteria are not appropriate or other criteria are more suitable.

(Comment 39) Several comments urged FDA to reduce the minimum 1 cm^2 test subsite area in § 352.72(d)(2). One comment proposed the minimum test subsite area be decreased to 0.5 cm^2. Two comments suggested that the test subsite area be defined by minimum diameters of 0.8 cm (circular area of 0.5 cm^2) and 0.15 cm (circular area of 0.017 cm^2), respectively.

The comment supporting the 0.5 cm^2 test subsite area referenced a study published in 1987 (Ref. 75) that was mentioned in relation to artificial light sources in comment 86 of the TFM (58 FR 28258 to 28261). This study was designed to evaluate the FDA sequential technique of dosing using a single-port solar simulator (SPSS), a series sequential method using a multi-port xenon arc solar simulator (MPSS), and the Deutsches Institut für Normung (DIN) simultaneous technique of dosing using an Osram Ultravitalux lamp. Five sunscreen formulations with SPF values from 4 to 15 were tested. The authors suggested that there was little systematic difference in estimates obtained using the SPSS and MPSS, but there was a large systematic deviation between the FDA and DIN methods. As this study was not designed specifically to compare irradiation areas, three different test subsite areas were used, and none was 0.5 cm^2. FDA cannot determine the suitability of a 0.5 cm^2 test subsite area compared to a 1 cm^2 test subsite area based on this study.

The comment advocating the 0.8 cm test subsite diameter argued that setting a lower area limit has the following four benefits:

- Does not preclude the use of larger irradiation areas,
- Will not affect the accuracy of resulting measurements,
- Permits lower wattage lamps as well as liquid light guides that have apertures of 0.8 cm diameter, and
- Provides more skin area for testing.

The comment provided statistical analysis of a study comparing multi-port and single-port solar simulators (Ref. 66). SPF 15 or SPF 4 products were tested along with the homosalate standard sunscreen. Two subsite areas were exposed to the multi-port solar simulator, and two were exposed to the single-port solar simulator. The comment concluded that similar SPF values are determined using the two types of solar simulators. However, the study report did not include details such as subject selection, product application, or specifications for the solar simulators. More importantly, the study report did not specify the size of each subsite. Thus, FDA cannot draw any conclusions regarding appropriate test subsite area from the submitted study.

The comment supporting the 0.15 cm test subsite diameter referenced two studies (Ref. 76). Significant discrepancies in the information submitted for the first study prevented evaluation of this study. The comment did not submit full details of the second study. Therefore, FDA could not reach any conclusions from the submitted studies.

FDA agrees, in principle, with the advantages of a smaller test subsite area. The Panel stated that, depending on instrumental design, irradiation test subsite areas less than 1 cm^2 can be utilized and that test subsite diameters greater than 0.4 cm present no difficulty in determining skin erythema (43 FR 38206 at 38260). While FDA does not consider the information provided by the comments adequate to support the suggested test subsite areas, it recognizes that considerable advances have been made since the Panel met. However, FDA requires data demonstrating that the monograph test produces valid and reproducible results using a smaller test subsite area before amending the monograph test. FDA will consider a reduction in test subsite area if adequate supporting data are provided. The studies should do the following:

- Compare the smaller subsite area to 1 cm^2 on the same subjects,
- Utilize high SPF products as well as products with SPF values below 15, and
- Demonstrate comparable results among several laboratories.

(Comment 40) Several comments either agreed or disagreed with the blinding procedures for the application of test materials described in § 352.72(e). One comment stated that unblinded SPF testing is bad science, and that exposure sites within test areas should always be randomized no matter how many products are being tested. Another comment stated that the blinding procedure is an unnecessary complication and does not contribute to the accuracy of the test. One comment agreed that, in order to approximate true blinding, the individual who grades erythemal responses should not be the same clinician who applied the test materials. Another comment contended that it is not reasonable to randomly irradiate test sites with varying doses of UV radiation. One comment recommended making the use of finger cots optional because some product vehicles are incompatible with finger cot material. Another comment suggested that the amount of product remaining on the finger cot is a source of variability in the SPF test and suggested that the extent of this variability be fully evaluated.

FDA agrees with the comments that favor blinding and randomization and is not proposing to remove the blinding and randomization requirements from § 352.72(e) (proposed § 352.70(c)(5)). According to § 352.72, blinding and randomization is required only when two or more sunscreen drug products are being evaluated at the same time. Because a test product is always tested in conjunction with the standard sunscreen, FDA proposes to delete the statement, ''If only one sunscreen drug product is being tested, testing subsites should be exposed to varying doses of UV radiation in a randomized manner.'' Section 352.72(h) (proposed § 352.70(c)(8)) specifies that the person who evaluates the MED responses must not be the same person who applied the sunscreen or administered the dose of UV radiation. The comments that disagreed did not provide evidence demonstrating that these requirements are unnecessary.

With regard to the suggestion that the use of finger cots be made optional, the

Panel's review of data found that numerous investigators have obtained more reproducible results by spreading a product using a finger cot than by spreading with a glass or plastic rod (43 FR 38206 at 38261). FDA agrees with the comment that some formulations may be chemically incompatible with latex finger cots, but there are finger cots composed of other materials that should be compatible with these sunscreens. Therefore, to increase reproducibility in sunscreen application, FDA is proposing to revise the application requirement in § 352.72(e) (proposed § 352.70(c)(5)) to read as follows:

* * * Use a finger cot compatible with the sunscreen to spread the product as evenly as possible. Pretreat the finger cot by saturating with the sunscreen and then wiping off material before application. Pretreatment is meant to ensure that sunscreen is applied at the correct density of 2 mg/cm^2.

FDA urges manufacturers of sunscreen drug products to investigate the extent of variability in the SPF test that may be caused by various applicators.

(Comment 41) One comment addressed illumination at the test site in § 352.72(h) and recommended that a level of at least 1,000 lux be used. The comment contended that 450 to 550 lux is too low to provide adequate illumination for reading erythema.

As discussed in the TFM, the Panel recommended an incandescent or warm fluorescent illumination source but did not specify a required illumination level (58 FR 28194 at 28269). In the TFM, FDA agreed with the Panel about the illumination source. FDA also proposed that the illumination level be 450 to 550 lux. The comment did not provide any data to support its contention that 1,000 lux is the appropriate illumination level. Thus, FDA is not revising the lux range in § 352.72(h) (proposed § 352.70(c)(8)) at this time. FDA invites data and information on levels of illumination currently used to evaluate MED responses in SPF testing laboratories and will consider adequately supported alternatives.

(Comment 42) One comment stated that the third sentence in § 352.73(b) should be modified to read: ''* * * wherein each exposure dose is 25 percent greater than the previous exposure dose to maintain the same relative uncertainty * * *.'' The comment explained that defining the exposure dose in terms of ''time'' is incorrect.

FDA discussed the Panel's definition of dose in terms of time intervals in comment 84 of the TFM (58 FR 28194 at 28256 to 28257). FDA stated that it is more accurate to express dose as the ''erythema-effective exposure,'' in units that define the total amount of erythema-effective energy applied to the testing subsite (i.e., as J/m^2). FDA discussed replacing ''exposure time interval'' with ''erythema-effective exposure (dose),'' but inadvertently used ''exposure time interval'' instead of ''dose'' in § 352.73(b). FDA agrees that § 352.73(b) (proposed § 352.70(d)(2)) should be modified and is amending this section as the comment suggested.

(Comment 43) Several comments suggested an alternative statistical procedure for calculating product SPF values and PCD in current § 352.73(d). The comments argued that the procedure described in the FM would result in significant lowering of SPF values. The comments advocated clinical equivalency testing (i.e., using a lower one-sided 95 percent confidence interval or a one-sided t test, with a delta of 5 percent). The comments noted that an upper and lower bound equivalency procedure with a delta of 20 percent would be an appropriate procedure. The comments added that SPF is not a precise value, but rather a valid estimate of product performance. Another comment suggested using the mean of the results to find the actual number and then round-off (either up or down) to the nearest whole number.

FDA is not proposing to modify the calculation of product SPF values and PCD in § 352.73(d) (proposed § 352.70(d)(4)) at this time. The distinct advantage of the t-test is that it provides a simple computational procedure for a statistical test that makes inferences about the population. The SPF is determined to be the largest whole number that is excluded by a lower one-sided 95 percent confidence interval. Simply finding a mean value, as one comment suggested, is not adequate because such a value does not provide information about the validity of the test (e.g., standard deviation) that should be taken into consideration.

FDA's evaluation of the equivalency testing approach for calculating SPF values indicates the method is less stringent than the FM method. The proposed equivalency test is essentially testing the following hypothesis:

H_0: $\mu \leq 0.95L$ versus H_a: $\mu > 0.95L$

where: H_0 = null hypothesis

H_a = alternative hypothesis

μ = population mean

L = confidence limit

FDA acknowledges that the equivalency test may be a valid method for determining SPF. In many cases, the same SPF would be determined for a sunscreen using either the equivalency test or the FM method. However, in some cases, a higher SPF would be determined for a sunscreen using the equivalency test than would be determined using the FM method. By contrast, a higher SPF would never be determined for a sunscreen using the FM method than would be determined using the equivalency test. Thus, the FM method results in a more conservative SPF value than the equivalency test. FDA believes it is in the best interest of public health to label sunscreens with the more conservative SPF value. If FDA adopted the equivalency test after over 30 years of using the FM method, consumers may, in some cases, overestimate the protection provided by a sunscreen based on a higher SPF number resulting from the equivalency test.

M. General Comments on UVA Testing Procedure

(Comment 44) Many comments discussed UVA radiation action spectra and skin damage (erythema, photocarcinogenesis, DNA damage, photosensitivity reactions, photoaging, mutagenicity, and immunosuppression). Some comments described various types of solar-induced skin damage and the wavelengths contributing to the specific biological events. Some comments stated that UVA II radiation (320 to 340 nm) is much more damaging than UVA I radiation (340 to 400 nm).

Other comments stated that there is presently no convincing evidence that the action spectra for damage from UV radiation have been clearly defined. One comment stated that until the separate dangers and risks of each portion of the UVB and UVA radiation action spectra are precisely and scientifically identified and quantified, FDA should consider the entire UVA radiation range as having significant biological risk. Another comment stated that protection against all UVA radiation wavelengths would seem to be both desirable and prudent considering the present state of our knowledge.

FDA agrees that the action spectra for various harmful effects on human skin from chronic UVA radiation have not been clearly defined and that it may be misleading to associate damage with any specific action spectrum based upon current knowledge. Information provided by comments suggests a relatively greater role for UVA radiation than UVB radiation in long-term sun damage even though there is little consensus about the amount of UVA radiation protection required. Therefore, FDA is proposing UVA radiation test methods that assess protection throughout the UVA spectrum (see section III.N, comment 45 of this document).

N. Comments on UVA Testing Procedure Design and Testing Criteria

(Comment 45) FDA is proposing that both an in vitro and an in vivo test be conducted to determine UVA radiation protection. The proposed in vitro test is the ratio of long wavelength UVA absorbance (UVA I) to total UV absorbance (i.e., UVB + UVA). The proposed in vivo test is the PPD test, which is similar to the SPF test except the endpoint is pigment darkening rather than erythema. FDA is proposing that UVA labeling consist of a UVA rating reflecting both the in vitro and in vivo test results. The rating will be the lowest ''high'' protection, then the sunscreen would be labeled as providing ''medium'' UVA protection.

FDA is proposing these UVA testing requirements based on many comments submitted in response to the TFM that contained data and information on possible test methods (and combinations or modifications of these methods). The comments discussed the following in vivo and in vitro test procedures:

- IPD,
- PPD,
- PFA,
- Photosensitivity methods,
- UVA radiation protection percent,
- Diffey/Robson method and modifications of that method,
- Standards Association of Australia,
- Diffuse reflectance method,
- Skin[2] method, and
- Psoralen photoadduct method.

On May 12, 1994, FDA held a public meeting to discuss these UVA radiation testing procedures (Ref. 77).

One comment suggested using either or both PPD and erythema skin responses to measure the UVA radiation protection effectiveness of OTC sunscreen drug products. The comment maintained that these two test methods have the following similarities:

- Same UVA radiation source,
- Same dose range, and
- Similar post exposure time lags for observation.

The only difference is in the skin types used, thus giving a variable balance in PPD and erythema responses. The comment added that such a combination of methods has the following advantages:

- Reproducibility and stability,
- Relevance,
- Persistence of skin response through 1 to 24 hours,
- Independence of source flux and accuracy,
- Utilization for static as well as for water resistance photoprotective predictions, and
- Practicability, convenience, and safety.

Stating that there is currently no convincing evidence that the action spectrum for UVA radiation damage has been clearly defined, another comment suggested that protection from UV radiation be measured using two factors based on the degree of attenuation of UV radiation across the full spectrum. One factor, the SPF value, is erythemally weighted and gives an indication of the power of protection provided by the product. The second factor should take into account the shape of the transmittance curve measured by either in vivo or in vitro means. The comment stated that it is potentially dangerous to associate skin damage with any single action spectrum (e.g., IPD, PPD, or PFA). The comment argued that all of these indicators are wavelength-specific and protection from specific wavelengths does not mean protection from damage. The comment added that if only the erythema action spectrum is used, it virtually ignores the effects of wavelengths over 320 nm. The comment contended that using an SPF value augmented by the shape of the transmission curve would give consumers the information necessary to make an effective and safe judgment about the protection provided by a sunscreen drug product. For example, the comment noted that a product with a high SPF and a uniform high level of attenuation across the spectrum (i.e., equal attenuation at all UVB and UVA wavelengths) will provide the most protection. The comment added that, at a later date, if sufficient evidence becomes available to describe a credible UVA radiation damage spectrum, this combined system could be used by convoluting the attenuation curve with the action spectrum curve.

One comment proposed a modification (''critical wavelength'') of the Diffey/Robson test method (Refs. 78 and 79). The comment noted that, when people are outdoors, they are not exposed to only UVB or UVA radiation but are exposed to solar UV radiation, which always contains both. In addition, biological effects against which people may wish to be protected are caused by all wavelengths in the solar UV radiation spectrum. The comment contended that investigators should not be exposing subjects to sources of radiation with spectra that have no practical application and using irrelevant biological effects as endpoints (e.g., IPD).

The comment proposed to assess the UVA radiation protection potential of an OTC sunscreen drug product by first spectrophotometrically determining the absorption spectrum of the product throughout the UV radiation range. Then, one calculates the wavelength value λ_c (the ''critical wavelength''), where the area under the absorption spectrum from 290 nm to λ_c is 90 percent of the integral of the absorption spectrum from 290 to 400 nm, and uses a five-point scale to classify products as follows:

TABLE 3.—BROAD SPECTRUM RATING BASED ON CRITICAL WAVELENGTH

Critical Wavelength (nm)	Broad Spectrum Rating
$\lambda_c < 325$	0
$325 \leq \lambda_c < 335$	1
$335 \leq \lambda_c < 350$	2
$350 \leq \lambda_c < 370$	3
$370 < \lambda_c$	4

The comment concluded that this test method makes no underlying assumptions about the form of action spectra for either acute or chronic photobiological damage. Because the efficiency of UV radiation to induce a given photobiological endpoint tends to decrease with increasing wavelength, the method utilizes wavelength intervals for classifying the ''broad spectrum'' rating, which increases in an approximately logarithmic manner.

One comment submitted a protocol for the ''critical wavelength'' (CW) modification of the Diffey/Robson method for classifying the relative degree of UVA radiation protection of sunscreen drug products (Ref. 80). The comment addressed product photostability by pre-irradiation of the sunscreen product with a UV radiation dose corresponding to one-third the labeled SPF value. The comment reported recommendations based on the results of a round-robin evaluation of the proposed CW method involving six laboratories using four test sunscreen formulations with various substrates. The comment concluded that the CW method is a convenient, reproducible in vitro method for measuring the uniformity of sunscreen absorbance spectra across the UV radiation spectrum to classify products into broad UVA radiation protection categories.

In response to the June 8, 2000, reopening of the administrative record for the rulemaking for OTC sunscreen drug products (65 FR 36319), FDA received additional comments on UVA radiation testing methods. While all comments supported some type of testing to differentiate the UVA radiation protection potential of sunscreen products, they disagreed

about the use of in vivo versus in vitro testing methods.

Comments from a group of sunscreen product manufacturers contended that an in vivo test method, such as PPD or PFA, best describes the photoprotective characteristics of a sunscreen drug product. These comments stated that an in vivo method measures the actual effect of UVA radiation on the skin and estimates the expected product performance under actual use conditions.

One comment presented test data that suggested PPD and PFA values are comparable (Ref. 6). The comment stated that an advantage of the PFA method is that it allows inclusion of skin type I, whereas the PPD test is conducted on darker skin types (II and III). However, the comment added that the PPD test has been accepted since 1996 by the JCIA for the assessment of UVA radiation protection efficacy of sunscreen products.

One comment contended that the PPD test should be used for the following reasons:

- It requires a relatively low dose of UV radiation.
- The reaction is stabilized in 2 to 4 hours.
- The test subject is left with no mark of irradiation and receives little or no injury.
- The test can be conducted with high precision.

Another comment stated that PPD values demonstrate the same correlative benefits that exist for SPF values and, therefore, do not give false impressions of magnitude. Another comment stated that products with the same SPF can have different levels of UVA radiation protection. Thus, PFA or PPD is not redundant with the SPF value.

Comments from other sunscreen product manufacturers opposed an in vivo method to determine UVA radiation protection. One of these comments stated that in vivo tests expose human subjects to doses of UVA radiation with unknown human health consequences. The comment added that because exposure to UVA radiation alone is never encountered in nature, full spectrum light is most relevant for product evaluations. This comment contended that PFA values are redundant with SPF testing because of an overemphasis on short wavelength UVA radiation (UVA II), and PFA values give a false impression of the magnitude of absorption differences. For example, the comment stated that two products with PFA values of 5 and 10 may attenuate 80 and 90 percent of UVA radiation, respectively. Thus, the real difference is small. The comment further stated that the proposed in vivo methods modeled after the SPF test generate protection factors that are protocol dependent and of indeterminate clinical relevance, as none are surrogates for long term concerns like cancer and photoaging. Another comment added that the PPD and PFA tests do not adequately assess the breadth of UVA radiation protection and that the biologic effects of full spectrum UV radiation differ from the effects of isolated wavelengths.

Several comments recommended using an in vitro method, and most considered the CW method as appropriate. One comment stated that CW allows for broad spectrum activity regardless of SPF so that, if consumers use a low SPF product, they will at least have the option of choosing one that provides a wide breadth of activity. Another comment stated that CW provides a simple, reproducible, and adaptable method that can account for sunscreen photostability and insure UVA radiation protection that is both commensurate with and independent from the SPF value. Another comment added that CW accounts for proportionality because, in order for a sunscreen to maintain a given CW, protection from both long and short UVA radiation wavelengths must increase as UVB radiation protection increases.

Several comments stated that the CW threshold should be 370 nm for a ''broad spectrum'' claim on a sunscreen. Other comments recommended a threshold of 360 nm. One comment stated that if FDA were to arbitrarily select a standard higher than 360 nm, it would cause a major reformulation effort within the industry, higher prices to consumers, and a shortage of ''broad spectrum'' products in the OTC marketplace. The comments did not provide data to support the use of a specific threshold number in relation to the prevention of specific photobiological effects.

Other comments opposed the CW method as not appropriate. One comment, which favored an in vivo method, stated that the CW method, based on an arbitrary, nonbiological criterion, fails to provide an accurate measure of the protection efficacy of a sunscreen product. This comment provided data to demonstrate that a significant failure of the CW method is its inherent inability to differentiate UVA radiation protection levels of sunscreen products relative to biological endpoints (e.g., premature skin aging) (Ref. 23). A second comment agreed with this assertion, while a third comment expressed concern that CW measurements may be misleading because two products can have the same CW with very different UVA radiation absorbance curves and, thus, provide different protection for consumers.

Some comments stated that a combination of methods may be appropriate for assessing the complete UVA radiation protection potential of a sunscreen product. One comment suggested combining either the PPD or PFA method with an in vitro method for a meaningful and rigorous test of both the magnitude and breadth of the biological protection (i.e., the level of protection and the UVB and UVA wavelengths that are protected against) provided by a sunscreen product. Another comment stated that complete assessment of a sunscreen product's UVA radiation protection must include both of the following:

- An in vitro measurement of the absorbance above 360 nm (i.e., demonstrate adequate breadth of absorbance), and
- An in vivo measurement of the quantity of UV radiation protection (i.e., demonstrate adequate magnitude of absorbance).

Other comments stated that a combination of the in vivo SPF method and the in vitro CW method provide a complete description of a product's inherent photoprotective characteristics with the SPF value describing the amplitude of protection and CW providing a reliable measure of the product's spectral absorption capability.

One comment suggested a UVA/UVB radiation proportionality scheme. The comment referred to FDA's previous discussions about UVA/UVB radiation proportionality (Refs. 11 and 81) and a recommendation from the AAD that ''an increase in SPF of a sunscreen must be accompanied by a proportional increase in the UVA protection value'' (Ref. 82). The comment added that the proportional contribution to sunburn from solar UVB and UVA radiation is 80 to 20 (4 to 1), respectively, and that this relationship gives the minimum UVA radiation attenuation needed to provide proportional UVA/UVB radiation protection for any SPF value. The comment concluded that a minimum UVA protection value of 2 should be required even at low SPF levels with proportionately higher UVA protection values for higher SPF values.

One comment suggested that the UVA protection value should be determined with an in vivo method while CW is appropriate to determine spectral broadness. Another comment stated that CW accounts for proportionality because both long and short UVA radiation protection must increase as UVB radiation protection increases in

order for a sunscreen to maintain a given CW. Another comment provided data (Ref. 23) for two products with the same CW value but different SPF values and concluded that the product with the higher SPF value did not provide greater UVA protection. Other comments stated that there is no biological basis for establishing strict UVB/UVA radiation proportionality and that the establishment of this kind of ratio is arbitrary.

The AAD (Ref. 83) referenced an international consensus conference on UVA radiation protection of sunscreens and recommended the following:

1. Both an in vitro and an in vivo testing method must be used to measure UVA radiation protection.
2. CW is the preferred method of in vitro testing for a broad spectrum claim (with a threshold for this claim at 370 nm).
3. CW must be combined with an in vivo method such as either PPD or PFA.
4. There must be a minimum four-fold increase in PPD or PFA value in the presence of a sunscreen (relative to the absence of sunscreen).

In the **Federal Registers** of May 12, 1993 (58 FR 28194 at 28248 to 28250), September 16, 1996 (61 FR at 48645 at 48652), and October 22, 1998 (63 FR 56584 at 56587), FDA discussed photosensitivity and erythemal UVA radiation testing procedures for OTC sunscreen drug products. Criteria discussed for UVA radiation claims included the requirement for an absorption spectrum extending to 360 nm or above, plus the demonstration of meaningful UVA radiation protection via testing procedures. IPD/PPD, PFA, photosensitivity, and in vitro UVA radiation testing methodologies were also discussed at a public meeting on May 12, 1994 (Ref. 77).

The selection of an appropriate UVA radiation testing procedure for OTC sunscreen drug products has been difficult for a number of reasons. The scientific community does not agree on which testing procedure is most appropriate. For example, Cole discusses the virtues and shortcomings of a variety of in vivo and in vitro test methods (Ref. 84). In addition, each test procedure has its own distinct advantages and disadvantages, as discussed in the following paragraphs.

FDA believes the IPD test method provides an appropriate endpoint for determining UVA protection, because pigment darkening is caused primarily by UVA (and not UVB) radiation. This method is advantageous over other suggested test methods in that it uses low doses of radiation and, therefore, exposes subjects to less risk than other suggested test methods. On the other hand, the IPD response has not been shown to represent a direct or surrogate endpoint for biological damage. The IPD response is also extremely difficult to read.

The PFA test method uses endpoints that reflect actual damage that can occur to normal skin as a result of UVA radiation exposure (i.e., erythema or tanning). The erythema action spectra may be similar to the action spectra of known chronic skin damage (e.g., solar elastosis) (Ref. 85). However, the PFA test method may not determine protection against skin melanoma or other skin damage thought to be caused by chronic exposure to UVA radiation (Refs. 29 and 86).

The CW method can assess how broadly a sunscreen can absorb across the UV radiation spectrum, but provides no information concerning product performance after interaction with human skin. While in vivo methods to assess UVA radiation protection may have possible sources of variability similar to the SPF test (e.g., test product application, differences in light sources, etc.), in vitro methods also possess possible sources of inherent variability (e.g., test product evaporation time, substrate orientation, instrumentation, use with color change sunscreen formulations, etc.).

In general, FDA would prefer the standard UVA radiation test method to have a clinically significant endpoint. After reviewing the data and information provided by the comments, FDA agrees that there is no convincing evidence that the action spectra for all possible types of UVA-induced damage have been clearly defined and that no one method is without disadvantages. At this time, FDA agrees with the recommendation provided by the AAD and other comments that an in vivo method is appropriate in combination with an in vitro testing method to assess the UVA radiation protection.

Because the action spectrum for UVA-induced skin damage is not clearly known, FDA considers it necessary to measure both the magnitude and breadth of UVA protection. The magnitude of UVA absorbance is a measure of how well a product absorbs UVA radiation. The magnitude of UVA absorbance is best measured by an in vivo method. An in vivo method measures a biological response on the skin (e.g., pigment darkening) and, therefore, correlates to actual use conditions. The breadth of the UVA absorbance is a measure of how broadly a product absorbs UVA radiation across the entire UVA radiation spectrum. Breadth can best be determined by appropriate in vitro test methods.

At this time, FDA believes a combination of existing in vivo and in vitro UVA radiation testing methods addresses the inadequacies of either method when used alone and provides a more complete UVA radiation attenuation profile for use in labeling OTC sunscreen drug products. Requiring the two test methods will ensure that both the magnitude and breadth of UVA protection is determined. As discussed later in this response, the proposed UVA labeling will reflect the results of both tests and, therefore, will reflect magnitude and breadth of UVA protection. FDA believes that the methods and labeling currently being proposed provide the best assurance for consumers to receive adequate protection across the entire UVA radiation spectrum.

FDA is proposing the PPD method as the in vivo part of the test to determine UVA radiation protection of a sunscreen drug product. This test assesses UVA radiation attenuation by measuring UVA radiation-induced tanning, a direct effect induced by UVA exposure. The PPD test is relatively easy to perform and relies on a stable, biological endpoint that can describe the magnitude of UVA radiation protection of sunscreen products. It is similar to the SPF determination as it is a ratio of a minimum pigmenting dose (MPD) on unprotected skin to that on protected skin. The endpoint is the PPD response, which is the stable, lasting residual part of the immediate pigment darkening or blue gray pigment that develops immediately during exposure to UVA radiation and quickly fades at the end of exposure. It provides consumers with a means to specifically compare the amount of UVA radiation protection between products and select an appropriate sunscreen product. The PPD test has been shown to produce reliable, reproducible data and to distinguish between varying levels of UVA radiation attenuation (Refs. 87 and 88). It has been shown to detect protection provided by ''broad spectrum'' sunscreens against both short and long wavelength UVA radiation. The endpoint is a stable skin response that is linearly dependent on the amount of UVA radiation that enters the viable epidermis. FDA also agrees with one comment that a UVA protection value of 2 should define the lowest end of acceptable PPD test results relative to the consideration of acceptable UVA radiation claims (see proposed § 352.72(d)(3)). FDA considers it desirable to incorporate measurable UVA radiation protection at all SPF

levels for products that claim to protect against both UVB and UVA radiation.

As one comment noted, the PPD test has been accepted and validated as the JCIA method since 1996 (Ref. 23) and is one of two in vivo methods suggested by the AAD (Ref. 83). Although data provided to FDA indicate that the PPD and PFA in vivo tests provide comparable results (Ref. 6), the PPD test provides the practical benefit of a shorter post exposure reading time. FDA agrees with the comments that PPD values are not redundant with SPF values as sunscreen drug products with the same SPF value can have very different levels of UVA radiation protection as measured by the PPD test. Accordingly, FDA is including the PPD method in proposed § 352.72 as part of the testing to determine the UVA radiation protection potential of an OTC sunscreen drug product.

FDA agrees with the comments that suggested modifications to the PPD method (i.e., the JCIA standard). Therefore, FDA is proposing modifications to the PPD method. One group of sunscreen manufacturers suggested that the previously validated ''high SPF'' padimate O/oxybenzone standard sunscreen under consideration by FDA (see section III.J, comment 27 of this document) should also be used as the control formulation for in vivo UVA radiation testing (Ref. 6). Based upon data provided by the comment, FDA is proposing the referenced ''high SPF'' padimate O/oxybenzone standard sunscreen for use as the standard sunscreen in the in vivo UVA radiation test in proposed § 352.72. FDA invites comment on the suitability of this formulation as a UVA radiation test standard, on alternative standards, and on preparation/assay/validation data for any suggested alternatives.

FDA also notes that the JCIA light source specification states that ''UV rays shorter than 320 nm shall be excluded through the use of an appropriate filter.'' FDA considers it important to set an exact limit for this specification and is proposing that optical radiation from the light source between 250 and 320 nm be less than 0.1 percent of the optical radiation between 320 and 400 nm. Also, the observation of pigment darkening in the JCIA standard is at 2 to 4 hours post irradiation. FDA notes that it appears the pigment darkening is most stable about 3 hours or more after post irradiation (Ref. 89), and is thus proposing that this observation occur at 3 to 24 hours post irradiation. This time range provides increased flexibility in the test method without sacrificing accuracy.

As the current state of technology allows for an instrumental measurement/quantification of skin color via spectral reflectance, FDA also invites comments regarding colorimetry as a method of evaluating pigment darkening. By avoiding the subjectivity of detecting pigment change by the human eye, the reproducibility of the PPD method should increase. Colorimetry could likewise be used in SPF testing if submitted data demonstrated increased accuracy and reproducibility of colorimetry over visual inspection.

As the PPD method is similar, overall, to the SPF method, FDA is also proposing that the directions for the PPD method be similar to those for the SPF test for determining MPDs on unprotected skin, individual UVA protection factors, test product UVA protection factors, and PCDs. Further, as discussed in section III.L, comment 37 of this document regarding the SPF test, FDA is proposing that a PPD test panel consist of 20 subjects who produce valid data, similar to the panel size for sunscreens having SPF values less than 30.

FDA is concerned, however, that use of the PPD method alone could result in some products yielding high UVA radiation protection factors without having broad absorbance throughout the UVA radiation spectrum due to strong absorbance in the UVA II region. In other words, a sunscreen could absorb high levels of UVA II but very little UVA I and achieve a high UVA rating under the PPD method. Therefore, FDA is proposing that an in vitro method be used (to assess the breadth of absorbance across the UV radiation spectrum) in conjunction with the PPD method to more completely assess a product's UVA radiation protection.

FDA disagrees with the comments that the CW method should be used as the in vitro testing method and proposes using a modification of the Boots adaptation of the Diffey/Robson method (Ref. 90). Both the CW and the in vitro test proposed by FDA measure the absorbance of a sunscreen product using in vitro spectrophotometry. However, FDA's proposed method calculates the ratio of long wavelength UVA absorbance (UVA I) to total UV absorbance to provide a measure of the relative UVA I radiation protection provided by a sunscreen drug product. FDA believes that this test, in combination with the PPD method, provides a better assessment of overall UVA radiation protection.

The Boots adaptation of the Diffey/Robson test method assesses the absorbance of a sunscreen drug product over the UV radiation range from 290 to 400 nm by measuring the quantity of UV radiation transmitted through surgical tape (Transpore™ tape) before and after application of a sunscreen drug product. The test product (2 mg/cm^2) is applied to the textured surface of the Transpore™ tape. A xenon arc solar simulator is used as the UV radiation source. Transmitted UV energy is collected and measured at 5 nm intervals over the UVB and UVA radiation range, which provides a profile of UV radiation absorbance. Mathematical calculations are made separately of the areas under the UVB and UVA radiation parts of the curve. The ratio below the curve is determined as follows:

$$\frac{\text{UVA area under curve per unit wavelength}}{\text{UVB area under curve per unit wavelength}}$$

As the ratio increases, the degree of UVA radiation protection increases.

FDA is concerned that this method, as described in previous paragraphs, determines the ratio of the entire UVA to UVB radiation spectra. Therefore, a sunscreen drug product that absorbs strongly in the UVA II radiation area, but does not absorb strongly in the UVA I radiation area, might still have an adequate ratio of UVA to UVB radiation protection to fulfill the test requirements, but would not provide adequate protection in the UVA radiation region where absorbance is lacking. FDA believes that this deficiency can be corrected by revising the calculations to take into account the ratio of UVA I and/or UVA II individually to UV radiation. Some comments were concerned that UVA II radiation may be the portion of the UVA spectrum most represented in the PPD test. FDA agrees that the UVA II spectrum is well represented by the PPD test. Therefore, to provide for a more balanced method, FDA is proposing that the in vitro component of the monograph UVA radiation method only need provide a measure of the relative UVA I radiation absorbance.

FDA is proposing to measure UVA I radiation absorbance relative to UV radiation absorbance rather than relative to UVB radiation absorbance. If UVA I radiation protection is measured relative to UVB radiation, then the test does not account for UVA II radiation protection. FDA's proposed modification of the Boots adaptation of the Diffey/Robson method accounts for the entire UV radiation spectrum. Further, the ratio of UVA I radiation to UV radiation has a convenient finite range and allows for the use of defined values to categorize UVA radiation protection.

FDA is proposing a modified Boots adaptation of the Diffey/Robson method instead of the CW method. The CW determination only reveals the shortest wavelength at which 90 percent of total UVB and UVA radiation is absorbed by a sunscreen. Thus, this method does not directly reveal the breadth of UV absorption, whereas the modified Boots adaptation of the Diffey/Robson method does. This point is demonstrated by data submitted by one comment (Ref. 23). The comment submitted the UV absorption spectra of two sunscreens having nearly identical SPF and CW values. The absorption spectra demonstrate that two sunscreens with similar CWs can have significantly different UVA absorption spectra. The ratios of UVA I/UV radiation absorbance for these formulations were markedly different: 0.85 and 0.52. Thus, FDA believes that the ratio method generally allows for better discrimination of products with these types of absorbance spectra.

FDA is also concerned that the activity of the sunscreen ingredients in the product may be diminished by exposure to UV radiation, i.e., that the sunscreen ingredients in the product might not be photostable. Therefore, in order to account for changes in absorbance as a function of UV radiation exposure, FDA is proposing to revise the Boots modification of the Diffey/Robson method by incorporating pre-irradiation dose (PID), which is defined as follows (see section III.O, comment 46 of this document):

PID (J/m^2-eff) = SPF * 1 MED * 2/3,
where 1 MED = 200 J/m^2-eff

FDA is also concerned about specifying the use of Transpore™ tape (used in the original Diffey/Robson method), an artificial substrate that mimics the surface topography of human stratum corneum. When sunscreen emulsions are applied to Transpore™ tape (Refs. 7 and 77), the emulsions may experience a micro environment that differs from human skin in several key aspects, including the following:

- Lack of electrolyte effect,
- Lack of moisturization/humectant plasticization of the substrate,
- Differences in pH and wetting effects, and
- Different degrees of sunscreen penetration and retention by the substrate.

The fourth aspect, different degrees of penetration and retention, is especially significant for oil soluble sunscreen ingredients. One comment suggested that either roughened quartz plates or a synthetic collagen should be used as the substrate, noting that COLIPA has used quartz plates for its in vitro studies and that quartz plates are reusable and inert. Diffey et al. have also used quartz plates as the substrate for the CW method (Ref. 91). Accordingly, at this time, FDA is proposing that roughened quartz plates be specified as the substrate in the in vitro portion of its UVA test method. FDA requests comment regarding the suitability and availability of quartz plates and other possible substrates.

FDA agrees with one comment that there is no biological basis for establishing a strict UVA to UVB ratio and that such a ratio would be arbitrary. FDA is proposing that data from the proposed in vitro and in vivo tests be integrated into a single labeled UVA rating. Similar to suggestions from some comments, FDA is proposing the categories of low, medium, high, and highest (corresponding to one, two, three, and four ''stars,'' respectively). Based on test data submitted by one comment (Ref. 6), FDA is proposing that test results for each in vitro or in vivo test be categorized as follows:

TABLE 4.—UVA RATING CATEGORIES

Category	In vitro result	In vivo result
Low	0.2 to 0.39	2 to under 4
Medium	0.40 to 0.69	4 to under 8
High	0.70 to 0.95	8 to under 12
Highest	greater than 0.95	12 or more

FDA is aware of the difficulty for current sunscreen formulations to meet the ''highest'' category and believes that allowing such a category will foster additional research and development in this area.

FDA is proposing that the overall UVA radiation category for use in product labeling be the lowest category determined by the in vitro and in vivo test results. For example, if the test results for a sunscreen indicate an in vitro category of ''low'' and an in vivo category of ''high'' (or the reverse), then the overall UVA classification on the sunscreen product label would be ''low'' (i.e., the lower of the two categories). FDA believes that using the lower of the two categories takes into account the following situations:

- A product that has a high in vivo rating because of substantial UVA II absorbance, but a low in vitro rating because of poor UVA I absorbance, or
- A product that has a low in vivo rating because of poor UVA II absorbance, but a high in vitro rating because of substantial UVA I absorbance.

FDA is further proposing that each overall UVA radiation category correspond to and (on product labeling) be used with the following number of graphical representations in the form of solid ''stars'':

TABLE 5.—GRAPHICAL UVA RATING BASED ON CATEGORY

Combined Category Rating	Star Rating
Low	★☆☆☆
Medium	★★☆☆
High	★★★☆
Highest	★★★★

FDA invites comment on these proposed test methods/criteria and encourages the continued development of biologically meaningful test procedures.

O. Comments on the Photostability of Sunscreen Drug Products

(Comment 46) Various comments discussed the photostability of OTC sunscreen formulations and active ingredients. One comment stated that photostability is important because many sunscreen ingredient combinations with avobenzone are not believed to be photostable. This comment stressed that a sunscreen drug product should maintain most of its UVA and UVB radiation protection throughout the expected consumer time in the sun. Another comment stated that the integrity of a sunscreen drug product depends on its degree of photostability and that a photostable product should maintain its protection over a wide range of UV radiation spectra.

Some comments supported a standard method using pre-irradiation to account for photostability of sunscreen ingredients. One comment favoring the CW method for measuring UVA radiation protection submitted a formula to establish a pre-irradiation dose to assess photostability (Ref. 7). This comment stated that pre-irradiation provides a reasonable estimate of what a consumer might expect when using the product and stressed that the dose should be both full spectrum (290 to 400 nm) and sufficient to detect significant changes in CW as a function of UV radiation exposure. This comment considered its pre-irradiation dose of solar-simulated UV radiation to be equivalent to about 1 1/2 hours of noonday sun or 3 hours of sun exposure in the early morning or late afternoon. One comment noted that avobenzone-containing formulations can be photostabilized by the addition of suitable ingredients and supported a protocol developed by Sayre and Dowdy for measuring UVA radiation protection

following a measured exposure of the test formulation to solar radiation (290 to 400 nm) (Ref. 92).

Another comment stressed the importance of a standard pre-irradiation dose and included data suggesting that a ''UVB-only'' sunscreen product formulation, at high pre-irradiation doses, could qualify for UVA ''broad spectrum'' labeling by the CW method (Ref. 23). This comment concluded that pre-irradiation does not always account for photostability and appears to be very formulation specific.

Another comment submitted an in vitro method for simultaneously predicting SPF and assessing photostability of sunscreen formulas (Ref. 65). The comment stated that pre-irradiation with measured UV radiation doses has permitted more accurate in vitro estimates of SPF.

FDA agrees that it is important to address the photostability for sunscreen drug product formulations. Unstable product formulations present the problem of degradation of product effectiveness during actual use. The assessment of overall protection provided by such formulations is difficult due to product effectiveness being heavily dependent on the UV radiation exposure dose. Sayre and Dowdy demonstrated, through a series of in vitro studies, how the UV radiation transmission of an avobenzone containing formula changes with UV radiation exposure and that most of the loss of protection occurred in the UVA radiation spectrum (Ref. 92).

FDA is proposing to address photostability by adding a pre-irradiation step to the in vitro test method for measuring UVA radiation protection (see section III.N, comment 45 of this document). As noted in the scientific literature, the choice of a pre irradiation dose is ''somewhat arbitrary, yet critical to the outcome of the test'' (Ref. 84). FDA received one comment with supporting data for a proposed pre-irradiation dose (Ref. 7). The comment suggested using a dose equivalent to the SPF times 2 J/cm^2 multiplied by a factor of 2/3. The comment stated that 2 J/cm^2 from a xenon arc solar simulator with 1 millimeter (mm) WG-320 and 1 mm UG-5 filters was equivalent to one MED. Because all solar simulators used by the industry may not use this exact filter combination and the spectral transmittance of filters can vary from lot to lot, FDA is proposing to specify the pre-irradiation dose in terms of ''erythemal effective dose.'' The erythemal effective dose of a solar simulator can by calculated as described in proposed § 352.70(d) by weighting the output spectrum of the solar simulator with the reference action spectrum for erythema as defined by CIE. A typical weighted value (J/m^2-eff) for an MED in a Skin Type II individual is 200 J/m^2-eff (Ref. 93). Thus, FDA is proposing to use the following formula to determine the required pre-irradiation dose:

PID (J/m^2-eff) = SPF * 1 MED * 2/3

where 1 MED = 200 J/m^2-eff

In considering the selection of the appropriate pre-irradiation dose of solar-simulated UV radiation, FDA agrees that the maximum pre-irradiation exposure would be a dose of UV radiation that equaled the SPF of the product times the MED. However, FDA believes that this calculated dose is probably greater than the dose that a sunscreen product would incur during typical consumer usage. Thus, the dose was reduced by a factor of one-third to represent a more reasonable exposure condition.

IV. FDA's Tentative Conclusions and Proposals

FDA tentatively concludes that the FM for OTC sunscreen drug products should be amended to include the combinations of avobenzone with ensulizole and avobenzone with zinc oxide when used in the concentrations established for each ingredient in § 352.10 (see section III.C, comment 7 of this document). However, before marketing may begin, the comment period for this proposal must end and FDA must publish another **Federal Register** notice setting forth our determination concerning interim marketing before publication of the final rule for OTC sunscreen drug products. FDA followed this procedure previously for avobenzone as a single active ingredient and in combination with some GRASE active ingredients other than ensulizole or zinc oxide (62 FR 23350).

FDA considers the UVA-related labeling in this proposal to supersede the labeling proposed in the TFM and its amendments of September 16, 1996, and October 22, 1998. While the prior proposed labeling can continue to be used until a FM is issued, FDA encourages manufacturers of OTC sunscreen drug products to voluntarily implement the UVA-related labeling changes as soon as possible after publication of this proposal, especially if product relabeling occurs in the normal course of business. We note, though, that any relabeling prior to issuance of the FM is subject to the possibility that FDA may change some of the labeling requirements as a result of comments filed in response to this proposal.

Mandating warnings in an OTC drug monograph does not require a finding that any or all of the OTC drug products covered by the monograph actually caused an adverse event, and FDA does not so find. Nor does FDA's requirement of warnings repudiate the prior OTC drug monographs and monograph rulemakings under which the affected drug products have been lawfully marketed. Rather, as a consumer protection agency, FDA has determined that warnings are necessary to ensure that these OTC drug products continue to be safe and effective for their labeled indications under ordinary conditions of use as those terms are defined in the act. This judgment balances the benefits of these drug products against their potential risks (see 21 CFR 330.10(a)).

FDA's decision to act in this instance need not meet the standard of proof required to prevail in a private tort action (*Glastetter* v. *Novartis Pharmaceuticals Corp.*, 252 F.3d 986, 991 (8th Cir. 2001)). To mandate warnings, or take similar regulatory action, FDA need not show, nor do we allege, actual causation. For an expanded discussion of the case law supporting FDA's authority to require such warnings without evidence of actual causation, see Labeling of Diphenhydramine-Containing Drug Products for Over-the-Counter Human Use, final rule (67 FR 72555, December 6, 2002).

V. Analysis of Impacts

FDA has examined the impacts of this proposed rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (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 economic 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. Section 202(a) of the Unfunded Mandates Reform Act requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure in any one year by State, local, and tribal governments, in the aggregate, or by the private sector, of

$100 million (adjusted annually for inflation).

FDA believes that this proposed rule is consistent with the principles set out in the Executive Order 12866 and in these two statutes. The proposed rule is not a significant regulatory action as defined by the Executive order and, therefore, is not subject to review under the Executive order. Further, because this proposed rule is not expected to result in any 1-year expenditure that would exceed $100 million adjusted for inflation, FDA need not prepare additional analyses under the Unfunded Mandates Reform Act. Because the rule may have a significant economic impact on a substantial number of small entities, this section of the preamble constitutes FDA's regulatory flexibility analysis.

An analysis of the costs and benefits of this regulation, conducted under Executive Order 12866, was discussed in the FM (64 FR 27666 at 27683 to 27686), which was later stayed (66 FR 67485). This analysis reflects the incremental costs of the revised or new requirements in this proposed amendment of the FM.

A. Background

The purpose of this document is to amend the conditions under which OTC sunscreen drug products are generally recognized as safe and effective (GRASE) and not misbranded. This amendment addresses formulation, labeling, and testing requirements for both UVB and UVA radiation protection.

Manufacturers would not need to reformulate their sunscreen products to comply with the proposed requirements. Manufacturers also would not need to retest their sunscreen products for UVB protection (i.e., they would not need to retest for SPF). The labeled SPF value determined from the SPF test in the FM would not likely change if a sunscreen product was retested using the modifications to the SPF test proposed in this document. In addition, manufacturers who have tested and labeled their sunscreen products as ''SPF 30+'' can relabel their products with the specific SPF value above 30 (but no greater than 50) without retesting.

However, all manufacturers would incur some relabeling costs due to proposed revisions to both the PDP and the Drug Facts section of the product label. If manufacturers wish to label their sunscreen products as providing UVA protection, then manufacturers of those sunscreen products would also incur UVA testing costs. Because UVA testing is not required, some manufacturers will choose not to test for UVA protection and the labeling for those sunscreens will state, ''No UVA Protection.''

B. Number of Products Affected

Estimating the number of products affected is difficult because we lack data on the number of products currently marketed. Our Drug Listing System currently does not have accurate information on the number of marketed OTC sunscreen products, especially the drug-cosmetic combination products. Proprietary databases that track retail sales of OTC drugs and other products do not distinguish cosmetics containing sunscreens from other cosmetic products and their surveys do not include many of the outlets where sunscreen products are sold. Based on earlier estimates (64 FR 27666 at 27684) and our knowledge of the industry, we assume there are about 3,000 OTC sunscreen drug products (different formulations, not including products that differ only by color), including drug-cosmetic combinations, and about 12,000 individual stock keeping units (SKUs) (individual products, packages, and sizes). All 12,000 SKUs will need to be relabeled, but manufacturers can choose whether to test their sunscreen products for UVA protection. We assume that about 75 percent (2,250) of the sunscreen products would be tested for UVA protection. We request comment on the accuracy of this assumption.

C. Cost to Relabel

The cost to relabel varies greatly depending on the printing method and number of colors used. The majority of sunscreen products are packaged in plastic bottles or tubes with the label printed directly on the container or applied as a decal or paper label during the packaging process. The proposed labeling requirements impact both the PDP and the Drug Facts section of the package and would be considered a major redesign.

Frequent label redesigns are typical for OTC sunscreen products, with redesigns generally implemented every 1 to 2 years for a product. To the extent that a scheduled redesign coincides with the regulatory-mandated relabeling, the impact on the manufacturer will be negligible.

We used a model developed for FDA by the consulting firm RTI to derive an estimate of the cost to relabel sunscreen products (Ref. 94). The model was developed to estimate the cost of food labels. However, we believe that the graphic and design estimates from that study are an appropriate proxy for the costs that would be incurred by OTC sunscreen manufacturers. RTI estimated that graphic design and prepress and engraving costs would range from $1,970 to $13,800 per SKU depending on the type of packaging and printing method used. There would also be administrative costs to account for contracting costs and obtaining final approvals for the new labels. RTI estimated administrative costs to range from $360 to $880 depending on the size of the firm. For this analysis, we are assuming an average design price of $7,000 per SKU and average administrative costs of $600 per SKU.[1] Therefore, the total relabeling cost per SKU would be $7,600 (i.e., $600 + $7,000).

While all sunscreen SKUs would need to be relabeled to comply with the proposed rule, we estimate that the timing of the scheduled relabeling would coincide with the regulatory-mandated changes for 50 percent of the SKUs (i.e., 6,000 SKUs). We estimate the total labeling cost of the proposed labeling changes for the SKUs with the coinciding scheduled redesign would be 50 percent of the administrative cost (i.e., $300). Therefore, the total one-time cost to industry for relabeling would be about $47.5 million (i.e., (6,000 x $7,600) + (6,000 x $300)).

D. Cost to Test or Retest Products for UVA Protection

This proposed rule will result in testing costs for products that make UVA protection claims. The approximate costs are $2,200 for in vivo UVA testing and $200 for in vitro UVA testing. Based on the number of sunscreen products currently labeled as providing UVA protection, we estimate that 75 percent (2,250) of the sunscreen products will be tested according to the proposed UVA tests. Therefore, FDA estimates a one-time UVA testing cost of approximately $5.4 million (i.e., 2,250 x $2,400).

E. Total Incremental Costs

The estimated total one-time incremental cost of this proposed rule is $53 million (i.e., $47.5 million + $5.4 million). The incremental cost for the UVA testing could be less should the rule become final because many manufacturers may voluntarily comply with the proposed rule when reformulating current products or marketing new products. Although the FM is not effective, manufacturers of sunscreen products comply with the

[1] We did not select the midpoint of the ranges because of the large number of private label products that have lower design and administrative costs than branded goods.

UVB (SPF) test in the FM for nearly all sunscreen products. Therefore, it is likely that manufacturers of sunscreen products will also voluntarily comply with the proposed UVA tests in this document.

It should also be noted that sunscreen products that are already distributed by the effective date of the FM will not be required to be relabeled or retested in conformity with these FM conditions, unless these products are subsequently relabeled or repackaged after the effective date. Therefore, there is no one-time cost associated with disposing of sunscreens that are already on the market at the time of the rule's effective date.

F. Small Business Impact

In the FM (64 FR 27666 at 27685), FDA estimated that 78 percent of the 180 domestic companies that manufacture OTC sunscreen products would be considered a small business (defined as fewer than 750 employees). FDA cannot estimate with certainty the number of small firms that will need to test or retest their OTC sunscreen products to provide for UVA protection claims, but projects that approximately 75 percent of all products may need to be tested for UVA protection. Costs will vary by firm, depending on the number of products requiring testing. The firm-specific impact may vary inversely with the volume of product sales, because per unit costs will be lower for products with high volume sales. Thus, the relative economic impact of product retesting may be greater for small firms than for large firms. Because the OTC drug industry is highly regulated, all firms are expected to have access to the necessary professional skills on staff or to have contractual arrangements to comply with the testing requirements of this rule.

G. Analysis of Alternatives

FDA could have proposed only an in vivo or an in vitro test for UVA. FDA recognizes that requiring only the in vitro test would mean significantly less cost to manufacturers. However, the proposed in vivo test measures the magnitude of UVA protection. The proposed in vitro test measures the breadth of UVA protection. FDA believes it is important to conduct both tests to determine the magnitude and breadth of UVA protection.

FDA plans to grant an extended compliance period when this proposed rule is finalized. Given the seasonal nature of these products, FDA is concerned that some manufacturers may not have sufficient time to incorporate labeling changes without disrupting their production schedules. By providing an additional 6 months to implement the changes, compliance costs to manufacturers will be reduced.

In addition, FDA reduced compliance costs when we chose to stay the labeling requirements for the FM (64 FR 27666), sparing industry the cost of an additional regulatory-mandated label change. In the stay, FDA estimated a cost savings of $1.5 million to industry. It should be noted that labeling costs were significantly less in the FM than in this proposed rule primarily because we assumed in the FM that the majority of relabeling would coinside with scheduled voluntary label redesigns at no additional cost. Manufacturers were also able to avoid or postpone incurring an additional industry total of $5 million when FDA chose to stay the UVB testing requirements of the FM.

FDA invites public comment regarding any substantial or significant economic impact that this proposed rule would have on manufacturers of OTC sunscreen drug products. Comments regarding the impact of this rulemaking on such manufacturers should be accompanied by appropriate documentation. FDA is providing a period of 90 days from the date of publication of this proposed rule in the **Federal Register** for comments to be developed and submitted. FDA will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the final rule.

VI. Paperwork Reduction Act of 1995

FDA tentatively 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 proposed 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)).

VII. Environmental Impact

FDA has determined under 21 CFR 25.31(a) 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. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized as proposed, would have a preemptive effect on State law. Section 4(a) of the Executive order requires agencies to ''construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' Section 751 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379r) is an express preemption provision. Section 751(a) of the act (21 U.S.C. 379r(a)) provides that ''no State or political subdivision of a State may establish or continue in effect any requirement—* * * (1) that relates to the regulation of a drug that is not subject to the requirements of section 503(b)(1) or 503(f)(1)(A); and (2) that is different from or in addition to, or that is otherwise not identical with, a requirement under this Act, the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 *et seq.*), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 *et seq.*).'' Currently, this provision operates to preempt States from imposing requirements related to the regulation of nonprescription drug products. Section 751(b) through (e) of the act outlines the scope of the express preemption provision, the exemption procedures, and the exceptions to the provision.

This proposed rule, if finalized as proposed, would amend the labeling and include new UVA testing for OTC sunscreen drug products. Any final rule would have a preemptive effect in that it would preclude States from issuing requirements related to the labeling and testing of OTC sunscreen drug products that are different from or in addition to, or not otherwise identical with a requirement in the final rule. This preemptive effect is consistent with what Congress set forth in section 751 of the act. Section 751(a) of the act displaces both State legislative requirements and State common law duties. We also note that even where the express preemption provision in section 751(a) of the act is not applicable, implied preemption may arise (see *Geier* v. *American Honda Co.*, 529 US 861 (2000)).

FDA believes that the preemptive effect of the proposed rule, if finalized as proposed, would be consistent with Executive Order 13132. Section 4(e) of the Executive order provides that ''when an agency proposes to act through adjudication or rulemaking to preempt State law, the agency shall provide all

affected State and local officials notice and an opportunity for appropriate participation in the proceedings.'' FDA is providing an opportunity for State and local officials to comment on this rulemaking.

IX. Request for Comments

In the **Federal Register** of January 10, 2005 (70 FR 1721), FDA announced the availability of a final guidance for industry entitled ''Labeling for Topically Applied Cosmetic Products Containing Alpha Hydroxy Acids as Ingredients.'' The purpose of this guidance is twofold:

- To educate consumers about the potential for increased skin sensitivity to the sun from the topical use of cosmetics containing alpha hydroxy acids (AHAs) as ingredients.
- To educate manufacturers to help ensure that their labeling for cosmetic products containing AHAs as ingredients is not false or misleading.

As discussed in the guidance, AHAs may increase skin sensitivity to UV radiation. Therefore, FDA recommends that manufacturers of cosmetic products containing AHAs include the following warning:

Sunburn Alert: This product contains an alpha hydroxy acid (AHA) that may increase your skin's sensitivity to the sun and particularly the possibility of sunburn. Use a sunscreen and limit sun exposure while using this product and for a week afterwards.

The guidance addresses only cosmetic products containing AHAs and does not address sunscreen drug products containing AHAs (i.e., drug-cosmetic products). FDA is considering an additional warning or direction for sunscreen drug products containing AHAs similar to the warning for the cosmetic products described in the guidance for industry. However, FDA invites interested parties to submit comments and data regarding such labeling. In particular, FDA would like the following questions addressed:

1. Does the body of existing evidence on AHAs and skin sensitivity warrant voluntary or mandatory labeling on OTC sunscreen drug products containing AHAs regarding possible risks of increased sun damage (e.g., sunburn)?

2. If additional labeling is warranted, what information should be conveyed in the labeling and why?

Comments along with supporting data will help enable FDA to determine how and what information, if any, related to UV hypersensitivity due to AHAs in sunscreen-cosmetic products should be communicated to consumers. FDA will also be evaluating any comments or data submitted in response to the final guidance for cosmetic products containing AHAs.

In addition to AHAs, FDA seeks comment on titanium dioxide and zinc oxide formulated in particle sizes as small as a few nanometers. FDA addressed issues concerning micronized sunscreen ingredients in the FM (64 FR 27666 at 27671 to 27672). The FM stated that FDA did not consider micronized titanium dioxide to be a new ingredient but rather a specific grade of the same active ingredient. The FM also stated that FDA was aware of concerns about potential risks associated with increased dermal penetration of such small particles. However, the FM explained that, based on the safety data submitted to FDA before publication of the FM, FDA was not aware of any evidence at that time demonstrating a safety concern from the use of micronized titanium dioxide in sunscreen products (64 FR 27666 at 27671 to 27672).

FDA recognizes that more sunscreens containing small particle size titanium dioxide and zinc oxide ingredients enter the market each year. FDA is interested in receiving comments and data about these sunscreen ingredients and products that contain these ingredients, their safety and effectiveness, and how they should be regulated. FDA received a citizen petition shortly before publication of this document that, among other things, raises these issues. FDA is currently evaluating the citizen petition, which is filed as CP17 in Docket No. 1978N–0038. FDA encourages other parties to submit additional data or information on the safety and effectiveness of sunscreen ingredients formulated in particle sizes as small as a few nanometers.

On April 14, 2006, FDA announced in the **Federal Register** that we were planning a public meeting on FDA-regulated products containing nanotechnology materials (71 FR 19523). As explained in the notice, the purpose of the meeting was to help FDA further its understanding of developments in nanotechnology materials that pertain to FDA-regulated products. The meeting was held on October 10, 2006, and FDA has received comments from interested members of the public which have been filed in the docket for this public meeting (Docket No. 2006N– 0107). Some of these comments concern sunscreen ingredients formulated with nanotechnology materials. FDA will file any comments concerning sunscreen ingredients formulated in nanometer particle sizes received in response to this proposed rule in the docket for this rulemaking and the citizen petition (Docket No. 1978N–0038) and the docket for the nanotechnology meeting.

X. Proposed Effective and Compliance Dates

FDA is proposing that any final rule that may issue based on this proposal become effective 18 months after its date of publication in the **Federal Register**. The compliance date for products with annual sales less than $25,000 would be 24 months after publication of the final rule in the **Federal Register**.

XI. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) under Docket No. 1978N–0038 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Comment No. CP6.
2. Comment Nos. CP8, C548, SUP22, and C555.
3. Comment Nos. LET166 and LET169.
4. Comment No. C538.
5. Comment No. C576.
6. Comment No. C565.
7. Comment No. C581.
8. Comment No. C567.
9. Comment No. C515.
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11. Comment No. MM22.
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13. Comment No. C573.
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90. Comment No. TS3.

91. Diffey, B.L. et al., ''Suncare Product Photostability: a Key Parameter for a More Realistic In Vitro Efficacy Evaluation,'' *European Journal of Dermatology*, 7:226–228, 1997.

92. Sayre, R.M., and J. Dowdy, ''Photostability Testing of Avobenzone,'' *Cosmetics and Toiletries*, 114:85–86, 88, 90–91, 1999.

93. Urbach, F., ''Man and Ultraviolet Radiation'' in *Human Exposure to Ultraviolet Radiation: Risks and Regulations*, Passchier, W.F. and Bosnjakovic, B.F.M. (eds.), Elsevier Science, New York, NY, pp. 3–6, 1987.

94. RTI International, ''FDA Labeling Cost Model, Final Report,'' prepared by Mary Muth, Erica Gledhill, and Shawn Karns, RTI. Prepared for Amber Jessup, FDA Center for Food Safety and Applied Nutrition, Revised January 2003.

List of Subjects

21 CFR Part 347

Labeling, Over-the-counter drugs.

21 CFR Part 352

Labeling, Over-the-counter drugs, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 347 and 352 be amended as follows:

PART 347—SKIN PROTECTANT DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 347 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

2. FDA is proposing to lift the stay of § 347.20(d) as published at 68 FR 33362, June 4, 2003.

PART 352—SUNSCREEN DRUG PRODUCTS FOR OVER THE COUNTER HUMAN USE

3. The authority citation for 21 CFR part 352 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

4. FDA is proposing to lift the stay of 21 CFR part 352 as published at 68 FR 33362, June 4, 2003.

5. Section 352.3 is amended by redesignating paragraphs (b) through (d) as (c) through (e), respectively; revising newly redesignated paragraphs (c) and (e); and adding new paragraph (b) to read as follows:

§ 352.3 Definitions.

* * * * *

(b) *Minimal pigmenting dose (MPD).* The quantity of erythema-effective energy (expressed as Joules per square meter) required to produce the first perceptible pigment darkening.

(c) *Product category designation (PCD).* A labeling designation for sunscreen drug products to aid in selecting the type of product best suited to an individual's complexion (pigmentation) and desired response to ultraviolet (UV) radiation.

(1) *Low UVB sunburn protection product.* A sunscreen product that provides a sunburn protection factor (SPF) value of 2 to under 15.

(2) *Medium UVB sunburn protection product.* A sunscreen product that provides an SPF value of 15 to under 30.

(3) *High UVB sunburn protection product.* A sunscreen product that provides an SPF value of 30 to 50.

(4) *Highest UVB sunburn protection product.* A sunscreen product that provides an SPF value over 50.

* * * * *

(e) *Sunburn protection factor (SPF) value.* The UV energy required to produce an MED on protected skin divided by the UV energy required to produce an MED on unprotected skin, which may also be defined by the following ratio: SPF value = MED (protected skin (PS))/MED (unprotected skin (US)), where MED(PS) is the minimal erythema dose for protected skin after application of 2 milligrams per square centimeter of the final formulation of the sunscreen product, and MED(US) is the minimal erythema dose for unprotected skin (i.e., skin to which no sunscreen product has been applied). In effect, the SPF value is the reciprocal of the effective transmission of the product viewed as a UV radiation filter.

6. Section 352.20 is amended by revising paragraph (a)(2) to read as follows:

§ 352.20 Permitted combinations of active ingredients.

* * * * *

(a) * * *

(2) Avobenzone in § 352.10(b) may be combined with one or more sunscreen active ingredients identified in § 352.10(c), (e), (f), (i) through (l), (n), (o), (q), and (r) in a single product when used in the concentrations established for each ingredient in § 352.10. The concentration of each active ingredient must be sufficient to contribute a minimum SPF of not less than 2 to the finished product. The finished product must have a minimum SPF of not less than the number of sunscreen active ingredients used in the combination multiplied by 2.

* * * * *

7. Section 352.50 is revised to read as follows:

§ 352.50 Principal display panel of all sunscreen drug products.

(a) *UVB sunburn protection designation*—(1) *For products with an SPF of 2 to under 15.* The labeling states ''UVB SPF [insert tested SPF value of the product] low''.

(2) *For products with an SPF of 15 to under 30.* The labeling states ''UVB SPF [insert tested SPF value of the product] medium''.

(3) *For products with an SPF of 30 to 50.* The labeling states ''UVB SPF [insert tested SPF value of the product] high''.

(4) *For products with an SPF over 50.* The labeling states ''UVB SPF 50 [select one of the following: 'plus' or '+'] highest''. Any statement accompanying the marketed product that states a specific SPF value over 50 or similar language indicating a person can stay in the sun more than 50 times longer than without sunscreen will cause the product to be misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352).

(b) *UVA protection designation*—(1) *For products not providing UVA protection according to § 352.73.* The labeling states ''no UVA protection''.

(i) The UVA protection designation shall appear on the principal display panel along with the UVB protection designation in an equally prominent manner that does not conflict with the UVB protection designation.

(ii) The font size of the UVA protection designation shall be the same size as the UVB protection designation.

(2) *For products providing UVA protection according to § 352.73.* The labeling states ''UVA [select one of the following in accordance with § 352.73: '★☆☆☆ Low,' '★★☆☆ Medium,' '★★★☆ High,' or '★★★★ Highest']''.

(i) The UVA protection designation shall appear on the principal display panel along with the UVB protection designation in an equally prominent manner that does not conflict with the UVB protection designation.

(ii) The font size of the UVA protection designation shall be the same size as the UVB protection designation.

(iii) All star borders and the color inside a solid star shall be the same while the color of ''empty'' stars must be lighter and distinctly different than solid stars. The color inside a solid star should be distinctly different than the background color.

(iv) The stars are to be filled in starting with the first star on the left and

are to appear in a straight horizontal line.

(c) Select one of the following: ''UV rays from the sun are made of UVB and UVA. It is important to protect against both UVB & UVA rays.'' or ''UV rays from the sun are made of UVB and UVA. It is important to protect against both UVB & UVA rays to prevent sunburn and other skin damage.''

(d) *For products that satisfy the water resistant sunscreen product testing procedures in § 352.76.* The labeling states (select one of the following: ''water,'' ''water/sweat,'' or ''water/perspiration'') ''resistant.''

(e) *For products that satisfy the very water resistant sunscreen product testing procedures in § 352.76.* The labeling states ''very'' (select one of the following: ''water,'' ''water/sweat,'' or ''water/perspiration'') ''resistant.''

8. Section 352.52 is amended by revising paragraphs (b), (c), (d), (e), the heading of paragraph (f), paragraphs (f)(1)(ii) through (f)(1)(vi) to read as follows:

§ 352.52 Labeling of sunscreen drug products.

* * * * *

(b) *Indications.* The labeling of the product states, under the heading ''Uses,'' all of the phrases listed in paragraph (b)(1) of this section that are applicable to the product and may contain any of the additional phrases listed in paragraph (b)(2) of this section, as appropriate. Other truthful and nonmisleading statements, describing only the uses that have been established and listed in this paragraph (b), may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the act (21 U.S.C. 352) relating to misbranding and the prohibition in section 301(d) of the act (21 U.S.C. 331(d)) against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act (21 U.S.C. 355(a)).

(1) *For products containing any ingredient in § 352.10.* (i) *For products with an SPF of 2 to under 15.* The labeling states ''[bullet][1] low UVB sunburn protection''.

(ii) *For products with an SPF of 15 to under 30.* The labeling states ''[bullet] medium UVB sunburn protection''.

(iii) *For products with an SPF of 30 to 50.* The labeling states ''[bullet] high UVB sunburn protection''.

(iv) *For products with an SPF over 50.* The labeling states ''[bullet] highest UVB sunburn protection''.

(v) *For products not providing UVA protection according to § 352.73.* The labeling states ''[bullet] no UVA protection.''

(vi) *For products providing UVA protection according to § 352.73.* The labeling states ''[bullet] [select one of the following in accordance with § 352.73: 'Low,' 'medium,' 'high,' or 'highest'] UVA protection''.

(vii) *For products that satisfy the water resistant testing procedures identified in § 352.76.* The labeling states ''[bullet] retains SPF after 40 minutes of [select one or more of the following: 'activity in the water,' 'swimming,' 'sweating,' 'perspiring,' 'swimming/sweating,' or 'swimming/perspiring']''.

(viii) *For products that satisfy the very water resistant testing procedures identified in § 352.76.* The labeling states ''[bullet] retains SPF after 80 minutes of [select one or more of the following: 'activity in the water,' 'swimming,' 'sweating,' 'perspiring,' 'swimming/sweating,' or 'swimming/perspiring']''.

(2) *Additional indications.* In addition to the indications provided in paragraph (b)(1) of this section, the following may be used for products containing any ingredient in § 352.10:

(i) *For products with an SPF of 2 to under 15.* Select one or both of the following: ''[Bullet] provides low protection against [select one of the following: 'sunburn' or 'sunburn and tanning']'' or ''[bullet] for skin that sunburns minimally''.

(ii) *For products with an SPF of 15 to under 30.* Select one or both of the following: ''[Bullet] provides medium protection against [select one of the following: 'sunburn' or 'sunburn and tanning']'' or ''[bullet] for skin that sunburns moderately''.

(iii) *For products with an SPF of 30 to 50.* Select one or both of the following: ''[Bullet] [select one of the following: 'provides high' or 'high'] protection against [select one of the following: 'sunburn' or 'sunburn and tanning']'' or ''[bullet] for skin highly sensitive to sunburn''.

(iv) *For products with an SPF over 50.* Select one or both of the following: ''[Bullet] [select one of the following: 'provides highest' or 'highest'] protection against [select one of the following: 'sunburn' or 'sunburn and tanning']'' or ''[bullet] for skin extremely sensitive to sunburn''.

(v) If the UVA descriptor in § 352.52(b)(1)(vi) is the same as the SPF descriptor in § 352.52(b)(1)(i) through (b)(1)(iv), then the statement in § 352.52(b)(1)(i) through (b)(1)(iv) may be combined with the statement in § 352.52(b)(1)(vi) as follows: ''[Bullet] [select one of the following descriptors in accordance with §§ 352.70 and 352.73: 'low,' 'medium,' 'high,' or 'highest'] UVB sunburn/UVA protection''.

(c) *Warnings.* The labeling of the product contains the following warnings under the heading ''Warnings:''

(1) The labeling states in bold type ''UV exposure from the sun increases the risk of skin cancer, premature skin aging, and other skin damage. It is important to decrease UV exposure by limiting time in the sun, wearing protective clothing, and using a sunscreen.''

(2) The labeling states ''When using this product [bullet] keep out of eyes. Rinse with water to remove.''

(3) The labeling states ''Stop use and ask a doctor if [bullet] skin rash occurs''.

(d) *Directions.* The labeling of the product contains the following statements, as appropriate, under the heading ''Directions.'' More detailed directions applicable to a particular product formulation (e.g., cream, gel, lotion, oil, spray, etc.) may also be included.

(1) *For products containing any ingredient in § 352.10.* (i) The labeling states ''[bullet] apply [select one of the following: 'liberally' or 'generously'] [and, as an option: 'and evenly'] [insert appropriate time interval, if a waiting period is needed] before sun exposure''.

(ii) The labeling states ''[bullet] apply and reapply as directed to avoid lowering protection''.

(iii) As an option, the labeling may state ''[bullet] apply to all skin exposed to the sun''.

(iv) The labeling states ''[bullet] children under 6 months of age: ask a doctor''.

(2) *For products that satisfy the water resistant or very water resistant testing procedures identified in § 352.76.* The labeling states ''[bullet] reapply after [select one of the following: '40 minutes of' or '80 minutes of' for products that satisfy either the water resistant or very water resistant test procedures in § 352.76, respectively] swimming or [select one or more of the following: 'sweating' or 'perspiring'] and after towel drying. Otherwise, reapply at least every 2 hours''.

(3) *For products that do not satisfy the water resistant or very water resistant testing procedures identified in § 352.76.* The labeling states ''[bullet] reapply at least every 2 hours and after towel drying, swimming, or [select one of the following: 'sweating' or 'perspiring']''.

(e) *Statement on product performance*—(1) *For products containing any ingredient identified in*

[1] See § 201.66(b)(4) of this chapter for definition of bullet symbol.

§ 352.10. The following product category designation (PCD) labeling claims may be used under the heading ''Other information'' or anywhere outside of the ''Drug Facts'' box or enclosure and shall not be intermixed with the information required under § 352.50(a).

(i) *For products with an SPF of 2 to under 15*. The labeling states ''low sunburn protection product''.

(ii) *For products with an SPF of 15 to under 30*. The labeling states ''medium sunburn protection product''.

(iii) *For products with an SPF of 30 to 50*. The labeling states ''high sunburn protection product''.

(iv) *For products with an SPF over 50*. The labeling states ''highest sunburn protection product''.

(2) *For products containing any ingredient identified in § 352.10*. The following labeling statement may be used under the heading ''Other information'' or anywhere outside of the ''Drug Facts'' box or enclosure and shall not be intermixed with the information required under § 352.50(a). The labeling states ''higher SPF products give more sun protection, but are not intended to extend the time spent in the sun''.

(3) *For products containing any ingredient identified in § 352.10 and that satisfy the requirements in § 352.73 for a labeled UVA protection value*. The following labeling statements may be used anywhere outside of the ''Drug Facts'' box or enclosure and shall not be intermixed with the information required under § 352.50(a).

(i) The labeling states ''broad spectrum sunscreen''.

(ii) The labeling states ''provides [select one of the following: 'UVA and UVB,' or 'broad spectrum'] protection''.

(iii) The labeling states ''protects from UVA and UVB [select one of the following: 'rays' or 'radiation']''.

(iv) The labeling states ''[select one of the following: 'absorbs' or 'protects'] within the UVA spectrum''.

(f) *Products, including cosmetic-drug products, containing any ingredient identified in § 352.10 labeled for use only on specific small areas of the face (e.g., lips, nose, ears, and/or around the eyes) and that meet the criteria established in § 201.66(d)(10) of this chapter*. * * *

(1) * * *

* * * * *

(ii) The indication required by § 201.66(c)(4) of this chapter may be limited to the following: ''Use [in bold type] helps prevent sunburn.''

(iii) The warnings required by § 201.66(c)(5)(i) through (c)(5)(ix) of this chapter may be limited to the following: ''UV exposure from the sun increases the risk of skin cancer, premature skin aging, and other skin damage. It is important to decrease UV exposure by limiting time in the sun, wearing protective clothing, and using a sunscreen. [in bold type]'' ''[bullet] keep out of eyes'' ''[bullet] stop use if skin rash occurs.''

(iv) The warning in § 201.66(c)(5)(x) of this chapter may be limited to the following: ''Keep out of reach of children.''

(v) *For lip protectant products containing any ingredient identified in § 352.10*. The heading and the indication required by § 201.66(c)(4) of this chapter may be limited to ''Use [in bold type] helps prevent sunburn and chapped lips''. The warnings required in paragraph (f)(1)(iii) of this section may be limited to the following: ''Stop use if skin rash occurs.'' The warning required in paragraph (f)(1)(iv) of this section may be omitted. The directions in paragraphs (d)(2) and (d)(3) of this section may be limited to the following: ''apply liberally and reapply at least every 2 hours for sunburn protection''.

(vi) *For lipsticks, lip products to prolong wear of lipstick, lip gloss, and lip balm containing any ingredient identified in § 352.10 and identified in § 720.4(c)(7) of this chapter*. The labeling is identical to that in paragraph (f)(1)(v) of this section except the heading and the indication required by § 201.66(c)(4) of this chapter are limited to ''Use [in bold type] helps prevent sunburn''.

* * * * *

9. Section 352.60 is amended by revising paragraphs (c) and (d) to read as follows:

§ 352.60 Labeling of permitted combinations of active ingredients.

* * * * *

(c) *Warnings*. The labeling of the product states, under the heading ''Warnings,'' the warning(s) for each ingredient in the combination, as established in the warnings section of the applicable OTC drug monographs, except that the warning for skin protectants in § 347.50(c)(3) of this chapter is not required for permitted combinations containing a sunscreen and a skin protectant identified in § 352.20(b). For products marketed as a lip protectant with sunscreen, § 352.52(f)(1)(vi) applies.

(d) *Directions*. The labeling of the product states, under the heading ''Directions,'' directions that conform to the directions established for each ingredient in the directions sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph. When the time intervals or age limitations for administration of the individual ingredients differ, the directions for the combination product may not contain any dosage that exceeds those established for any individual ingredient in the applicable OTC drug monograph(s), and may not provide for use by any age group lower than the highest minimum age limit established for any individual ingredient. For permitted combinations containing a sunscreen and a skin protectant identified in § 352.20(b), the directions for sunscreens in § 352.52(d) must be used. For products marketed as a lip protectant with sunscreen, § 352.52(f)(1)(vi) applies.

10. Sections 352.70 through 352.73 are revised as follows:

Subpart D—Testing Procedures

Sec.

* * * * *

§ 352.70 SPF testing procedure.

(a) *Standard sunscreens*—(1) *Laboratory validation*. A standard sunscreen shall be used concomitantly in the testing procedures for determining the SPF value of a sunscreen drug product to ensure the uniform evaluation of sunscreen drug products.

(i) *For products with an SPF of 2 to 15*. The standard sunscreen shall be an 8-percent homosalate preparation with a mean SPF value of 4.47 (standard deviation = 1.28). In order for the SPF determination of a test product to be considered valid, the SPF of the standard sunscreen must fall within the standard deviation range of the expected SPF (i.e., 4.47 ± 1.28). Optionally, the standard sunscreen in paragraph (a)(1)(ii) of this section may be used.

(ii) *For products with an SPF over 15 (optional for SPF values of 2 to 15)*. The standard sunscreen shall be an SPF 15 formulation containing 7 percent padimate O and 3 percent oxybenzone with a mean SPF value of 16.3 (standard deviation = 3.43). In order for the SPF determination of a test product to be considered valid, the SPF of the standard sunscreen must fall within the standard deviation range of the expected SPF (i.e., 16.3 ± 3.43).

(2) *Standard homosalate sunscreen*—(i) *Preparation of the standard homosalate sunscreen*. (A) The standard homosalate sunscreen is prepared from two different preparations (preparation

A and preparation B) with the following compositions:

COMPOSITION OF PREPARATION A AND PREPARATION B OF THE HOMOSALATE STANDARD SUNSCREEN

Ingredients	Percent by weight
Preparation A	
Lanolin	5.00
Homosalate	8.00
White petrolatum	2.50
Stearic acid	4.00
Propylparaben	0.05
Preparation B	
Methylparaben	0.10
Edetate disodium	0.05
Propylene glycol	5.00
Triethanolamine	1.00
Purified water USP	74.30

(B) Preparation A and preparation B are heated separately to 77 to 82 °C, with constant stirring, until the contents of each part are solubilized. Add preparation A slowly to preparation B while stirring. Continue stirring until the emulsion formed is cooled to room temperature (15 to 30 °C). Add sufficient purified water to obtain 100 grams of standard sunscreen preparation.

(ii) *High performance liquid chromatography (HPLC) assay of the standard homosalate sunscreen.* Assay the standard homosalate sunscreen preparation by the following method to ensure proper concentration:

(A) *Reagents.* (*1*) Acetic acid, glacial, ACS grade.

(*2*) Isopropanol, HPLC grade.

(*3*) Methanol, HPLC grade.

(*4*) Homosalate, USP reference standard.

(B) *Instrumentation.* Equilibrate a suitable liquid chromatograph to the following or equivalent conditions:

Column	Ultrasphere ODS 150 x 4.6 millimeters (5 microns), or Ultrasphere ODS 250 x 4.6 millimeters (5 microns)
Mobile Phase	85:15:0.5 methanol:water:acetic acid
Flow Rate	1.5 milliliters per minute
Temperature	Ambient
Detector	UV spectrophotometer at 308 nanometers
Attenuation	As needed
Injection Amount	10 microliters

(C) *Standard preparation.* (*1*) Accurately weigh 0.50 gram of homosalate USP reference standard into a 250-milliliter volumetric flask. Dissolve and dilute to volume with isopropanol. Mix well.

(*2*) Accurately pipet 20.0 milliliters of the homosalate solution (described in paragraph (a)(2)(ii)(C)(*1*) of this section) into a 100-milliliter volumetric flask. Dilute to volume with isopropanol and mix well. This is the standard preparation.

(D) *Sample preparation.* (*1*) Accurately weigh 2.0 grams of sample into a 100-milliliter volumetric flask.

(*2*) Add approximately 75 milliliters of isopropanol and heat with swirling until the sample is evenly dispersed.

(*3*) Cool to room temperature (15 to 30 °C) and dilute to volume with isopropanol. Mix well.

(*4*) Pipet 25.0 milliliters of this sample preparation into a 100-milliliter volumetric flask and dilute to volume with isopropanol. Mix well.

(E) *System suitability.* (*1*) Three replicate injections of the standard preparation (described in paragraph (a)(2)(ii)(C)(*2*) of this section) will yield a relative standard deviation of not more than 2.0 percent calculated on peak areas for homosalate.

(*2*) In case a system fails to meet this criterion, adjusting the mobile phase or replacing the column may be necessary to obtain suitable chromatography.

(F) *Analysis.* (*1*) Inject 10 microliters of the standard preparation (described in paragraph (a)(2)(ii)(C) of this section) in triplicate and collect data for about 15 minutes or until both homosalate (two isomers) peaks have completely eluted.

(*2*) Similarly inject 10 microliters of each sample preparation.

(*3*) The system suitability requirements must be met.

(G) *Calculation.* Sum the peak areas of the two homosalate isomers for each injection and calculate the percent (weight/weight) homosalate content in the sample preparation as follows:

$$\frac{\text{(Total homosalate peak area for sample) (Standard weight}^1\text{) (DF}^2\text{)}}{\text{(Average total homosalate peak area for standard) (Sample weight}^1\text{)}}$$

[1] weight in grams
[2] DF is a dilution factor calculated as follows:

$$\frac{WStd}{Vd} \times \frac{AStd}{Vd} \times \frac{Vd}{WSmp} \times \frac{Vd}{ASmp} \times 100 = \text{percent weight/weight}$$

where:
WStd = standard weight (in grams)
Vd = volume of dilution
AStd = aliquot of prepared standard solution
WSmp = sample weight (in grams)
ASmp = aliquot of prepared sample solution

(3) *Standard padimate O/oxybenzone sunscreen*—(i) *Preparation of the standard padimate O/oxybenzone sunscreen.* The standard sunscreen is prepared from four different parts (parts A, B, C, and D) with the following compositions:

COMPOSITION OF THE PADIMATE O/OXYBENZONE STANDARD SUNSCREEN

Ingredients	Percent by weight
Part A	
Lanolin	4.50
Cocoa butter	2.00
Glyceryl monostearate	3.00
Stearic acid	2.00
Padimate O	7.00
Oxybenzone	3.00
Propylparaben	0.10
Part B	
Purified water USP	71.60
Sorbitol solution	5.00

COMPOSITION OF THE PADIMATE O/OXYBENZONE STANDARD SUNSCREEN—Continued

Ingredients	Percent by weight
Triethanolamine, 99 percent	1.00
Methylparaben	0.30
Part C	
Benzyl alcohol	0.50
Part D	
Purified water USP	QS1

[1] Quantity sufficient to make 100 grams

(A) *Step 1.* Add the ingredients of Part A into a suitable stainless steel kettle equipped with a propeller agitator. Mix at 77 to 82 °C until uniform.

(B) *Step 2.* Add the water of Part B into a suitable stainless steel kettle equipped with a propeller agitator and begin mixing and heating to 77 to 82 °C. Add the remaining ingredients of Part B and mix until uniform. Maintain temperature at 77 to 82 °C.

(C) *Step 3.* Add the batch of Step 1 at 77 to 82 °C to the batch of Step 2 at 77 to 82 °C, and mix until smooth and uniform. Slowly cool the batch to 49 to 54 °C.

(D) *Step 4.* Add the benzyl alcohol of Part C to the batch of Step 3 at 49 to 54 °C. Mix until uniform. Continue to cool batch to 35 to 41 °C.

(E) *Step 5.* Add sufficient water of Part D to the batch of Step 4 at 35 to 41 °C to obtain 100 grams of standard sunscreen preparation. Mix until uniform. Cool batch to 27 to 32 °C.

(ii) *HPLC assay of the standard padimate O/oxybenzone sunscreen.* To ensure that the standard sunscreen contains proper amounts of padimate O and oxybenzone, analyze it against USP reference standards for padimate O and oxybenzone in a high performance liquid chromatography procedure using the following parameters:

(A) *Reagents.* (*1*) Acetic acid, glacial, ACS grade.

(*2*) Isopropanol, HPLC grade.

(*3*) Methanol, HPLC grade.

(*4*) Oxybenzone, USP reference standard.

(*5*) Padimate O, USP reference standard.

(B) *Instrumentation.* Equilibrate a suitable liquid chromatograph to the following or equivalent conditions:

Column	Ultrasphere ODS 250 x 4.6 millimeters (5 microns), or Supelcosil LC-18 DB 250 x 4.6 millimeters (5 microns)
Mobile Phase	85:15:0.5 methanol:water:acetic acid
Flow Rate	1.5 milliliters per minute
Temperature	Ambient
Detector	UV spectrophotometer at 308 nanometers
Attenuation	As needed
Injection Amount	10 microliters

(C) *Standard preparation.* (*1*) Weigh 0.50 gram of oxybenzone reference standard into a 250-milliliter volumetric flask. Dissolve and dilute to volume with isopropanol. Mix well.

(*2*) Weigh 0.50 gram of padimate O reference standard into a 250-milliliter volumetric flask. Dissolve and dilute to volume with isopropanol. Mix well.

(*3*) Pipet 3.0 milliliters of the oxybenzone solution and 7.0 milliliters of the padimate O solution into a 100-milliliter volumetric flask. Dilute to volume with isopropanol and mix well. This is the standard preparation.

(D) *Sample preparation.* (*1*) Weigh 1.0 gram of sample into a 50-milliliter volumetric flask.

(*2*) Add approximately 30 milliliters of isopropanol and heat with swirling until the sample is evenly dispersed.

(*3*) Cool to room temperature (15 to 30 °C) and dilute to volume with isopropanol. Mix well.

(*4*) Pipet 5.0 milliliters of this sample preparation into a 50-milliliter volumetric flask and dilute to volume with isopropanol. Mix well.

(E) *System suitability.* (*1*) Three replicate injections of the standard preparation (described in paragraph (a)(3)(ii)(C) of this section) will yield a relative standard deviation of not more than 2.0 percent calculated on peak areas for oxybenzone and padimate O.

(*2*) A calculated resolution between the oxybenzone and padimate O peaks will be not less than 3.0.

(*3*) In case a system fails to meet this criterion, adjusting the mobile phase or replacing the column may be necessary to obtain suitable chromatography.

(F) *Analysis.* (*1*) Inject 10 microliters of the standard preparation (described in paragraph (a)(3)(ii)(C) of this section) in triplicate and collect data for about 15 minutes or until the padimate O peak has completely eluted. Elution order is oxybenzone, then padimate O.

(*2*) Similarly inject 10 microliters of each sample preparation.

(*3*) The system suitability requirements must be met.

(G) *Calculation.* Calculate the percent (weight/weight) of each sunscreen ingredient in the sample preparation as follows:

(*1*) Oxybenzone (percent weight)

$$\frac{(\text{Sample oxybenzone peak area})(\text{Standard oxybenzone weight}^1)(\text{DF}^2)}{(\text{Standard oxybenzone peak area})(\text{Sample weight}^1)}$$

[1] weight in grams
[2] DF is a dilution factor calculated as in paragraph (a)(2)(ii)(G) of this section.

(*2*) Padimate O (percent weight)

$$\frac{(\text{Sample padimate O peak area})(\text{Standard padimate O weight}^1)(\text{DF}^2)}{(\text{Standard padimate O peak area})(\text{Sample weight}^1)}$$

[1] weight in grams
[2] DF is a dilution factor calculated as in paragraph (a)(2)(ii)(G) of this section.

(b) *Light source (solar simulator)*—(1) *Emission spectrum.* A solar simulator used for determining the SPF of a sunscreen drug product should be filtered so that it provides a continuous emission spectrum from 290 to 400 nanometers (nm) with a limit of 1,500 watts per square meter (W/m^2) on total solar simulator irradiance for all wavelengths between 250 and 1400 nm and the following percentage of erythema-effective radiation in each specified range of wavelengths:

SOLAR SIMULATOR EMISSION SPECTRUM

Wavelength range (nm)	Percent erythemal contribution
< 290	< 0.1
290–310	46.0–67.0
290–320	80.0–91.0
290–330	86.5–95.0
290–340	90.5–97.0
290–350	93.5–98.5
290–400	93.5–100.0

(2) *Operation.* A solar simulator should have no significant time related fluctuations (within 20 percent) in radiation emissions after an appropriate warmup time and good beam uniformity (within 20 percent) in the exposure plane. The average delivered dose to the UV exposure site must be within 10 percent of the prescribed dose.

(3) *Periodic measurement.* To ensure that the solar simulator delivers the appropriate spectrum of UV radiation, the emission spectrum of the solar simulator must be measured every 6 months with an appropriate and accurately calibrated spectroradiometer system (results should be traceable to the National Institute for Standards and Technology). In addition, the solar simulator must be recalibrated if there is any change in the lamp bulb or the optical filtering components (i.e., filters, mirrors, lenses, collimating devices, or focusing devices). Daily solar simulator radiation intensity should be monitored with a broadband radiometric device that is sensitive primarily to UV radiation. The broadband radiometric device should be calibrated using side by side comparison with the spectroradiometer at the time of the semiannual spectroradiometric measurement of the solar simulator. If a lamp must be replaced due to failure or aging during a phototest, broadband device readings consistent with those obtained for the original calibrated lamp will suffice until measurements can be performed with the spectroradiometer at the earliest possible opportunity.

(c) *General testing procedures*—(1) *Medical history.* Obtain a medical history from each subject with emphasis on the effects of sunlight on his/her skin. Determine that each subject is in good general health with skin type I, II, or III (as described in this paragraph).

Skin Type and Sunburn and Tanning History (Based on first 30 to 45 minutes of sun exposure after a winter season of no sun exposure).

I: Always burns easily; never tans (sensitive).
II: Always burns easily; tans minimally (sensitive).
III: Burns moderately; tans gradually (light brown) (normal).
IV: Burns minimally; always tans well (moderate brown) (normal).
V: Rarely burns; tans profusely (dark brown) (insensitive).
VI: Never burns; deeply pigmented (insensitive).

Determine that the subject is not taking topical or systemic medication that is known to alter responses to ultraviolet radiation and that the subject has no history of sensitivities to topical products and/or abnormal responses to sunlight, such as a phototoxic or photoallergic response.

(2) *Physical examination.* Conduct a physical examination to determine the presence of sunburn, suntan, scars, active dermal lesions, and uneven skin tones on the areas of the back to be tested. A suitable source of low power UVA, such as a Woods lamp, is helpful in this process. If any of these conditions are present, the subject is not qualified to participate in the study. The presence of nevi, blemishes, or moles will be acceptable if in the physician's judgment they will neither compromise the study, nor jeopardize subject safety. Subjects with dysplastic nevi should not be enrolled. Excess hair on the back is acceptable if the hair is clipped. Shaving is unacceptable because it may remove a significant portion of the stratum corneum and temporarily increase skin permeability to ultraviolet radiation.

(3) *Informed consent.* Obtain legally effective written informed consent from all subjects.

(4) *Test site delineation*—(i) *Test site.* A test site is the location on the back for determining the subject's initial and final minimal erythema dose (MED) for unprotected skin and for determining SPF values after application of the sunscreen standard and the test sunscreen product(s). There typically are 4 to 6 test sites for each subject. Test sites should be located on the back between the beltline and the shoulder blades (scapulae) and lateral to the midline. Each test site shall be a minimum of 50 square centimeters, e.g., 5 x 10 centimeters. Outline the test sites to which the sunscreen standard and the test sunscreen product(s) will be applied with indelible ink. If the subject is to receive the doses of ultraviolet radiation in an upright (seated) position, draw the lines on the skin with the subject upright (seated). If the subject is to receive the doses of ultraviolet radiation while prone, draw the lines with the subject prone.

(ii) *Test subsite.* Test subsites are the locations to which ultraviolet radiation is administered within a test site. At least 5 test subsites will receive UV doses within each test site. Test subsites will be at least 1 square centimeter (cm^2) in area and will be separated from each other by at least 1 cm. Mark the location of each test subsite with indelible ink.

(5) *Application of test materials.* Apply the test sunscreen product and the standard sunscreen at 2 milligrams per square centimeter (mg/cm^2) to their respective test sites to establish standard films. Test sites will be randomly located on the back in a blinded manner. Use a finger cot compatible with the sunscreen to spread the product as evenly as possible. Pretreat the finger cot by saturating with the sunscreen and then wiping off material before application. Pretreatment is meant to ensure that sunscreen is applied at the correct density of 2 mg/cm^2.

(6) *Waiting period.* Before exposing the test site areas after applying a product, wait at least 15 minutes.

(7) *Number of subjects*—(i) *For products with an expected SPF under 30.* A test panel shall consist of 20 to 25 subjects with at least 20 subjects who produce valid data for analysis. Data are valid unless rejected in accordance with paragraph (c)(9) of this section. If more than 5 subjects are rejected based on paragraph (c)(9) of this section, the panel is disqualified, and a new panel must be created.

(ii) *For products with an expected SPF of 30 or over.* A test panel shall consist of 25 to 30 subjects with at least 25 subjects who produce valid data for analysis. Data are valid unless rejected in accordance with paragraph (c)(9) of this section. If more than 5 subjects are rejected based on paragraph (c)(9) of this section, the panel is disqualified, and a new panel must be created.

(8) *Response criteria.* In order that the person who evaluates the MED responses is not biased, he/she must not be the same person who applied the sunscreen drug product to the test site or administered the doses of UV radiation. After UV radiation exposure from the solar simulator is completed, all immediate responses shall be recorded. These may include an immediate darkening or tanning, typically grayish or purplish in color, which fades in 30 to 60 minutes; an immediate reddening at the subsite, due to heating of the skin, which fades rapidly; and an immediate generalized heat response, spreading beyond the subsite, which fades in 30 to 60 minutes. After the immediate responses are noted, each subject shall shield the exposed area from further UV radiation until the MED response is evaluated. Determine the MED 16 to 24 hours after exposure. Evaluate the erythema

responses of each test site using either tungsten or warm white fluorescent lighting that provides 450 to 550 lux of illumination at the test site. For the evaluation, the test subject should be in the same position used when the test site was irradiated. For each test site, determine the smallest UV dose that produced redness reaching the borders of the test subsite. The MED is the quantity of erythema-effective energy required to produce the first perceptible, redness reaction with clearly defined borders at 16 to 24 hours post-exposure. To determine the MED, there must be at least one subsite that received a smaller UV dose and does not produce redness as well as a subsite(s) with somewhat more intense redness. For subsites showing an erythema response, the maximal exposure should be no more than twice the total energy of the minimal exposure.

(9) *Rejection of test data.* Reject test data if the exposure series fails to elicit an MED response on either the treated or unprotected skin sites; or all subsites within a test site show more intense responses than the threshold erythema response; or the responses are inconsistent with the series of UV doses administered; or the subject was noncompliant, e.g., the subject withdraws from the test due to illness or work conflicts or does not shield the exposed testing sites from further UV radiation until the MED is read.

(d) *Determination of SPF*—(1) *Determination of erythema action spectrum.* (i) Use the following erythema action spectrum as weighting factors to calculate the erythema-effective exposure produced by a solar simulator:

$V_i(\lambda) = 1.0$ $(250 < \lambda < 298$ nm)

$V_i(\lambda) = 10^{0.094 * (298 - \lambda)}$ $(298 < \lambda < 328$ nanometers)

$V_i(\lambda) = 10^{0.015 * (140 - \lambda)}$ $(328 < \lambda < 400$ nanometers)

(ii) Integrate the erythemally-effective spectral irradiance over wavelength and time to calculate the erythema-effective UV dose delivered by a solar simulator as follows:

$$E = \sum_{250}^{400} V_i(\lambda) * I(\lambda) * t_{exp}$$

where: E = Erythema-Effective Dose (Effective Joules per square meter (J/m^2-eff))
V^i = Weighting Factor (Erythema Action Spectrum)
I = Spectral Irradiance (Watts per square meter per nanometer)
t_{exp} = exposure time (seconds)

(iii) The erythema action spectrum may be determined using a handheld radiometer with a response weighted to match the spectrum in ''CIE S 007/E Erythemal Reference Action Spectrum and Standard Erythema Dose,'' dated 1998, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from CIE Central Bureau, Kegelgasse 27, A–1030, Vienna, Austria, or may be examined at the Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 22, Silver Spring, MD, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC. It is advisable to measure the solar simulator output before and after each phototest or, at a minimum, at the beginning and end of each test day. This radiometer should be calibrated using side by side comparison with the spectroradiometer (using the weighting factors determined according to paragraph (d)(1)(i) of this section) at the time of the semiannual spectroradiometric measurement of the solar simulator.

(2) *Determination of MED of unprotected skin.* Administer a series of five UV radiation doses expressed as J/m^2-eff (adjusted to the erythema action spectrum calculated according to paragraph (d)(1) of this section) to the subsites within each test site on a subject using an accurately calibrated solar simulator. Use the series of five exposures to the unprotected test site to determine the initial unprotected MED. Select the doses that are a geometric series represented by (1.25^n), wherein each exposure dose is 25 percent greater than the previous exposure dose to maintain the same relative uncertainty (expressed as a constant percentage), independent of the subject's sensitivity to UV radiation. Usually, the UV radiation for determining the initial unprotected MED is administered the day prior to applying the sunscreen product and standard sunscreen, and the responses then are evaluated immediately prior to applying the sunscreen product and sunscreen standard. Determine the final unprotected MED on the same day that UV radiation is administered to the sunscreen-protected test sites. Use the final unprotected MED (MED(US)) in calculating SPF.

(3) *Determination of individual SPF values.* Administer a series of five UV radiation doses expressed as J/m^2-eff (adjusted to the erythema action spectrum calculated according to paragraph (d)(1) of this section) to the subsites within each test site on a subject using an accurately calibrated solar simulator. The five UV doses will be a geometric series as described in paragraph (d)(2) of this section, where the middle exposure represents the expected SPF. For products with an expected SPF less than 8, use exposures that are the product of the initial unprotected MED times 0.64X, 0.80X, 1.00X, 1.25X, and 1.56X, where X equals the expected SPF of the test product. For products with an expected SPF between 8 and 15, use exposures that are the initial unprotected MED times 0.69X, 0.83X, 1.00X, 1.20X, and 1.44X, where X equals the expected SPF of the test product. For products with an expected SPF greater that 15, use exposures that are the initial unprotected MED times 0.76X, 0.87X, 1.00X, 1.15X, and 1.32X, where X equals the expected SPF of the test product. The MED is the smallest erythemally-effective UV dose required to produce mild redness within the subsite border at 16 to 24 hours post-exposure. Calculate the SPF value of each sunscreen product and sunscreen standard using the MED of sunscreen-protected skin (MED(PS)) and the final unprotected skin MED (MED(US)) as follows:

$$SPF = \frac{MED(PS)\ (J/m^2\text{-eff})}{MED(US)\ (J/m^2\text{-eff})}$$

(4) *Determination of the test product SPF and PCD.* Use data from at least 20 test subjects with n representing the number of subjects used. First, compute the SPF value for each subject as stated in paragraphs (d)(2) and (d)(3) of this section. Second, compute the mean SPF value, $\bar{x}$, and the standard deviation, s, for these subjects. Third, obtain the upper 5-percent point from Student's t distribution table with n-1 degrees of freedom. Denote this value by t. Fourth, compute $ts/\sqrt{n}$. Denote this quantity by A (i.e., $A = ts/\sqrt{n}$). Fifth, calculate the SPF value to be used in labeling as

follows: The label SPF equals the largest whole number less than $\bar{x}$ - A. Sixth and last, the sunscreen product is classified into a PCD as follows: If 50 + A < $\bar{x}$, the PCD is Highest; if 30 + A ≤ $\bar{x}$ ≤ 50 + A, the PCD is High; if 15 + A ≤ $\bar{x}$ < 30 + A, the PCD is Medium; if 2 + A ≤ $\bar{x}$ < 15 + A, the PCD is Low; if $\bar{x}$ < 2 + A, the product shall not be labeled as an OTC sunscreen drug product and may not display an SPF value.

§ 352.71 UVA in vitro testing procedure.

(a) *Light source for transmittance/absorbance measurements.* The light source should satisfy the requirements for solar simulators described in § 352.70(b).

(b) *Substrate.* Use optical-grade quartz plate suitable for substrate spectrophotometry that has been roughened on one side.

(c) *Sample holder.* The sample holder should hold the substrate in a horizontal position to avoid flowing of the sunscreen drug product from one edge of the substrate to the other. It should be mounted as close as possible to the input optics of the spectroradiometer to maximize capture of forward scattered radiation. The sample holder should be a thin, flat plate with a suitable aperture through which UV radiation can pass. The substrate will be placed on the upper surface of the sample holder.

(d) *Spectroradiometer input optics.* Unless the spectroradiometer is equipped with an integrating sphere, an ultraviolet radiation diffuser should be placed between the sample and the input optics of the spectroradiometer. The diffuser will be constructed from any UV radiation transparent material (e.g., Teflon® or quartz). The diffuser ensures that the radiation received by the spectroradiometer is not collimated. The spectroradiometer input slits should be set to provide a bandwidth that is less than or equal to 5 nanometers.

(e) *Sunscreen drug product application to substrate.* The accuracy of the test depends upon the application of a precisely controlled amount of sunscreen product with a uniform distribution over the application area of the substrate. The product is applied at 2 milligrams per square centimeter to the substrate. To achieve uniform distribution over the substrate, the sunscreen product should be applied in a series of small dots over the application area of the substrate and then spread evenly using a gloved finger. A very light spreading action for a short period of time (approximately 10 seconds) should be used when distributing the product to ensure complete coverage without excessive buildup of product in the troughs of the substrate.

(f) *Pre-irradiation to account for differences in photostability.* To account for potentially varying degrees of photostability between sunscreen drug products, irradiate the sunscreen product on the substrate with a dose of UV radiation equal to the SPF of the sunscreen product multiplied by 200 J/m²-eff multiplied by 2/3. A UV radiation dose of 200 J/m²-eff is equivalent to one minimal erythema dose (MED). The UV dose to be delivered is determined by multiplying the light source spectral irradiance action spectrum for erythema in ''CIE S 007/E Erythemal Reference Action Spectrum and Standard Erythema Dose,'' at each wavelength, integrating over wavelength, and multiplying the integral by the exposure time. ''CIE S 007/E Erythemal Reference Action Spectrum and Standard Erythema Dose,'' dated 1998, is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from CIE Central Bureau, Kegelgasse 27, A–1030, Vienna, Austria, or may be examined at the Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 22, Silver Spring, MD 20993, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(g) *Calculation of the spectral transmittance at each wavelength interval.* The dynamic range of the measurement system and the intensity of the light source should be sufficiently high that signals measured at all UV wavelengths (290 to 400 nanometers) through a highly absorbing sunscreen product are above the noise level of the measurement system. Spectral irradiance will be measured at 5 nanometer intervals, from 290 to 400 nanometers. At least 12 measurements of spectral irradiance transmitted through the substrate without sunscreen drug product present will be obtained from different locations on the substrate surface ($C(\lambda)_1$, $C(\lambda)_2$, $C(\lambda)_3$, . . . $C(\lambda)_{12}$). In addition, a minimum of 12 measurements of spectral irradiance transmitted through the substrate with the sunscreen drug product present will be similarly obtained after pre-irradiation of the sunscreen drug product ($P(\lambda)_1$, $P(\lambda)_2$, $P(\lambda)_3$, . . . $P(\lambda)_{12}$). The mean transmittance for wavelength λ, $\overline{T(\lambda)}$, is the ratio of the mean of the C(λ) values to the mean of the P(λ) values, as follows:

$$\overline{T(\lambda)} = \frac{\sum_1^n P(\lambda)/n}{\sum_1^n C(\lambda)/n}$$

The standard deviation, s, associated with the spectral transmittance is evaluated using Taylor's approximation, as follows:

$$s = \sqrt{\left[\frac{\overline{P(\lambda)} * s(C(\lambda))}{\overline{(C(\lambda))^2}}\right]^2 + \left[\frac{(sP(\lambda))}{\overline{C(\lambda)}}\right]^2}$$

where $\overline{C(\lambda)}$ = mean of the measurements of C at wavelength λ.

$\overline{P(\lambda)}$ = mean of the measurements of P at wavelength λ.

s(C(λ)) = standard deviation of the measurements of C at wavelength λ.

s(P(λ)) = standard deviation of the measurements of P at wavelength λ.

s(C(λ)) is calculated as follows:

$$s(C(\lambda)) = \sqrt{\frac{\sum_1^n (C(\lambda) - \overline{C(\lambda)})^2}{(n-1)}}$$

s(P(λ)) is calculated as follows:

$$s(P(\lambda)) = \sqrt{\frac{\sum_1^n (P(\lambda) - \overline{P(\lambda)})^2}{(n-1)}}$$

This calculation gives 23 spectral transmittance values with associated standard deviations, one for each 5 nanometer wavelength increment from 290 to 400 nanometers. The standard deviation values will provide an indication of the uniformity of sunscreen drug product spreading during application to the substrate. The coefficient of variation, which is the standard deviation divided by the mean, and expressed as a percentage, should be less than 10 percent.

(h) *Calculation of the UVA I/UV ratio.* (1) Spectral transmittance values, T(λ), are converted into absorbance values, A(λ), by taking the negative logarithm of

the spectral transmittance value as follows:

$A(\lambda) = -\log T(\lambda)$

The calculation yields 23 monochromatic absorbance values in 5 nanometer increments from 290 to 400 nanometers.

(2) The index of UVA I protection is calculated as the area (per unit wavelength) under the UVA I portions of a plot of wavelength versus A(λ), divided by the area (per unit wavelength) under the total curve, as follows:

$$\text{UVA I/UV ratio} = \frac{\text{UVA I area per unit wavelength}}{\text{UV area per unit wavelength}}$$

UVA I area per unit λ is given as:

$$\int_{340}^{400} A(\lambda)\, d(\lambda)\, B(\lambda) \;/\; \int_{340}^{400} d(\lambda)$$

UV area per unit λ is given as:

$$\int_{290}^{400} A(\lambda)\, d(\lambda)\, B(\lambda) \;/\; \int_{290}^{400} d(\lambda)$$

where: A(λ) = effective absorbance given as -log T(λ)

d(λ) = wavelength interval between measurements

B(λ) = any biological action spectrum factor

Because no appropriate biological action spectrum for UVA radiation damage has been universally accepted, no action spectrum is specified. The value of B(λ) is, therefore, equal to 1.0 for all wavelengths.

(3) The integrals in the formulae in paragraphs (h)(1) and (h)(2) of this section are evaluated using Simpson's Rule for irregular areas, which states:

$\text{Area} = h/3 \times [Y_0 + Y_{2m} + 4(Y_1 + Y_3 \ldots + Y_{2m-1}) + 2(Y_2 + Y_4 + \ldots Y_{2m-2})]$

In this equation, Y_0, Y_1, Y_2, . . . Y_{2m} are the lengths of 2m parallel lines drawn vertically to divide the area under the curve of a graph into 2m-1 segments of equal width, h. In practice, the values of Y_0, Y_1, Y_2, . . . Y_{2m} are the A(λ) values determined and h is the wavelength interval at which the spectral transmittance is determined (i.e., 5 nanometers).

(4) UVA I area per unit wavelength (aUVA I/λ) is calculated as follows:

$aUVA\ I/\lambda = 5/3 \times [A_{340} + A_{400} + 4(A_{345} + \ldots + A_{395}) + 2(A_{350} + A_{360} + A_{370} + \ldots + A_{390})]/60$

UV area per unit wavelength (aUV/λ) is calculated as follows:

$aUV/\lambda = 5/3 \times [A_{290} + A_{400} + 4(A_{295} + A_{305} + A_{315} + \ldots + A_{395}) + 2(A_{300} + A_{310} + \ldots + A_{390})]/110$

UVA I/UV ratio is calculated as follows:

$$\text{UVA I/UV ratio} = \frac{aUVA\ I/\lambda}{aUV/\lambda}$$

(i) *Category determination of the UVA I/UV ratio.* Perform at least 5 separate determinations of the UVA I/UV ratio, from which the mean can be calculated. Using the mean, the sunscreen drug product is classified by in vitro UVA I/UV ratio as follows:

UVA I/UV Ratio	Category
0.20 to 0.39	Low
0.40 to 0.69	Medium
0.70 to 0.95	High
greater than 0.95	Highest

§ 352.72 UVA in vivo testing procedure.

(a) *Standard sunscreen.* A standard sunscreen shall be tested concomitantly in the procedure for determining the UVA protection factor (UVA–PF) value by means of persistent pigment darkening to ensure the uniform evaluation of sunscreen drug products. The standard sunscreen shall be a preparation containing 7 percent padimate O and 3 percent oxybenzone as specified in § 352.70(a)(3). For the test to be valid, the measured mean UVA–PF value of the standard preparation shall be 3.2 with a standard deviation less than or equal to 0.5.

(b) *Light source.* The light source used for determining the UVA–PF value of a sunscreen drug product shall provide a continuous emission spectrum in the range of 320 to 400 nanometers. The ratio of UVA I (340 to 400 nanometers) to UVA II (320 to 340 nanometers) in the final beam shall be close to that of sunlight, i.e., emitted UVA II shall be 8 to 20 percent of the total UVA radiation. Optical radiation from 250 to 320 nanometers shall be less than 0.1 percent of the optical radiation between 320 to 400 nanometers. Exclude visible and infrared light to avoid the darkening effects of visible light and the effect of heat. Perform monitoring and maintenance of the light source as specified in § 352.70(b)(3).

(c) *General testing procedures*—(1) *Medical history.* Obtain a medical history from each subject with emphasis on the effects of sunlight on his/her skin. Determine that each subject is in good general health and has skin type II or III (as described in this paragraph).

Skin Type and Sunburn and Tanning History (Based on first 30 to 45 minutes of sun exposure after a winter season of no sun exposure).

I: Always burns easily; never tans (sensitive).

II: Always burns easily; tans minimally (sensitive).

III: Burns moderately; tans gradually (light brown) (normal).

IV: Burns minimally; always tans well (moderate brown) (normal).

V: Rarely burns; tans profusely (dark brown) (insensitive).

VI: Never burns; deeply pigmented (insensitive).

Determine that the subject is not taking topical or systemic medication that is known to alter responses to ultraviolet radiation and that the subject has no history of sensitivities to topical products and/or abnormal responses to sunlight, such as a phototoxic or photoallergic response.

(2) *Physical examination.* The physical examination shall be conducted as specified in § 352.70(c)(1).

(3) *Informed consent.* Obtain legally effective written informed consent from all subjects.

(4) *Test site delineation*—(i) *Test site.* A test site is the location on the back for determining the subject's initial and final minimal pigmenting dose (MPD) for unprotected skin and for determining UVA–PF values after application of the sunscreen standard and the test sunscreen product(s). There typically are 4 to 6 test sites for each subject. Test sites should be located on the back between the beltline and the shoulder blades (scapulae) and lateral to the midline. Each test site shall be a minimum of 50 square centimeters (cm^2) (i.e., 5 x 10 centimeters). Outline the test sites to which the sunscreen standard and the test sunscreen product(s) will be applied with indelible ink. If the subject is to receive the doses of ultraviolet radiation in an upright (seated) position, draw the lines on the skin with the subject upright (seated). If the subject is to receive the doses of ultraviolet radiation while prone, draw the lines with the subject prone.

(ii) *Test subsite.* Test subsites are the locations to which ultraviolet radiation is administered within a test site. At least 5 test subsites will receive UV doses within each test site. Test subsites will be at least 1 cm^2 in area and will be separated from each other by at least 1 cm. Mark the location of each test subsite with indelible ink.

(5) *Application of test materials.* Apply the test sunscreen product and the standard sunscreen as specified in § 352.70(c)(5).

(6) *Waiting period.* Before exposing the test site areas after applying a product, wait at least 15 minutes.

(7) *Number of subjects.* A test panel shall consist of 20 to 25 subjects with at least 20 subject who produce valid data for analysis. Data is valid unless rejected in accordance with § 352.70(c)(9). If more than 5 subjects are rejected based on § 352.70(c)(9), the panel is disqualified, and a new panel must be created.

(8) *Response criteria.* In order that the person who evaluates the MPD responses is not biased, he/she must not be the same person who applied the sunscreen drug product to the test site or administered the doses of UV radiation. After UV radiation exposure from the solar simulator is completed, all immediate responses shall be recorded. These may include an immediate darkening or tanning, typically grayish or purplish in color, which fades in 30 to 60 minutes; an immediate reddening at the subsite, due to heating of the skin, which fades rapidly; and an immediate generalized heat response, spreading beyond the subsite, which fades in 30 to 60 minutes. After the immediate responses are noted, each subject shall shield the exposed area from further UV radiation until the MPD response is evaluated. Determine the MPD 3 to 24 hours after exposure. Evaluate the pigmentation responses of each test site using either tungsten or warm white fluorescent lighting that provides 450 to 550 lux of illumination at the test site. For the evaluation, the test subject should be in the same position used when the test site was irradiated. For each test site, determine the smallest UV dose that produced mild pigmentation reaching the borders of the test subsite. The MPD is the smallest UV dose required to produce the first perceptible pigment darkening at 3 to 24 hours post-exposure. To determine the MPD, there must be at least one subsite that received a smaller UV dose and does not produce pigmentation as well as a subsite(s) with somewhat more intense pigmentation. For subsites showing pigmentation, the maximal exposure should be no more than twice the total energy of the minimal exposure.

(9) *Rejection of test data.* Reject test data if the exposure series fails to elicit an MPD response on either the treated or unprotected skin sites, or all subsites within a test site show more intense responses than the threshold pigmentation response, or the responses are inconsistent with the series of UV doses administered, or the subject was noncompliant, e.g., the subject withdraws from the test due to illness or work conflicts or does not shield the exposed testing sites from further UV radiation until the MPD is read.

(d) *Determination of UVA–PF values*—(1) *Determination of MPD of unprotected skin.* Administer a series of five UV radiation doses expressed as Joules per square meter to the subsites within each test site on a subject using the light source described in paragraph (b) of this section. Use the series of five exposures to the unprotected test site to determine the initial unprotected MPD. Select the doses that are a geometric series represented by (1.25^n), wherein each exposure dose is 25 percent greater than the previous exposure dose to maintain the same relative uncertainty (expressed as a constant percentage), independent of the subject's sensitivity to UV radiation. Usually, the UV radiation for determining the initial unprotected MPD is administered the day prior to applying the sunscreen product and standard sunscreen, and the responses are then evaluated immediately prior to applying the sunscreen product and sunscreen standard. Determine the final unprotected MPD on the same day that UV radiation is administered to the sunscreen-protected test sites. Use the final unprotected MPD (MPD(US)) in calculating UVA–PF.

(2) *Determination of individual UVA–PF values.* Administer a series of five UV radiation doses expressed as Joules per square meter to the subsites within each test site on a subject using the light source described in paragraph (b) of this section. The five UV doses will be a geometric series as described in paragraph (d)(1) of this section, where the middle exposure represents the expected UVA–PF. Use exposures that are the product of the initial unprotected MPD times 0.64X, 0.80X, 1.00X, 1.25X, and 1.56X, where X equals the expected UVA–PF of the test product. The MPD is the smallest UV dose required to produce pigmentation at 3 to 24 hours post-exposure. Calculate the UVA–PF value of each sunscreen product and sunscreen standard using MPD of sunscreen-protected skin (MPD(PS)) and the final unprotected MPD (MPD(US)) as follows:

$$\text{UVA-PF} = \frac{\text{MPD(PS) (J/m}^2\text{)}}{\text{MPD(US) (J/m}^2\text{)}}$$

(3) *Determination of test product UVA–PF and UVA product category designation (PCD).* Use data from at least 20 test subjects with n representing the number of subjects used. First, compute the UVA–PF value for each subject as stated in paragraph (d)(2) of this section. Second, compute the mean UVA–PF value, x, and the standard deviation, s, for these subjects. Third, obtain the upper 5-percent point from Student's t distribution table with n-1 degrees of freedom. Denote this value by t. Fourth, compute $ts/\sqrt{n}$. Denote this quantity by A (i.e., $A = ts/\sqrt{n}$). Fifth, calculate the UVA–PF value to be used in labeling as follows: The label UVA–PF equals the largest whole number less than x - A. Sixth and last, the drug product is classified into a PCD as follows: If $12 + A \leq x$, the PCD is Highest; if $8 + A \leq x < 12 + A$, the PCD is High; if $4 + A < x < 8 + A$, the PCD is Medium; if $2 + A \leq x < 4 + A$, the PCD is Low; if $x < 2 + A$, the product shall not display a UVA–PF value.

§ 352.73 Determination of the labeled UVA protection value.

Test the sunscreen product in accordance with §§ 352.71 and 352.72. The UVA category on the principal display panel (PDP) of the tested sunscreen product, as specified in § 352.50, shall be the lower of either the UVA I/UV ratio category determined in § 352.71(j) or the UVA–PF product category designation (PCD) determined in § 352.72(d)(3). If the product does not attain at least a ''low'' category rating for both the UVA–PF and the UVA I/UV ratio, the product shall not display a UVA claim. State the final combined category rating (i.e., the lower of either the UVA I/UV ratio or UVA–PF PCD categories) on the PDP of the product along with the corresponding number of stars for that combined category rating as follows:

Combined Category Rating	Star Rating
Low	★☆☆☆
Medium	★★☆☆
High	★★★☆
Highest	★★★★

11. Section 352.76 is amended by revising the introductory paragraph and paragraphs (a) introductory text, (a)(6), (b) introductory text, and (b)(10) to read as follows:

§ 352.76 Determination if a product is water resistant or very water resistant.

The general testing procedures in § 352.70(c) shall be used as part of the following tests, except where modified in this section. An indoor fresh water pool, whirlpool, and/or jacuzzi maintained at 23 to 32 °C shall be used in these testing procedures. Fresh water is clean drinking water that meets the standards in 40 CFR part 141. The pool and air temperature and the relative humidity shall be recorded.

(a) *Procedure for testing the water resistance of a sunscreen product.* For sunscreen products making the claim of ''water resistant,'' the label SPF and, if appropriate, UVA values shall be the label SPF and UVA values determined after 40 minutes of water immersion using the following procedure for the water resistance test:

* * * * *

(6) Begin light source exposure to test site areas as described in § 352.70(b) and, if appropriate, § 352.72(b).

(b) *Procedure for testing a very water resistant sunscreen product.* For

sunscreen products making the claim of ''very water resistant,'' the label SPF and, if appropriate, UVA values shall be the label SPF and UVA values determined after 80 minutes of water immersion using the following procedure for the water resistance test:

* * * * *

(10) Begin light source exposure to test site areas as described in § 352.70(b) and, if appropriate, § 352.72(b).

Dated: August 10, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 07–4131 Filed 8–23–07; 8:45 am]

BILLING CODE 4160–01–S

Federal Register

Monday,
August 27, 2007

Part IV

Department of Housing and Urban Development

24 CFR Parts 320 and 350
Government National Mortgage Association: Mortgage-Backed Securities (MBS) Program—Payments to Securityholders; Book-Entry Procedures; and Financial Reporting; Final Rule

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 320 and 350

[Docket No. FR–5063–F–02]

RIN 2503–AA19

Government National Mortgage Association: Mortgage-Backed Securities (MBS) Program—Payments to Securityholders; Book-Entry Procedures; and Financial Reporting

AGENCY: Government National Mortgage Association, HUD.

ACTION: Final rule.

SUMMARY: On May 7, 2007, the Government National Mortgage Association (Ginnie Mae) published a proposed rule that would restrict the issuance of physical certificates representing Ginnie Mae mortgage-backed securities (MBS) and clarify that book-entry securities may be withdrawn from the Federal Reserve book-entry system after Ginnie Mae has approved a request for physical certificates, also known as definitive securities, in the same amount. The rule also proposed to eliminate the requirement for a classified balance sheet. Ginnie Mae did not receive any public comments on this rule. Ginnie Mae is adopting, at this final rule stage, the proposed rule without change.

DATES: *Effective Date:* September 26, 2007.

FOR FURTHER INFORMATION CONTACT: Thomas R. Weakland, Senior Vice President, Office of Program Operations, Government National Mortgage Association, Department of Housing and Urban Development, 451 Seventh Street, SW., Room B–133, Washington, DC 20410; telephone number (202) 475–4915 (this is not a toll-free number). Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Information Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION:

I. Background and the May 7, 2007, Proposed Rule

Ginnie Mae guarantees privately issued securities backed by trusts or pools of mortgage loans that are insured or guaranteed by the Federal Housing Administration, the Rural Housing Service, the Department of Veterans Affairs, and the Department of Housing and Urban Development (HUD). Ginnie Mae is a government corporation within HUD, authorized by the National Housing Act (12 U.S.C. 1716 *et seq.*). The regulations governing Ginnie Mae are located at 24 CFR part 300.

Ginnie Mae-guaranteed securities are issued in book-entry form. Under current Ginnie Mae regulations, a securityholder may request that the book-entry security be converted into certificated form after initial issuance. Certificates are physical documentation of the ownership of the security. On May 7, 2007 (72 FR 25925), Ginnie Mae published a rule that proposed to revise its regulations to state that for all securities issued after particular issue dates, physical certificates may only be issued as approved by Ginnie Mae. Also, in the proposed rule, Ginnie Mae proposed to clarify that book-entry securities may be withdrawn after Ginnie Mae has approved a request for definitive Ginnie Mae securities. Additionally, in order to conform to industry practice, Ginnie Mae proposed to revise the financial reporting rule for issuers participating in its MBS programs, by removing the requirement that issuers submit classified balance sheets.

II. This Final Rule

At this final rule stage, Ginnie Mae is adopting the proposed rule without change. The public comment period for the May 7, 2007, proposed rule closed on July 6, 2007, and Ginnie Mae did not receive any comments on the proposed rule. The revised regulations, which are promulgated by this final rule, restrict the issuance of physical certificates representing Ginnie Mae MBS and clarify that book-entry securities may be withdrawn from the Federal Reserve book-entry system after Ginnie Mae has approved a request for physical certificates, also known as definitive securities, in the same amount. This rule also eliminates the requirement for a classified balance sheet.

III. Findings and Certifications

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) (UMRA) establishes requirements for federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments, and the private sector. This rule does not impose any Federal mandate on any State, local, or tribal government, or the private sector within the meaning of UMRA.

Environmental Impact

This rule does not direct, provide for assistance or loan and mortgage insurance for, or otherwise govern or regulate, real property acquisition, disposition, leasing, rehabilitation, alteration, demolition, or new construction, or establish, revise, or provide for standards for construction or construction materials, manufactured housing, or occupancy. Accordingly, under 24 CFR 50.19(c)(1), this rule is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) 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. This rule introduces a streamlining amendment to the financial reporting regulations and a change in the maintenance of Ginnie Mae book-entry and certificated securities. Small entities will not be adversely affected by the more streamlined financial reporting requirement or the book-entry requirement; in fact, a more streamlined financial reporting requirement may alleviate some burden. Furthermore, all such issuers, regardless of size, are subject to the new requirements proposed by the rule. Therefore, the undersigned certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Executive Order 13132, Federalism

Executive Order 13132 (entitled ''Federalism'') prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial direct compliance costs on State and local governments and is not required by statute, or the rule preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the order. This rule will not have federalism implications and would not impose substantial direct compliance costs on State and local governments or preempt State law within the meaning of the order.

Paperwork Reduction Act

The information collection requirements contained in this rule are currently approved by the Office of Management and Budget (OMB) under section 3504(h) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) and assigned OMB control number 2503–0033. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of

information, unless the collection displays a currently valid control number.

List of Subjects in 24 CFR Parts 320 and 350

Mortgages, Securities.

■ Accordingly, for the reasons described in the preamble, HUD amends 24 CFR parts 320 and 350, as follows:

PART 320—GUARANTY OF MORTGAGE-BACKED SECURITIES

■ 1. The authority citation for 24 CFR part 320 continues to read as follows:

Authority: 12 U.S.C. 1721(g) and 1723a(a); and 42 U.S.C. 3535(d).

■ 2. Revise § 320.5(e) to read as follows:

§ 320.5 Securities.

* * * * *

(e) *Issue Date.* Securities backed by single-family mortgages with issue dates of October 1, 1998, or before, serial notes with issue dates of July 1, 2002, or before, and securities backed by multifamily mortgages with issue dates of February 1, 2002, or before, have been issued in certificated form. Securities issued after these dates will be issued in book-entry form. The Association may approve the issuance of certificated securities for good cause.

* * * * *

■ 3. Revise § 320.10 to read as follows:

§ 320.10 Financial reporting.

Issuers shall submit to the Association audited annual financial statements within 90 days of their fiscal year end. All financial statements shall include a balance sheet and a statement of operations and cash flows. The audit shall be conducted in accordance with the standards for financial audits of the U.S. Government Accountability Office's *Government Auditing Standards,* issued by the Comptroller General of the United States.

PART 350—BOOK-ENTRY PROCEDURES

■ 4. The authority citation for 24 CFR part 350 continues to read as follows:

Authority: 12 U.S.C. 1721(g) and 1723a(a); and 42 U.S.C. 3535(d).

■ 5. Revise § 350.8(a) to read as follows:

§ 350.8(a) Withdrawal of eligible book-entry Ginnie Mae securities for conversion to definitive form.

(a) Eligible book-entry Ginnie Mae securities may be withdrawn from the book-entry system after Ginnie Mae has approved a request for the delivery of definitive Ginnie Mae securities in the same amount.

* * * * *

Dated: August 17, 2007.

Roy A. Bernardi,

Deputy Secretary.

[FR Doc. E7–16890 Filed 8–24–07; 8:45 am]

BILLING CODE 4210–67–P

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Federal Register

Vol. 72, No. 165

Monday, August 27, 2007

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FEDERAL REGISTER PAGES AND DATE, AUGUST

CFR PARTS AFFECTED DURING AUGUST

At the end of each month, the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

REMINDERS

The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

RULES GOING INTO EFFECT AUGUST 27, 2007

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Nonprocurement debarment and suspension; OMB guidance, implementation; published 6-26-07

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Air pollution control:

State operating permits programs—

New Jersey; published 7-26-07

Air quality implementation plans; approval and promulgation; various States:

Idaho and Washington; published 6-26-07

Iowa; published 6-26-07

Superfund program:

National oil and hazardous substances contingency plan priorities list; published 6-28-07

FEDERAL COMMUNICATIONS COMMISSION

Radio stations; table of assignments:

Tennessee; published 8-1-07

HEALTH AND HUMAN SERVICES DEPARTMENT

Centers for Medicare & Medicaid Services

Health care access:

Group health insurance market requirements; mental health parity; published 7-27-07

HEALTH AND HUMAN SERVICES DEPARTMENT

Health care access:

Individual health insurance market requirements—

Qualified high risk pools operation; State grants; published 7-27-07

HOUSING AND URBAN DEVELOPMENT DEPARTMENT

Public and Indian housing:

Indian Housing Block Grant Program; annual performance report due date extension; published 7-26-07

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TREASURY DEPARTMENT

Internal Revenue Service

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Tentative carryback adjustment computation and allowance; section 6411 clarification; published 8-27-07

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AGENCY FOR INTERNATIONAL DEVELOPMENT

Commodity transactions financed by USAID; applicable rules and procedures; miscellaneous amendments; comments due by 9-7-07; published 7-9-07 [FR 07-03309]

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Swine, cattle, lamb, and boxed beef; reporting regulations reestablishment and revision; comments due by 9-7-07; published 8-8-07 [FR 07-03857]

Walnuts grown in California; comments due by 9-4-07; published 8-17-07 [FR E7-16199]

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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 "PLUS" (Public Laws Update Service) on 202–741–6043. This list is also available online at *http://www.archives.gov/federal-register/laws.html*.

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H.R. 2863/P.L. 110–75

To authorize the Coquille Indian Tribe of the State of Oregon to convey land and interests in land owned by the Tribe. (Aug. 13, 2007; 121 Stat. 724)

H.R. 2952/P.L. 110–76

To authorize the Saginaw Chippewa Tribe of Indians of the State of Michigan to convey land and interests in lands owned by the Tribe. (Aug. 13, 2007; 121 Stat. 725)

H.R. 3006/P.L. 110–77

To improve the use of a grant of a parcel of land to the State of Idaho for use as an agricultural college, and for other purposes. (Aug. 13, 2007; 121 Stat. 726)

S. 375/P.L. 110–78

To waive application of the Indian Self-Determination and Education Assistance Act to a specific parcel of real property transferred by the United States to 2 Indian tribes in the State of Oregon, and for other purposes. (Aug. 13, 2007; 121 Stat. 727)

S. 975/P.L. 110–79

Granting the consent and approval of the Congress to an interstate forest fire protection compact. (Aug. 13, 2007; 121 Stat. 730)

S. 1716/P.L. 110–80

To amend the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act, 2007, to strike a requirement relating to forage producers. (Aug. 13, 2007; 121 Stat. 734)

Last List August 13, 2007

CORRECTION

In the last **List of Public Laws** printed in the *Federal Register* on August 13, 2007, H.R. 2025, Public Law 110-65, and H.R. 2078, Public Law 110-67, were printed incorrectly. They should read as follows:

H.R. 2025/P.L. 110–65

To designate the facility of the United States Postal Service located at 11033 South State Street in Chicago, Illinois, as the "Willye B. White Post Office Building". (Aug. 9, 2007; 121 Stat. 568)

H.R. 2078/P.L. 110–67

To designate the facility of the United States Postal Service located at 14536 State Route 136 in Cherry Fork, Ohio, as the "Staff Sergeant Omer T. 'O.T.' Hawkins Post Office". (Aug. 9, 2007; 121 Stat. 570)

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An asterisk (*) precedes each entry that has been issued since last week and which is now available for sale at the Government Printing Office.

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1	(869–062–00001–4)	5.00	[4] Jan. 1, 2007
2	(869–062–00002–2)	5.00	Jan. 1, 2007
3 (2006 Compilation and Parts 100 and 102)	(869–062–00003–1)	35.00	[1] Jan. 1, 2007
4	(869–062–00004–9)	10.00	[5] Jan. 1, 2007
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1–699	(869–062–00005–7)	60.00	Jan. 1, 2007
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6	(869–062–00008–1)	10.50	Jan. 1, 2007
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10 Parts:			
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18 Parts:			
1–399	(869–062–00054–5)	62.00	Apr. 1, 2007
400–End	(869–062–00055–3)	26.00	Apr. 1, 2007
19 Parts:			
1–140	(869–062–00056–1)	61.00	Apr. 1, 2007
141–199	(869–062–00057–0)	58.00	Apr. 1, 2007
200–End	(869–062–00058–8)	31.00	Apr. 1, 2007
20 Parts:			
1–399	(869–062–00059–6)	50.00	Apr. 1, 2007
*400–499	(869–062–00060–0)	64.00	Apr. 1, 2007
500–End	(869–062–00061–8)	63.00	Apr. 1, 2007
21 Parts:			
1–99	(869–062–00062–6)	40.00	Apr. 1, 2007
100–169	(869–062–00063–4)	49.00	Apr. 1, 2007
170–199	(869–062–00064–2)	50.00	Apr. 1, 2007
200–299	(869–062–00065–1)	17.00	Apr. 1, 2007
300–499	(869–062–00066–9)	30.00	Apr. 1, 2007
500–599	(869–062–00067–7)	47.00	Apr. 1, 2007
600–799	(869–062–00068–5)	17.00	Apr. 1, 2007
800–1299	(869–062–00069–3)	60.00	Apr. 1, 2007
1300–End	(869–062–00070–7)	25.00	Apr. 1, 2007
22 Parts:			
1–299	(869–062–00071–5)	63.00	Apr. 1, 2007
300–End	(869–062–00072–3)	45.00	Apr. 1, 2007
23	(869–062–00073–7)	45.00	Apr. 1, 2007
24 Parts:			
0–199	(869–062–00074–0)	60.00	Apr. 1, 2007
200–499	(869–062–00075–8)	50.00	Apr. 1, 2007
500–699	(869–062–00076–6)	30.00	Apr. 1, 2007
700–1699	(869–062–00077–4)	61.00	Apr. 1, 2007
1700–End	(869–062–00078–2)	30.00	Apr. 1, 2007
25	(869–062–00079–1)	64.00	Apr. 1, 2007
26 Parts:			
§§ 1.0–1–1.60	(869–062–00080–4)	49.00	Apr. 1, 2007
§§ 1.61–1.169	(869–062–00081–2)	63.00	Apr. 1, 2007
§§ 1.170–1.300	(869–062–00082–1)	60.00	Apr. 1, 2007
§§ 1.301–1.400	(869–062–00083–9)	47.00	Apr. 1, 2007
§§ 1.401–1.440	(869–062–00084–7)	56.00	Apr. 1, 2007
§§ 1.441–1.500	(869–062–00085–5)	58.00	Apr. 1, 2007
§§ 1.501–1.640	(869–062–00086–3)	49.00	Apr. 1, 2007
§§ 1.641–1.850	(869–062–00087–1)	61.00	Apr. 1, 2007
§§ 1.851–1.907	(869–062–00088–0)	61.00	Apr. 1, 2007
§§ 1.908–1.1000	(869–062–00089–8)	60.00	Apr. 1, 2007
§§ 1.1001–1.1400	(869–062–00090–1)	61.00	Apr. 1, 2007
§§ 1.1401–1.1550	(869–062–00091–0)	58.00	Apr. 1, 2007
§§ 1.1551–End	(869–062–00092–8)	50.00	Apr. 1, 2007
2–29	(869–062–00093–6)	60.00	Apr. 1, 2007
30–39	(869–062–00094–4)	41.00	Apr. 1, 2007
40–49	(869–062–00095–2)	28.00	[7] Apr. 1, 2007
50–299	(869–062–00096–1)	42.00	Apr. 1, 2007

Title	Stock Number	Price	Revision Date
300–499	(869–062–00097–9)	61.00	Apr. 1, 2007
500–599	(869–062–00098–7)	12.00	[6] Apr. 1, 2007
600–End	(869–062–00099–5)	17.00	Apr. 1, 2007
27 Parts:			
*1–39	(869–062–00100–2)	64.00	Apr. 1, 2007
*40–399	(869–062–00101–1)	64.00	Apr. 1, 2007
400–End	(869–062–00102–9)	18.00	Apr. 1, 2007
28 Parts:			
0–42	(869–060–00102–6)	61.00	July 1, 2006
43–End	(869–060–00103–4)	60.00	July 1, 2006
29 Parts:			
*0–99	(869–062–00105–3)	50.00	[9] July 1, 2007
100–499	(869–060–00105–1)	23.00	July 1, 2006
*500–899	(869–062–00107–0)	61.00	[9] July 1, 2007
*900–1899	(869–062–00108–8)	36.00	July 1, 2007
1900–1910 (§§ 1900 to 1910.999)	(869–060–00108–5)	61.00	July 1, 2006
1910 (§§ 1910.1000 to end)	(869–060–00109–3)	46.00	July 1, 2006
1911–1925	(869–060–00110–7)	30.00	July 1, 2006
1926	(869–060–00111–5)	50.00	July 1, 2006
1927–End	(869–060–00112–3)	62.00	July 1, 2006
30 Parts:			
1–199	(869–060–00113–1)	57.00	July 1, 2006
200–699	(869–060–00114–0)	50.00	July 1, 2006
700–End	(869–060–00115–8)	58.00	July 1, 2006
31 Parts:			
0–199	(869–060–00116–6)	41.00	July 1, 2006
200–499	(869–060–00117–4)	46.00	July 1, 2006
500–End	(869–060–00118–2)	62.00	July 1, 2006
32 Parts:			
1–39, Vol. I		15.00	[2] July 1, 1984
1–39, Vol. II		19.00	[2] July 1, 1984
1–39, Vol. III		18.00	[2] July 1, 1984
1–190	(869–060–00119–1)	61.00	July 1, 2006
191–399	(869–060–00120–4)	63.00	July 1, 2006
400–629	(869–060–00121–2)	50.00	July 1, 2006
*630–699	(869–062–00123–1)	37.00	July 1, 2007
700–799	(869–060–00123–9)	46.00	July 1, 2006
*800–End	(869–062–00125–8)	47.00	July 1, 2007
33 Parts:			
1–124	(869–060–00125–5)	57.00	July 1, 2006
125–199	(869–060–00126–3)	61.00	July 1, 2006
200–End	(869–060–00127–1)	57.00	July 1, 2006
34 Parts:			
1–299	(869–060–00128–0)	50.00	July 1, 2006
300–399	(869–060–00129–8)	40.00	July 1, 2006
400–End & 35	(869–060–00130–1)	61.00	[8] July 1, 2006
36 Parts:			
1–199	(869–060–00131–0)	37.00	July 1, 2006
200–299	(869–060–00132–8)	37.00	July 1, 2006
300–End	(869–060–00133–6)	61.00	July 1, 2006
37	(869–060–00134–4)	58.00	July 1, 2006
38 Parts:			
*0–17	(869–062–00136–3)	60.00	July 1, 2007
18–End	(869–060–00136–1)	62.00	July 1, 2006
39	(869–060–00137–9)	42.00	July 1, 2006
40 Parts:			
1–49	(869–060–00138–7)	60.00	July 1, 2006
50–51	(869–060–00139–5)	45.00	July 1, 2006
52 (52.01–52.1018)	(869–060–00140–9)	60.00	July 1, 2006
52 (52.1019–End)	(869–060–00141–7)	61.00	July 1, 2006
53–59	(869–060–00142–5)	31.00	July 1, 2006
60 (60.1–End)	(869–060–00143–3)	58.00	July 1, 2006
60 (Apps)	(869–060–00144–7)	57.00	July 1, 2006
61–62	(869–060–00145–0)	45.00	July 1, 2006
63 (63.1–63.599)	(869–060–00146–8)	58.00	July 1, 2006
63 (63.600–63.1199)	(869–060–00147–6)	50.00	July 1, 2006
63 (63.1200–63.1439)	(869–060–00148–4)	50.00	July 1, 2006
63 (63.1440–63.6175)	(869–060–00149–2)	32.00	July 1, 2006
63 (63.6580–63.8830)	(869–060–00150–6)	32.00	July 1, 2006
63 (63.8980–End)	(869–060–00151–4)	35.00	July 1, 2006
64–71	(869–060–00152–2)	29.00	July 1, 2006
72–80	(869–060–00153–1)	62.00	July 1, 2006
81–85	(869–060–00154–9)	60.00	July 1, 2006
86 (86.1–86.599–99)	(869–060–00155–7)	58.00	July 1, 2006
86 (86.600–1–End)	(869–060–00156–5)	50.00	July 1, 2006
87–99	(869–060–00157–3)	60.00	July 1, 2006
100–135	(869–060–00158–1)	45.00	July 1, 2006
136–149	(869–060–00159–0)	61.00	July 1, 2006
150–189	(869–060–00160–3)	50.00	July 1, 2006
*190–259	(869–062–00162–2)	39.00	[9] July 1, 2007
260–265	(869–060–00162–0)	50.00	July 1, 2006
266–299	(869–060–00163–8)	50.00	July 1, 2006
300–399	(869–060–00164–6)	42.00	July 1, 2006
*400–424	(869–062–00166–5)	56.00	[9] July 1, 2007
425–699	(869–060–00166–2)	61.00	July 1, 2006
700–789	(869–060–00167–1)	61.00	July 1, 2006
790–End	(869–060–00168–9)	61.00	July 1, 2006
41 Chapters:			
1, 1–1 to 1–10		13.00	[3] July 1, 1984
1, 1–11 to Appendix, 2 (2 Reserved)		13.00	[3] July 1, 1984
3–6		14.00	[3] July 1, 1984
7		6.00	[3] July 1, 1984
8		4.50	[3] July 1, 1984
9		13.00	[3] July 1, 1984
10–17		9.50	[3] July 1, 1984
18, Vol. I, Parts 1–5		13.00	[3] July 1, 1984
18, Vol. II, Parts 6–19		13.00	[3] July 1, 1984
18, Vol. III, Parts 20–52		13.00	[3] July 1, 1984
19–100		13.00	[3] July 1, 1984
1–100	(869–060–00169–7)	24.00	July 1, 2006
101	(869–060–00170–1)	21.00	[8] July 1, 2006
102–200	(869–060–00171–9)	56.00	July 1, 2006
201–End	(869–060–00172–7)	24.00	July 1, 2006
42 Parts:			
1–399	(869–060–00173–5)	61.00	Oct. 1, 2006
400–413	(869–060–00174–3)	32.00	Oct. 1, 2006
414–429	(869–060–00175–1)	32.00	Oct. 1, 2006
430–End	(869–060–00176–0)	64.00	Oct. 1, 2006
43 Parts:			
1–999	(869–060–00177–8)	56.00	Oct. 1, 2006
1000–end	(869–060–00178–6)	62.00	Oct. 1, 2006
44	(869–060–00179–4)	50.00	Oct. 1, 2006
45 Parts:			
1–199	(869–060–00180–8)	60.00	Oct. 1, 2006
200–499	(869–060–00181–6)	34.00	Oct. 1, 2006
500–1199	(869–060–00182–4)	56.00	Oct. 1, 2006
1200–End	(869–060–00183–2)	61.00	Oct. 1, 2006
46 Parts:			
1–40	(869–060–00184–1)	46.00	Oct. 1, 2006
41–69	(869–060–00185–9)	39.00	Oct. 1, 2006
70–89	(869–060–00186–7)	14.00	Oct. 1, 2006
90–139	(869–060–00187–5)	44.00	Oct. 1, 2006
140–155	(869–060–00188–3)	25.00	Oct. 1, 2006
156–165	(869–060–00189–1)	34.00	Oct. 1, 2006
166–199	(869–060–00190–5)	46.00	Oct. 1, 2006
200–499	(869–060–00191–3)	40.00	Oct. 1, 2006
500–End	(869–060–00192–1)	25.00	Oct. 1, 2006
47 Parts:			
0–19	(869–060–00193–0)	61.00	Oct. 1, 2006
20–39	(869–060–00194–8)	46.00	Oct. 1, 2006
40–69	(869–060–00195–6)	40.00	Oct. 1, 2006
70–79	(869–060–00196–4)	61.00	Oct. 1, 2006
80–End	(869–060–00197–2)	61.00	Oct. 1, 2006
48 Chapters:			
1 (Parts 1–51)	(869–060–00198–1)	63.00	Oct. 1, 2006
1 (Parts 52–99)	(869–060–00199–9)	49.00	Oct. 1, 2006
2 (Parts 201–299)	(869–060–00200–6)	50.00	Oct. 1, 2006
3–6	(869–060–00201–4)	34.00	Oct. 1, 2006

Title	Stock Number	Price	Revision Date
7–14	(869–060–00202–2)	56.00	Oct. 1, 2006
15–28	(869–060–00203–1)	47.00	Oct. 1, 2006
29–End	(869–060–00204–9)	47.00	Oct. 1, 2006
49 Parts:			
1–99	(869–060–00205–7)	60.00	Oct. 1, 2006
100–185	(869–060–00206–5)	63.00	Oct. 1, 2006
186–199	(869–060–00207–3)	23.00	Oct. 1, 2006
200–299	(869–060–00208–1)	32.00	Oct. 1, 2006
300–399	(869–060–00209–0)	32.00	Oct. 1, 2006
400–599	(869–060–00210–3)	64.00	Oct. 1, 2006
600–999	(869–060–00211–1)	19.00	Oct. 1, 2006
1000–1199	(869–060–00212–0)	28.00	Oct. 1, 2006
1200–End	(869–060–00213–8)	34.00	Oct. 1, 2006
50 Parts:			
*1–16	(869–060–00214–6)	11.00	[10] Oct. 1, 2006
17.1–17.95(b)	(869–060–00215–4)	32.00	Oct. 1, 2006
17.95(c)–end	(869–060–00216–2)	32.00	Oct. 1, 2006
17.96–17.99(h)	(869–060–00217–1)	61.00	Oct. 1, 2006
*17.99(i)–end and 17.100–end	(869–060–00218–9)	47.00	[10] Oct. 1, 2006
18–199	(869–060–00219–7)	50.00	Oct. 1, 2006
200–599	(869–060–00220–1)	45.00	Oct. 1, 2006
600–659	(869–060–00221–9)	31.00	Oct. 1, 2006
660–End	(869–060–00222–7)	31.00	Oct. 1, 2006
CFR Index and Findings Aids	(869–062–00050–2)	62.00	Jan. 1, 2007
Complete 2007 CFR set		1,389.00	2007
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Subscription (mailed as issued)		332.00	2007
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Complete set (one-time mailing)		325.00	2005

[1] Because Title 3 is an annual compilation, this volume and all previous volumes should be retained as a permanent reference source.

[2] The July 1, 1985 edition of 32 CFR Parts 1–189 contains a note only for Parts 1–39 inclusive. For the full text of the Defense Acquisition Regulations in Parts 1–39, consult the three CFR volumes issued as of July 1, 1984, containing those parts.

[3] The July 1, 1985 edition of 41 CFR Chapters 1–100 contains a note only for Chapters 1 to 49 inclusive. For the full text of procurement regulations in Chapters 1 to 49, consult the eleven CFR volumes issued as of July 1, 1984 containing those chapters.

[4] No amendments to this volume were promulgated during the period January 1, 2005, through January 1, 2006. The CFR volume issued as of January 1, 2005 should be retained.

[5] No amendments to this volume were promulgated during the period January 1, 2006, through January 1, 2007. The CFR volume issued as of January 6, 2006 should be retained.

[6] No amendments to this volume were promulgated during the period April 1, 2000, through April 1, 2006. The CFR volume issued as of April 1, 2000 should be retained.

[7] No amendments to this volume were promulgated during the period April 1, 2006 through April 1, 2007. The CFR volume issued as of April 1, 2006 should be retained.

[8] No amendments to this volume were promulgated during the period July 1, 2005, through July 1, 2006. The CFR volume issued as of July 1, 2005 should be retained.

[9] No amendments to this volume were promulgated during the period July 1, 2006, through July 1, 2007. The CFR volume issued as of July 1, 2006 should be retained.

[10] No amendments to this volume were promulgated during the period October 1, 2005, through October 1, 2006. The CFR volume issued as of October 1, 2005 should be retained.