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FOR: Any person who uses the Federal Register and Code of Federal Regulations.

WHO: Sponsored by the Office of the Federal Register.

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

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

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3. The important elements of typical Federal Register documents.

4. An introduction to the finding aids of the FR/CFR system.

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

WHEN: Tuesday, December 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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To subscribe to the Federal Register Table of Contents LISTSERV electronic mailing list, go to http://listserv.access.gpo.gov and select Online mailing list archives, FEDREGTOC-L, Join or leave the list (or change settings); then follow the instructions.

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 905

[Docket No. AMS–FV–07–0088; FV07–905–1 FIR]

Oranges, Grapefruit, Tangerines, and Tangelos Grown in Florida; Decreased Assessment Rate

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: The Department of Agriculture (USDA) is adopting, as a final rule, without change, an interim final rule which decreased the assessment rate established for the Citrus Administrative Committee (Committee) for the 2007–08 and subsequent fiscal periods from $0.008 to $0.0072 per 4/5 bushel carton of oranges, grapefruit, tangerines, and tangelos handled. The Committee locally administers the marketing order which regulates the handling of oranges, grapefruit, tangerines, and tangelos grown in Florida. Assessments upon Florida citrus handlers are used by the Committee to fund reasonable and necessary expenses of the program. The fiscal period begins August 1 and ends July 31. The assessment rate will remain in effect indefinitely unless modified, suspended, or terminated.

EFFECTIVE DATE: January 4, 2008.

FOR FURTHER INFORMATION CONTACT: Doris Jamieson, Marketing Specialist, or Christian D. Nissen, Regional Manager, Southeast Marketing Field Office, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA; Telephone: (863) 324–3375, Fax: (863) 325–8793, or E-mail: *Doris.Jamieson@usda.gov* or *Christian.Nissen@usda.gov*.

Small businesses may request information on complying with this regulation by contacting Jay Guerber, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or E-mail: *Jay.Guerber@usda.gov*.

SUPPLEMENTARY INFORMATION: This rule is issued under Marketing Agreement No. 84 and Marketing Order No. 905, both as amended (7 CFR part 905), regulating the handling of oranges, grapefruit, tangerines, and tangelos grown in Florida, hereinafter referred to as the "order." The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the "Act."

USDA is issuing this rule in conformance with Executive Order 12866.

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under the marketing order now in effect, Florida citrus handlers are subject to assessments. Funds to administer the order are derived from such assessments. It is intended that the assessment rate as issued herein will be applicable to all assessable oranges, grapefruit, tangerines, and tangelos grown in Florida beginning August 1, 2007, and continue until amended, suspended, or terminated. This rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This rule continues in effect the action that decreased the assessment rate established for the Committee for the 2007–08 and subsequent fiscal periods from $0.008 per 4/5 bushel carton to $0.0072 per 4/5 bushel carton of oranges, grapefruit, tangerines, and tangelos grown in Florida.

The Florida citrus marketing order provides authority for the Committee, with the approval of USDA, to formulate an annual budget of expenses and collect assessments from handlers to administer the program. The members of the Committee are producers and handlers of oranges, grapefruit, tangerines, and tangelos. They are familiar with the Committee's needs and with the costs for goods and services in their local area and are thus in a position to formulate an appropriate budget and assessment rate. The assessment rate is formulated and discussed in a public meeting. Thus, all directly affected persons have an opportunity to participate and provide input.

For the 2005–06 and subsequent fiscal periods, the Committee recommended, and USDA approved, an assessment rate that would continue in effect from fiscal period to fiscal period unless modified, suspended, or terminated by USDA upon recommendation and information submitted by the Committee or other information available to USDA.

The Committee met on May 29, 2007, and unanimously recommended 2007–08 expenditures of $275,000 and an assessment rate of $0.0072 per 4/5 bushel of oranges, grapefruit, tangerines, and tangelos grown in Florida. In comparison, last year's budgeted expenditures were $241,000. The assessment rate of $0.0072 is $0.0008 lower than the rate previously in effect. This reduction was recommended because the Committee experienced an unanticipated increase in shipments for the 2006–07 fiscal period and had revenues greater than expenses. In addition, the industry has continued to recover from the hurricane damage sustained during the 2004–05 and 2005–06 seasons, which is expected to have a positive affect on total production.

The major expenditures recommended by the Committee for the 2007–08 fiscal year include $112,000 for salaries, $25,000 for Manifest

Department—Florida Department of Agriculture and Customer Services (FDACS), $17,800 for retirement plan, and $14,550 for insurance and bonds. Budgeted expenses for these items in 2006–07 were $110,000, $25,000, $17,250, and $14,550, respectively.

The assessment rate recommended by the Committee was derived by dividing anticipated expenses by expected shipments of oranges, grapefruit, tangerines, and tangelos. Florida citrus shipments for the year are estimated at 30 million 4/5 bushels which should provide $216,000 in assessment income. Income derived from handler assessments, along with interest income and funds from the Committee's authorized reserve will be adequate to cover budgeted expenses. Funds in the reserve (currently approximately $60,000) will be kept within the maximum permitted by the order of not to exceed one half of one fiscal period's expenses as stated in § 905.42(a).

The assessment rate will continue in effect indefinitely unless modified, suspended, or terminated by USDA upon recommendation and information submitted by the Committee or other available information.

Although this assessment rate is in effect for an indefinite period, the Committee will continue to meet prior to or during each fiscal period to recommend a budget of expenses and consider recommendations for modification of the assessment rate. The dates and times of Committee meetings are available from the Committee or USDA. Committee meetings are open to the public and interested persons may express their views at these meetings. USDA will evaluate Committee recommendations and other available information to determine whether modification of the assessment rate is needed. Further rulemaking will be undertaken as necessary. The Committee's 2007–08 budget and those for subsequent fiscal periods will be reviewed and, as appropriate, approved by USDA.

Final Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Agricultural Marketing Service (AMS) has considered the economic impact of this rule on small entities. Accordingly, AMS has prepared this final regulatory flexibility analysis.

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

There are approximately 8,000 producers of oranges, grapefruit, tangerines, and tangelos in the production area and approximately 55 handlers subject to regulation under the marketing order. Small agricultural producers are defined by the Small Business Administration (SBA) as those having annual receipts less than $750,000, and small agricultural service firms are defined as those whose annual receipts are less than $6,500,000 (13 CFR 121.201).

Based on industry and Committee data, the average annual f.o.b. price for fresh Florida citrus during the 2005–06 season was approximately $11.50 per 4/5-bushel carton, and total fresh shipments were approximately 29.1 million cartons. Using the average f.o.b. price, at least 70 percent of the Florida citrus handlers could be considered small businesses under SBA's definition. In addition, based on production and producer prices reported by the National Agricultural Statistics Service, and the total number of Florida citrus producers, the average annual producer revenue is approximately $55,540. Therefore, the majority of handlers and producers of Florida citrus may be classified as small entities.

This rule continues in effect the action that decreased the assessment rate established for the Committee and collected from handlers for the 2007–08 and subsequent fiscal periods from $0.008 to $0.0072 per 4/5 bushel carton of oranges, grapefruit, tangerines, and tangelos. The Committee unanimously recommended 2007–08 expenditures of $275,000 and an assessment rate of $0.0072 per 4/5 bushel carton. The assessment rate of $0.0072 is $0.0008 lower than the 2006–07 rate. The quantity of assessable oranges, grapefruit, tangerines, and tangelos for the 2007–08 season is estimated at 30 million 4/5 bushel cartons. Thus, the $0.0072 rate should provide $216,000 in assessment income. Income derived from handler assessments, along with interest income and funds from the Committee's authorized reserve will be adequate to cover budgeted expenses.

The major expenditures recommended by the Committee for the 2007–08 fiscal year include $112,000 for salaries, $25,000 for Manifest Department—FDACS, $17,800 for retirement plan, and $14,550 for insurance and bonds. Budgeted expenses for these items in 2006–07 were $110,000, $25,000, $17,250, and $14,550, respectively.

The reduction in the assessment rate was recommended by the Committee as a result of an unanticipated increase in shipments for the 2006–07 fiscal period, which produced revenues that were greater than expenses. In addition, the industry has continued to recover from the hurricane damage sustained during the 2004–05 and 2005–06 seasons, which is expected to have a positive impact on production.

The Committee reviewed and unanimously recommended 2007–08 expenditures of $275,000. Prior to arriving at this budget, the Committee considered information from various sources including the Committee's Budget Subcommittee. Alternative expenditure levels were discussed by this group, based on different estimates of assessable cartons and budget expenses. The assessment rate of $0.0072 per 4/5 bushel carton of assessable oranges, grapefruit, tangerines, and tangelos was then determined by dividing the total recommended budget by the quantity of assessable Florida citrus, estimated at 30 million 4/5 bushel cartons for the 2007–08 season, taking into consideration the availability of reserve funds and interest income. This is approximately $59,000 under anticipated expenses, which the Committee determined to be acceptable.

A review of historical information and preliminary information pertaining to the upcoming fiscal period indicates that the producer price for the 2007–08 season could range between $1.83 and $9.76 per 4/5 bushels of oranges, grapefruit, tangerines, and tangelos. Therefore, the estimated assessment revenue for the 2007–08 fiscal period as a percentage of total producer revenue could range between .07 and .39 percent.

This action continues in effect the action that decreased the assessment obligation imposed on handlers. Assessments are applied uniformly on all handlers, and some of the costs may be passed on to producers. However, decreasing the assessment rate reduces the burden on handlers, and may reduce the burden on producers. In addition, the Committee's meeting was widely publicized throughout the Florida citrus industry and all interested persons were invited to attend the meeting and participate in Committee deliberations on all issues. Like all Committee meetings, the May 29, 2007, meeting was a public meeting and all entities, both large and small, were able to express views on this issue.

This action imposes no additional reporting or recordkeeping requirements

on either small or large Florida citrus handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

AMS is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

An interim final rule concerning this action was published in the **Federal Register** on July 30, 2007 (72 FR 41423). Copies of that rule were also mailed or sent via facsimile to all citrus handlers. Finally, the interim final rule was made available through the Internet by USDA and the Office of the **Federal Register**. A 60-day comment period was provided for interested persons to respond to the interim final rule. The comment period ended on September 28, 2007, and no comments were received.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *http://www.ams.usda.gov/fv/moab.html*. Any questions about the compliance guide should be sent to Jay Guerber at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

After consideration of all relevant material presented, including the information and recommendation submitted by the Committee and other available information, it is hereby found that this rule, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

List of Subjects in 7 CFR Part 905

Grapefruit, Marketing agreements, Oranges, Reporting and recordkeeping requirements, Tangelos, Tangerines.

PART 905—ORANGES, GRAPEFRUIT, TANGERINES, AND TANGELOS GROWN IN FLORIDA

■ Accordingly, the interim final rule amending 7 CFR part 905 which was published at 72 FR 41423 on July 30, 2007, is adopted as a final rule without change.

Dated: November 29, 2007.

Lloyd C. Day,

Administrator, Agricultural Marketing Service.

[FR Doc. E7–23529 Filed 12–4–07; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 11, 13, 17, 36, 91, 139, 150, 193, 404, and 406

Change In Address for the Department of Transportation (DOT) and DOT Migration to the Federal Docket Management System (FDMS)

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; technical amendment.

SUMMARY: This action updates the Department of Transportation (DOT) addresses, changes references from the Docket Management System to the Federal Docket Management System (FDMS), and removes obsolete information listed in FAA regulations as a result of DOT's relocation, migration to the Federal electronic docket system, and closure of the DOT Branch Library. The intended effect of this action is to ensure that the regulated public is informed of address changes, electronic docket changes, and other administrative matters.

DATES: Effective December 5, 2007.

FOR FURTHER INFORMATION CONTACT: Barbara Dinkins, Office of Rulemaking, ARM–210, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202–493–4657); facsimile: (202–267–5075); e-mail: *barbara.b.dinkins@faa.gov*.

SUPPLEMENTARY INFORMATION: This technical amendment addresses the following administrative changes—

(1) The Department of Transportation (DOT) relocation of its entire headquarters to 1200 New Jersey Avenue, SE., Washington, DC;

(2) The DOT migration to the governmentwide electronic Federal Document Management System (FDMS) which replaces the old DOT Docket Management System (DMS); and

(3) Closure of DOT Transportation Branch Library.

As a result of these changes, the FAA is amending 14 CFR parts 11, 13, 17, 36, 91, 139, 150, 193, 404, and 406.

Because these actions are merely administrative in nature and removes outdated references, the FAA finds that notice and public procedure under 5 U.S.C. 553(b) is unnecessary. For the same reason, the FAA finds that good cause exists under 5 U.S.C. 5553(d) for making this amendment effective upon publication.

List of Subjects

14 CFR Part 11

Administrative practice and procedure, Reporting and recordkeeping requirements.

14 CFR Part 13

Administrative practice and procedure, Air transportation, Aviation safety, Hazardous materials transportation, Investigations, Law enforcement, Penalties.

14 CFR Part 17

Administrative practice and procedure, Authority delegations (Government agencies), Government contracts.

14 CFR Part 36

Agriculture, Aircraft, Noise control.

14 CFR Part 91

Afghanistan, Agriculture, Air traffic control, Aircraft, Airmen, Airports, Aviation Safety, Canada, Cuba, Ethiopia, Freight, Mexico, Noise control, Political candidates, Reporting and recordkeeping requirements, Yugoslavia.

14 CFR Part 139

Air carriers, Airports, Aviation safety, Reporting and recordkeeping requirements.

14 CFR Part 150

Airports, Noise control.

14 CFR Part 193

Air transportation, Aviation safety, Reporting and recordkeeping requirements, Security measures.

14 CFR Part 404

Administrative practice and procedure, Space transportation and exploration.

14 CFR Part 406

Administrative practice and procedure, Confidential business information, Investigations, Penalties, Space transportation and exploration.

The Amendments

■ In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR chapters I and III as follows:

PART 11—GENERAL RULEMAKING PROCEDURES

■ 1. The authority citation for part 11 continues to read as follows:

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

■ 2. Amend § 11.25 by revising the last sentence in paragraph (a) introductory text to read as follows:

§ 11.25 How does FAA issue rules?

(a) * * * We also make all documents available to the public by posting them in the Federal Docket Management System at *http://www.regulations.gov.*

* * * * *

■ 3. Amend § 11.33 by revising paragraph (a) to read as follows:

§ 11.33 How can I track FAA's rulemaking activities?

* * * * *

(a) *Docket ID.* We assign a docket ID to each rulemaking document proceeding. Each rulemaking document FAA issues in a particular rulemaking proceeding, as well as public comments on the proceeding, will display the same docket ID. This ID allows you to search the Federal Docket Management System (FDMS) for information on most rulemaking proceedings. You can view and copy docket materials during regular business hours at the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590. Or you can view and download docketed materials through the Internet at *http://www.regulations.gov.* If you can't find the material in the electronic docket, contact the person listed under **FOR FURTHER INFORMATION CONTACT** in the document you are interested in.

* * * * *

■ 4. Revise § 11.35 section heading to read as follows:

§ 11.35 Does FAA include sensitive security information and proprietary information in the Federal Docket Management System (FDMS)?

* * * * *

■ 5. Amend § 11.45 by revising paragraph (a) introductory text, (a)(1), (a)(2), and (c) to read as follows:

§ 11.45 Where and when do I file my comments?

(a) Send your comments to the location specified in the rulemaking document on which you are commenting. If you are asked to send your comments to the Federal Document Management System, you may send them in either of the following ways:

(1) By mail to: U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

(2) Through the Internet to *http://www.regulations.gov.*

* * * * *

(c) We may reject your paper or electronic comments if they are frivolous, abusive, or repetitious. We may reject comments you file electronically if you do not follow the electronic filing instructions at the Federal Docket Management System Web site.

■ 6. Amend § 11.63 by revising paragraphs (a)(2), (b)(1), and (b)(2) to read as follows:

§ 11.63 How and to whom do I submit my petition for rulemaking or petition for exemption?

(a) * * *

(2) To the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590 or to this Internet address: *http://www.regulations.gov.*

(b) * * *

(1) By paper submission, send the original signed copy of your petition for rulemaking or exemption to this address: U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

(2) By electronic submission, submit your petition for rulemaking or exemption to FAA through the Internet using the Federal Document Management System Web site at *http://www.regulations.gov.*

* * * * *

PART 13—INVESTIGATIVE AND ENFORCEMENT PROCEDURES

■ 7. The authority citation for part 13 continues to read as follows:

Authority: 18 U.S.C. 6002; 28 U.S.C. 2461 (note); 49 U.S.C. 106(g), 5121–5124, 40113–40114, 44103–44106, 44702–44703, 44709–44710, 44713, 46101–46110, 46301–46316, 46318, 46501–46502, 46504–46507, 47106, 47111, 47122, 47306, 47531–47532; 49 CFR 1.47.

■ 8. Amend § 13.210 by revising paragraph (e)(1) to read as follows:

§ 13.210 Filing of documents.

* * * * *

(e) *Internet accessibility of documents filed in the Hearing Docket.* (1) Unless protected from public disclosure by an order of the ALJ under § 13.226, all documents filed in the Hearing Docket are accessible through the Federal Docket Management System (FDMS): *http://www.regulations.gov.* To access a particular case file, use the FDMS number assigned to the case.

* * * * *

■ 9. Amend § 13.230 by revising paragraph (b) to read as follows:

§ 13.230 Record.

* * * * *

(b) *Examination and copying of record.* Any person may examine the record at the Hearing Docket, Federal Aviation Administration, 600 Independence Avenue, SW., Wilbur Wright Building—Room 2014, Washington, DC 20591. Documents may also be examined and copied at the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590. Any person may have a copy of the record after payment of reasonable costs to copy the record.

PART 17—PROCEDURES FOR PROTESTS AND CONTRACTS DISPUTES

■ 10. The authority citation for part 17 continues to read as follows:

Authority: 5 U.S.C. 570–581, 49 U.S.C. 106(f)(2), 40110, 40111, 40112, 46102, 46014, 46105, 46109, and 46110.

■ 11. Amend § 17.15 by revising paragraph (b)(1) to read as follows:

§ 17.15 Filing a protest.

* * * * *

(b) * * *

(1) Office of Dispute Resolution for Acquisition, Federal Aviation Administration, AGC–70, 3rd Floor, 800 Independence Avenue, SW., Washington, DC 20591, telephone: (202) 267–3290, facsimile: (202) 267–3720; or

* * * * *

■ 12. Amend § 17.25 by revising paragraph (b)(1) to read as follows:

§ 17.25 Filing a contract dispute.

* * * * *

(b) * * *

(1) Office of Dispute Resolution for Acquisition, Federal Aviation Administration, AGC–70, 3rd Floor, 800 Independence Avenue, SW., Washington, DC 20591, telephone: (202) 267–3290, facsimile: (202) 267–3720; or

* * * * *

■ 13. Amend § 17.27 by revising paragraph (c)(1) to read as follows:

§ 17.27 Submission of joint or separate statements.

* * * * *

(c) * * *

(1) Office of Dispute Resolution for Acquisition, Federal Aviation

Administration, AGC–70, 3rd Floor, 800 Independence Avenue, SW., Washington, DC 20591, telephone: (202) 267–3290, facsimile: (202) 267–3720; or

* * * * *

PART 36—NOISE STANDARDS: AIRCRAFT TYPE AND AIRWORTHINESS CERTIFICATION

■ 14. The authority citation for part 36 continues to read as follows:

Authority: 42 U.S.C. 4321, *et seq.*; 49 U.S.C. 106(g), 40113, 44701–44702, 44704, 44715; sec. 305, Pub. L. 96–193, 94 Stat. 50, 57; E.O. 11514, 35 FR 4247, 3 CFR, 1966–1970 Comp,, P. 902.

■ 15. Amend § 36.6 by revising paragraph (e)(1) to read as follows, removing paragraph (e)(2), and redesignating paragraphs (e)(3) and (e)(4) as paragraphs (e)(2) and (e)(3) respectively:

§ 36.6 Incorporation by reference.

* * * * *

(e) * * *

(1) U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

* * * * *

PART 91—GENERAL OPERATING AND FLIGHT RULES

■ 16. The authority citation for part 91 continues to read as follows:

Authority: 49 U.S.C. 106(g), 1155, 40103, 40113, 40120, 44101, 44111, 44701, 44704, 44709, 44711, 44712, 44715, 44716, 44717, 44722, 46306, 46315, 46316, 46504, 46506–46507, 47122, 47508, 47528–47531, articles 12 and 29 of the Convention on International Civil Aviation (61 Stat. 1180).

■ 17. Amend § 91.851 by revising the definition of *Chapter 4 noise level* to read as follows:

§ 91.851 Definitions.

* * * * *

Chapter 4 noise level means a noise level at or below the maximum noise level prescribed in Chapter 4, Paragraph 4.4, Maximum Noise Levels, of the International Civil Aviation Organization (ICAO) Annex 16, Volume I, Amendment 7, effective March 21, 2002. The Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 approved the incorporation by reference of this document, which can be obtained from the International Civil Aviation Organization (ICAO), Document Sales Unit, 999 University Street, Montreal, Quebec H3C 5H7, Canada. Also, you may obtain documents on the Internet at *http://www.ICAO.int/eshop/index.cfm.* Copies may be reviewed at the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590 or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

* * * * *

PART 139—CERTIFICATION OF AIRPORTS

■ 18. The authority citation for part 139 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701–44706, 44709, 44719.

■ 19. Amend § 139.111 by revising paragraph (c)(2) to read as follows:

§ 139.111 Exemptions.

* * * * *

(c) * * *

(2) Federal Docket Management System, as specified under 14 CFR part 11.

PART 150—AIRPORT NOISE COMPATIBILITY PLANNING

■ 20. The authority citation for part 150 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44715, 47101, 47501–47504.

§ 150.13 [Amended]

■ 21. Amend § 150.13 by removing paragraph (e)(2) and redesignating paragraphs (e)(3) and (e)(4) as (e)(2) and (e)(3), respectively.

PART 193—PROTECTION OF VOLUNTARILY SUBMITTED INFORMATION

■ 22. The authority citation for part 193 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 40123.

■ 23. Amend § 193.11 by revising the first sentence in paragraph (a) to read as follows:

§ 193.11 What is the notice procedure?

* * * * *

(a) *Application.* You may apply to have information designated as protected under this part by submitting an application addressed to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590 for paper submissions, and the Federal Docket Management System (FDMS) Web page at *http://www.regulations.gov* for electronic submissions.* * *

* * * * *

PART 404—REGULATIONS AND LICENSING REQUIREMENTS

■ 24. The authority citation for part 404 continues to read as follows:

Authority: 49 U.S.C. 70101–70121.

■ 25. Amend § 404.3 by revising paragraph (b)(1)(ii) to read as follows:

§ 404.3 Filing of petitions to the Associate Administrator.

* * * * *

(b) * * *

(ii) Be submitted in duplicate to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590;

* * * * *

PART 406—INVESTIGATIONS, ENFORCEMENT, AND ADMINISTRATIVE REVIEW

■ 26. The authority citation for part 406 continues to read as follows:

Authority: 49 U.S.C. 70101–70121.

■ 27. Amend § 406.9 by revising paragraph (g)(1) to read as follows:

§ 406.9 Civil penalties.

* * * * *

(g) * * *

(1) The respondent must file a written request for hearing with the Federal Docket Management System (U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590) and must serve a copy of the request on the agency attorney. Sections 406.113 and 406.115 state how filing and service must be done.

* * * * *

■ 28. Amend § 406.109 by revising paragraphs (b)(1), (b)(2), and (b)(3) to read as follows:

§ 406.109 Administrative law judges—powers and limitations.

* * * * *

(b) * * *

(1) The administrative law judge must file with the FDMS, or instruct the party to file with the FDMS, a copy of each document that is submitted to the administrative law judge that has not bee filed with FDMS, except the portions of those documents that contain confidential information.

(2) The administrative law judge must file with the FDMS a copy of each ruling and order issued by the administrative law judge, except those portions that contain confidential information.

(3) The administrative law judge must file with the FDMS, or instruct the court reporter to file with the FDMS, a copy of each transcript and exhibit, except those portions that contain confidential information.

* * * * *

■ 29. Amend § 406.113 by revising paragraphs (a), (b), (c), (d) introductory text, (d)(1), (d)(2), (e), (f)(1), (f)(2), and (f)(3) to read as follows:

§ 406.113 Filing documents with the Federal Docket Management System (FDMS) and sending documents to the administrative law judge and Assistant Chief Counsel for Litigation.

(a) *The Federal Docket Management System (FDMS).* (1) Documents filed in a civil penalty adjudication are kept in the Federal Docket Management System (FDMS), except for documents that contain confidential information in accordance with § 406.117. The FDMS is an electronic docket. Documents that are filed are scanned into the electronic docket and an index is made of all documents that have been filed so that any person may view the index and documents as provided in paragraph (f) of this section.

(2) A party is not required to file written interrogatories and responses, requests for production of documents or tangible items and responses, and requests for admission and responses with the Federal Docket Management System or submit them to administrative law judge, except as provided in § 406.143.

(b) *Method of filing.* A person filing a document must mail or personally deliver the signed original and one copy of each document to the FDMS at the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590. A person must serve a copy of each document on each party in accordance with § 406.115.

(c) *Date of filing.* The date of filing is the date of personal delivery, or if mailed, the mailing date shown on any certificate of service, the date shown on the postmark if there is no certificate of service, or other mailing data shown by other evidence if there is no certificate of service or postmark. The date shown in the FDMS index is not necessarily the date of service. It is the date the FDMS received the document.

(d) *Form.* FDMS scans the document into its electronic docket. To ensure that FDMS can scan the document and correctly identify it in the index, each person filing a document must comply with the following:

(1) Each document must be legible. It may be handwritten, typewritten, or printed from a computer.

(2) Each document must have a caption on its first page, clearly visible, with the following information:

(i) "FAA Space Adjudication."

(ii) Case name, such as "In the matter of X Corporation."

(iii) FAA Case Number and FDMS docket number, if assigned.

(iv) Name of the document being filed, including the party filing the document, such as "Respondent's Motion to Dismiss."

(v) "Confidential information filed with administrative law judge" or "Confidential information filed with Assistant Chief Counsel for Litigation" if the party is filing confidential information under § 406.117.

* * * * *

(e) *Sending documents to the administrative law judge or Assistant Chief Counsel for Litigation.* Sending the document directly to the administrative law judge or to the Assistant Chief Counsel for Litigation is not a substitute for filing the original with the FDMS, except for confidential information under § 406.117.

(f) * * *

(1) During regular business hours at the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

(2) Through the Internet at *http://www.regulations.gov*.

(3) By requesting it from the FDMS and paying reasonable costs.

■ 30. Amend § 406.115 by revising paragraphs (a), (c), and (d) to read as follows:

§ 406.115 Serving documents on other parties.

(a) *Service required.* A person must serve on each other party at the time of filing a copy of any document filed with the Federal Docket Management System. Service on a party's attorney or representative of record is adequate service on the party.

* * * * *

(c) *Certificate of service.* A person may attach a certificate of service to a document filed with the FDMS. Any certificate of service must include a statement, dated and signed by the individual filing the document, that the document was served on each party, the method of service, and the date of service.

(d) *Date of service.* The date of service is the date of personal delivery; or if mailed, the mailing date shown on the certificate of service, the date shown on the postmark if there is no certificate of service, or other mailing date shown by other evidence if there is no certificate of service or postmark. The date shown in the FDMS index is not necessarily the date of service. It is the date the FDMS received the document.

* * * * *

■ 31. Amend § 406.121 by revising paragraphs (a) and (b) to read as follows:

§ 406.121 Extension of time.

* * * * *

(a) *Extension of time by agreement of the parties.* The parties may agree to extend for a reasonable period of time for filing a document under this subpart with the agreement of the administrative law judge. The party seeking the extension of time must submit a draft order to the administrative law judge for signature, file it with the Federal Docket Management System, and serve it on each party.

(b) *Motion for extension of time.* If the parties do not agree to an extension of time for filing a document, a party desiring an extension may file with the Federal Docket Management System and serve a written motion for an extension of time not later than 7 days before the document is due unless good cause for the late filing is shown. The administrative law judge may grant the extension of time if good cause for the extension is shown.

* * * * *

■ 32. Amend § 406.127 by revising paragraphs (a)(1) and (b)(3) to read as follows:

§ 406.127 Complaint and answer in civil penalty adjudications.

(a) *Complaint—(1) Filing.* The complainant must file the original and one copy of the complaint with the Federal Docket Management System, or may file a written motion pursuant to § 406.141(f)(1) instead of filling a complaint, not later than 20 days after receipt by the complainant of a request for hearing. The complainant should suggest a location for the hearing when filing the complaint.

* * * * *

(b) * * *

(3) *Filing and service.* A respondent must file the answer with the Federal Docket Management System and serve a copy of the answer on the agency attorney who filed the complaint.

* * * * *

■ 33. Amend § 406.133 by revising paragraph (a) introductory text to read as follows:

§ 406.133 Amendments of pleadings.

(a) *Time.* A party must file with the Federal Docket Management System and serve on each other party any amendment to a complaint or an answer as follows:

* * * * *

■ 34. Amend § 406.137 by revising paragraph (a) to read as follows:

§ 406.137 Intervention.

(a) A person may file with the Federal Docket Management System and serve on each other party a motion for leave to intervene as party in an adjudication. Except for good cause shown, a motion for leave to intervene must be filed not later than 10 days before the hearing.

* * * * *

■ 35. Amend § 406.139 by revising paragraphs (b) introductory text and (d) to read as follows:

§ 406.139 Joint procedural or discovery schedule.

* * * * *

(b) *Form and content of schedule.* If the parties agree to a joint procedural or discovery schedule, one of the parties must file with the Federal Docket Management System and serve the joint schedule, setting forth the dates to which the parties have agreed. One of the parties must draft an order establishing a joint schedule for the administrative law judge.

* * * * *

(d) *Order establishing joint schedule.* The administrative law judge must approve the joint schedule filed by the parties by signing the joint schedule and filing it with the Federal Docket Management System.

* * * * *

■ 36. Amend § 406.141 by revising paragraph (c) to read as follows:

§ 406.141 Motions.

* * * * *

(c) *Form and time.* Except for oral motions heard on the record, a motion made prior to the hearing must be in writing. Unless otherwise agreed by the parties or for good cause shown, a party must file any prehearing motion with the Federal Docket Management System and serve each other party not later than 30 days before the hearing.

* * * * *

■ 37. Amend § 406.143 by revising the second sentence in paragraph (b) and by revising the first sentence in paragraph (j)(3) to read as follows:

§ 406.143 Discovery.

* * * * *

(b) * * * A party is not required to file written interrogatories and responses, requests for production of documents or tangible items and responses, and requests for admission and responses with the Federal Docket Management System or submit any of them to the administrative law judge.

* * *

* * * * *

(j) * * *

(3) *Notice of deposition.* A party must serve a notice of deposition, stating the time and place of the deposition and the name and address of each person to be examined, on the person to be deposed, must submit the notice to the administrative law judge, and must file the notice with the Federal Docket Management System, and must serve the notice on each party, not later than 7 days before the deposition. * * *

* * * * *

■ 38. Amend § 406.173 by revising the first and second sentence in paragraph (d) to read as follows:

§ 406.173 Interlocutory appeals.

* * * * *

(d) *Procedure.* A party must file with the Federal Docket Management System and serve each other party a notice of interlocutory appeal, with supporting documents, not later than 10 days after the administrative law judge's decision forming the basis of an interlocutory appeal of right or not later than 10 days after the administrative law judge's decision granting an interlocutory appeal for cause. A party must file with the Federal Docket Management System a reply brief, if any, and serve a copy of the reply brief on each party, not later than 10 days after service of the appeal brief. * * *

* * * * *

■ 39. Amend § 406.175 by revising paragraphs (a), (d) introductory text, and (e) introductory text, by revising the third sentence in paragraph (f), and by revising paragraph (g) to read as follows:

§ 406.175 Appeal from initial decision.

(a) *Notice of appeal.* A party may appeal the initial decision, and any decision not previously appealed pursuant to § 406.173, by filing with the Federal Docket Management System and serving on each party a notice of appeal. A party must file the notice of appeal not later than 10 days after entry of the oral initial decision on the record or service of the written initial decision on the parties.

* * * * *

(d) *Appeal briefs.* A party must file the appeal brief with the Federal Docket Management System and serve each party.

* * * * *

(e) *Reply brief.* Unless otherwise agreed by the parties, any party may file a reply brief with the Federal Docket Management System and serve on each other party not later than 35 days after the appeal brief has been served on that party. If the party relies on evidence contained in the record for the reply, the party must specifically refer to the pertinent evidence contained in the record in the reply brief.

* * * * *

(f) * * * A party may file with the Federal Docket Management System a motion for permission to file an additional brief and must serve a copy of the motion on each other party. * * *

(g) *Number of copies.* A party must file the original brief and two copies of the brief with the Federal Docket Management System and serve one copy on each other party.

* * * * *

■ 40. Amend § 406.177 by revising the second sentence in paragraph (a) to read as follows:

§ 406.177 Petition to reconsider or modify a final decision and order of the FAA decisionmaker on appeal.

(a) * * * A party must file a petition to reconsider or modify with the Federal Docket Management System not later than 30 days after service of the FAA decisionmaker's final decision and order on appeal and must serve a copy of the petition on each party. * * *

* * * * *

Issued in Washington, DC on November 28, 2007.

Pamela Hamilton-Powell,

Director, Office of Rulemaking, Aviation Safety.

[FR Doc. E7–23422 Filed 12–4–07; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

Oral Dosage Form New Animal Drugs; Carprofen

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the

animal drug regulations to reflect approval of an original abbreviated new animal drug application (ANADA) filed by Belcher Pharmaceuticals, Inc. The ANADA provides for veterinary prescription use of carprofen caplets in dogs.

DATES: This rule is effective December 5, 2007.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0169, e-mail: *john.harshman@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Belcher Pharmaceuticals, Inc., 12393 Belcher Rd., Suite 420, Largo, FL 33773, filed ANADA 200–397 for VETPROFEN (carprofen) Caplets. The ANADA provides for veterinary prescription use in dogs for the relief of pain and inflammation associated with osteoarthritis, and for the control of postoperative pain associated with soft tissue and orthopedic surgeries. Belcher Pharmaceuticals, Inc.'s VETPROFEN Caplets are approved as a generic copy of RIMADYL Caplets, sponsored by Pfizer, Inc., under NADA 141–053. The ANADA is approved as of November 7, 2007, and 21 CFR 520.309 is amended to reflect the approval.

In addition, Belcher Pharmaceuticals, Inc., has not been previously listed in the animal drug regulations as a sponsor of an approved application. At this time, 21 CFR 510.600(c) is being amended to add entries for the firm.

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

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

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 520

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 520 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding a new entry for "Belcher Pharmaceuticals, Inc." and in the table in paragraph (c)(2) by numerically adding a new entry for "062250" to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * *	* *
Belcher Pharmaceuticals, Inc., 12393 Belcher Rd., suite 420, Largo, FL 33773	062250
* * *	* *

(2) * * *

Drug labeler code	Firm name and address
* *	* * *
062250	Belcher Pharmaceuticals, Inc., 12393 Belcher Rd., suite 420, Largo, FL 33773
* *	* * *

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 520.309 [Amended]

■ 4. In paragraph (b)(2) of § 520.309, remove "No. 000115" and add in its place "Nos. 000115 and 062250".

Dated: November 20, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7–23516 Filed 12–4–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use in Animal Feeds; Monensin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Elanco Animal Health. The supplemental NADA revises the concentration of monensin in two-way Type B and Type C medicated feeds containing monensin and tylosin to cattle fed in confinement for slaughter and a revision to bacterial pathogen nomenclature.

DATES: This rule is effective December 5, 2007.

FOR FURTHER INFORMATION CONTACT: Daniel A. Benz, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0223, e-mail: *daniel.benz@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 104–646 that provides for use of RUMENSIN (monensin USP) and TYLAN (tylosin phosphate) Type A medicated articles to make dry and liquid two-way combination medicated feeds for cattle fed in confinement for slaughter. The supplemental NADA provides for an increased level of monensin in combination Type B and Type C medicated feeds and a revision to bacterial pathogen nomenclature. The supplemental NADA is approved as of October 30, 2007, and the regulations in 21 CFR 558.355 are amended to reflect the approval.

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

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

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

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

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

■ 2. In § 558.355, revise paragraphs (f)(3)(ii) and (f)(3)(xii) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(3) * * *

(ii) *Amount per ton.* Monensin, 5 to 40 grams; plus tylosin, 8 to 10 grams.

(*a*) *Indications for use.* Cattle fed in confinement for slaughter: For improved feed efficiency; and reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes.*

(*b*) *Limitations.* Feed only to cattle being fed in confinement for slaughter. Feed continuously as sole ration at the rate of 50 to 480 milligrams of monensin and 60 to 90 milligrams of tylosin per head per day. Combination drug liquid Type B medicated feeds may be used to manufacture dry Type C medicated feeds and shall conform to mixing instructions as in § 558.625(c) of this chapter.

* * * * *

(xii) *Amount per ton.* Monensin, 10 to 40 grams; plus tylosin, 8 to 10 grams.

(*a*) *Indications for use.* Cattle fed in confinement for slaughter: For prevention and control of coccidiosis due to *E. bovis* and *E. zuernii*; and reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes.*

(*b*) *Limitations.* Feed only to cattle being fed in confinement for slaughter. For prevention and control of coccidiosis, feed at a rate of 0.14 to 0.42 milligrams monensin per pound of body weight per day, depending upon the severity of challenge, up to maximum of 480 milligrams per head per day; and 60 to 90 milligrams of tylosin per head per day.

* * * * *

Dated: November 20, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7–23519 Filed 12–4–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use in Animal Feeds; Monensin USP

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Elanco Animal Health. The supplemental NADA removes the requirement for 30-day expiration on labeling of monensin Type C medicated feeds for several classes of cattle and goats.

DATES: This rule is effective December 5, 2007.

FOR FURTHER INFORMATION CONTACT: Daniel A. Benz, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0223, e-mail: *daniel.benz@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 95–735 that provides for use of RUMENSIN 80 (monensin) Type A medicated articles. The supplement removes the requirement for 30-day expiration on labeling of monensin Type C medicated feeds for several classes of cattle and goats. The supplemental NADA is approved as of November 9, 2007, and the regulations in 21 CFR 558.355 are amended to reflect the approval.

In addition, the regulations are being amended to remove a redundant entry for combination use of monensin USP and melengestrol acetate, with or without tylosin phosphate, in medicated feed for heifers fed in confinement for slaughter. This action is being taken to improve the clarity of the regulations.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

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

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

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

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

■ 2. In § 558.355, remove and reserve paragraphs (d)(2), (d)(3), and (f)(3)(viii); and revise paragraph (f)(6)(i)(*b*)(*1*) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(6) * * *

(i) * * *

(*b*) * * *

(*1*) *Feed continuously.* Feed only to goats being fed in confinement. Do not

feed to lactating goats. Type C feeds may be manufactured from monensin liquid Type B feeds. The liquid Type B feeds have a pH of 4.3 to 7.1 and their labels must bear appropriate mixing directions, as defined in paragraph (d)(12) of this section. See special labeling considerations in paragraph (d) of this section.

* * * * *

Dated: November 20, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7–23517 Filed 12–4–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 630

[FHWA Docket No. FHWA–2006–25203]

RIN 2125–AF10

Temporary Traffic Control Devices

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Final rule.

SUMMARY: The FHWA is adding a new Subpart K to 23 CFR part 630 to supplement existing regulations that govern work zone safety and mobility in highway and street work zones to include conditions for the appropriate use of, and expenditure of funds for, uniformed law enforcement officers, positive protective measures between workers and motorized traffic, and installation and maintenance of temporary traffic control devices during construction, utility, and maintenance operations. These regulations are intended to decrease the likelihood of fatalities and injuries to road users, and to workers who are exposed to motorized traffic (vehicles using the highway for purposes of travel) while working on Federal-aid highway projects. The regulations are issued in accordance with section 1110 of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU), Public Law 109–59, 119 Stat. 1227, codified at 23 U.S.C. 109(e) and 112(g).

DATES: *Effective Date:* December 4, 2008.

The incorporation by reference of certain publications listed in this rule is approved by the Director of the Federal Register as of December 4, 2008.

FOR FURTHER INFORMATION CONTACT: Mr. Chung Eng, Office of Transportation Operations, HOTO–1, (202) 366–8043; or Mr. Raymond W. Cuprill, Office of the Chief Counsel, HCC–30, (202) 366–0791, U.S. Department of Transportation, Federal Highway Administration, 1200 New Jersey Avenue, SE., Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

This document, the notice of proposed rulemaking (NPRM), and all comments received may be viewed online through the Federal eRulemaking portal at: *http://www.regulations.gov.* The Web site is available 24 hours each day, 365 days each year. Electronic submission and retrieval help and guidelines are available under the help section of the Web site.

An electronic copy of this document may also be downloaded from the Office of the **Federal Register**'s home page at: *http://www.archives.gov* and the Government Printing Office's Web page at: *http://www.access.gpo.gov/nara.*

Background

History

In 2004, the FHWA published a final rule updating its regulations on Work Zone Safety and Mobility (23 CFR 630, subpart J). Section 630.1006 of subpart J (Work Zone Safety and Mobility Policy) stated that "Each State shall implement a policy for the systematic consideration and management of work zone impacts on all Federal-aid highway projects. This policy shall address work zone impacts throughout the various stages of the project development and implementation process. This policy may take the form of processes, procedures, and/or guidance, and may vary based on the characteristics and expected work zone impacts of individual projects or classes of projects. The States should institute this policy using a multidisciplinary team and in partnership with the FHWA. The States are encouraged to implement this policy for non-Federal-aid projects as well." This final rule on Temporary Traffic Control Devices provides additional guidance on the development of such Work Zone Safety and Mobility Policies, and specifically addresses the requirements of section 1110 of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU), Public Law 109–59, 119 Stat. 1227, which have been codified at 23 U.S.C. 109(e) and 112(g).

Section 109(e)(2) of title 23, United States Code, states that no funds shall be approved for expenditure on any Federal-aid highway "unless proper temporary traffic control devices to improve safety in work zones will be installed and maintained during construction, utility, and maintenance operations on that portion of the highway with respect to which such expenditures are to be made. Installation and maintenance of the devices shall be in accordance with the Manual on Uniform Traffic Control Devices." Additionally, section 112(g)(1) requires that "[t]he Secretary, after consultation with appropriate Federal and State officials, shall issue regulations establishing the conditions for the appropriate use of, and expenditure of funds for, uniformed law enforcement officers, positive protective measures between workers and motorized traffic, and installation and maintenance of temporary traffic control devices during construction, utility, and maintenance operations."

A NPRM proposing the creation of a new Subpart K of 23 CFR part 630 was published on November 1, 2006, at 71 FR 64173. The purpose was to emphasize the need to appropriately consider and manage worker safety as part of the project development process by providing guidance on key factors to consider in reducing worker exposure and risk from motorized traffic. The FHWA proposed to require that each agency's policy for the systematic consideration and management of work zone impacts be established in accordance with the recently updated 23 CFR part 630 subpart J (effective October 12, 2007), and address the consideration and management of worker safety as follows:

1. Avoid or minimize worker exposure to motorized traffic through the application of appropriate positive protective strategies including, but not limited to, full road closures; ramp closures; crossovers; detours; and rolling road blocks during work zone setup and removal;

2. Where exposure cannot be adequately managed through the application of the above strategies, reduce risk to workers from being struck by motorized traffic through the use of appropriate positive protective devices;

3. Where exposure and risk reduction is not adequate, possible, or practical, manage risk through the application of appropriate intrusion countermeasures including, but not limited to, the use of uniformed law enforcement officers; and

4. Assure that the quality and adequacy of deployed temporary traffic control devices are maintained for the project duration.

The FHWA received a substantial number of comments in response to the NPRM. On December 19, 2006, at 71 FR 75898, the comment period was extended to February 16, 2007, in response to a concern expressed by the National Committee on Uniform Traffic Control Devices (NCUTCD) that the closing date did not provide sufficient time for discussion of the issues in committee and a subsequent comprehensive response to the docket. The extension provided the NCUTCD and other interested parties additional time to discuss, evaluate, and submit comments to the docket.

A major focus of the comments to the rule as proposed was the need for greater flexibility in selecting and applying the specific strategies advanced for the required policies and procedures. There was also a general interest in providing a balance between the need for ensuring the safety of construction and maintenance workers as they carry out their tasks in work zones, and the safety of road users as they traverse highway work zones.

In developing this final rule the FHWA has carefully considered the comments and suggestions of respondents. Some changes have been made to the overall structure of the rule in order to enhance the clarity and consistency of each section. Other changes have been made to revise the terminology, making it more consistent with the stated intent of section 1110 of SAFETEA–LU, and adjusting the language to clarify the rule's intent.

Among the key issues addressed in the development of this final rule were the following:

- Revisions to terms and definitions to address all treatments and traffic control devices;
- Presentation of treatments as options, not in priority order;
- Provision of appropriate pay items for all traffic control treatments and operations;
- Flexibility on pay items, acknowledging that either lump sum or unit pricing may be appropriate, depending upon circumstances; and
- Reference to the need to manage risks associated with work vehicles and equipment when they are exiting or entering travel lanes.

Summary Discussion of Comments Received in Response to the NPRM

The following discussion provides an overview of the comments received in response to the NPRM, and the FHWA's actions to resolve and address the issues raised by the respondents.

Profile of Respondents

Comments were submitted by a broad cross-section of organizations and individuals, including national organizations representing the interests of State departments of transportation and contractors, respectively; other industry groups representing manufacturers and suppliers of highway construction safety equipment; State and local departments of transportation and public authorities; and law enforcement agencies, as well as private consultants and other individuals. The trade associations providing comments were the Associated General Contractors (AGC) of America; the Association of Road and Transportation Builders of America (ARTBA); the Laborers' Health and Safety Fund of North America (LHSFNA) and the New Jersey State Laborers Health and Safety Fund (NJSLHSF); the NCUTCD; the American Traffic Safety Services Association (ATSSA); the Water Barrier Manufacturers' Association (WBMA); the American Highway Users' Alliance (AHUA); the National Association of County Engineers (NACE); Advocates for Highway and Auto Safety (AHAS); the Maryland Highway Contractors Association (MHCA); and the Colorado Association of Traffic Control Professionals (CATCP). FHWA categorized the comments of the American Association of State Highway and Transportation Officials (AASHTO) with those of State Departments of Transportation (DOTs), because AASHTO represents State DOTs. The AASHTO comments noted that their submission was a consolidated response to the NPRM on behalf of its member States. Many State DOTs provided additional comments individually.

Overall Position of Respondents

Taken as a whole, the responses to the NPRM were supportive of the intent of the rule, noting the vulnerability of highway workers in work zones and the need to reduce work zone hazards to workers and road users alike. Some respondents thought that the rule as proposed went too far in imposing requirements on agencies undertaking highway construction projects, while others felt that the rule as proposed did not go far enough in protecting workers.

In all, there were 80 entries into the docket for comments on the proposed rule. Of these entries, 4 were posted by FHWA (the proposed rule, two background documents providing supporting information to respondents, and a notice extending the comment period for the NPRM). An additional three comments were requests for an extension of the comment period. Thirteen entries into the docket were duplicates of previous entries, or comments that were substantially the same but provided some additional information in support of the comments. Of the 60 remaining responses to the NPRM, 29 respondents supported the proposed rule; in general, these respondents supported the rule as proposed and agreed with the overall purpose, structure, and language, though their comments may have included specific recommendations for clarification or revisions. Another 27 respondents indicated opposition to the NPRM. These respondents generally opposed the rule as proposed; most of these respondents agreed with the overall purpose of the proposed rule, but may have opposed the structure and language of the NPRM (e.g., most State DOTs agreed with the intent of the rule, but disagreed with some specific language). Other respondents may have been neutral toward the rule as a whole, but had some specific recommendations for changes.

Most respondents restricted their comments to the proposed regulatory language. However, some addressed material contained in the preamble. One respondent suggested that the approach described in the NPRM would have the potential for increased congestion, inconvenience, and increased travel time and cost to deliver goods and services, which would seem inconsistent with the goals set forth in the National Strategy to Reduce Congestion on America's Transportation Network, and that project characteristics, system capacity, and mobility needs may dictate other approaches. FHWA concurs with the comments that safety measures should be implemented on the basis of project characteristics and that agencies should take into consideration the possible impacts of such measures on system capacity and mobility. However, FHWA feels that the final rule provides sufficient flexibility for operating agencies to select measures that will provide an appropriate level of protection both to road users and to workers in work zone activity areas, while maintaining adequate levels of mobility.

Section-by-Section Analysis of the NPRM Comments and FHWA Response

Because of the restructuring of the rule in response to FHWA's review of the comments received, the numbering of sections in the final rule is not entirely consistent with the proposed rule. Therefore, comments will be

addressed below as they relate to the applicable section of the final rule.

Section 630.1102 Purpose

Most State DOTs agreed in general terms with the purpose as written. Twenty State DOTs (out of 26 submitting comments) explicitly endorsed AASHTO's response, which included suggested changes to the language. Among AASHTO's suggestions was that the purpose recognize that road user safety should not be compromised by the implementation of any of the rule's requirements. The Maryland State Highway Administration (SHA) noted that the "section-by-section" discussion in the NPRM for the "Purpose" section says, "[b]y emphasizing worker safety, the proposed rule would attempt to enhance the safety of both the motorist and worker during the project." However, the SHA felt that the proposed rule seems to be tilted in favor of worker safety, and the balance between the safety of workers and those of the traveling public has not been attained.

The FHWA agrees that the objective is to ensure both worker and road user safety. In emphasizing worker safety in the purpose of the proposed rule, the FHWA attempted to provide a better balance between consideration of the safety of workers and those of the traveling public. The FHWA recognizes that the safety of both workers and road users are equally important and has revised the purpose to clearly reflect that this regulation is intended to improve work zone safety for workers and road users alike.

AASHTO's comments also proposed that the final rule should not apply to "all State and local highway agencies that receive Federal-aid highway funding," but rather make the rule applicable to all "Federal-aid projects." AASHTO also suggested that the FHWA consider including a statement encouraging States to implement these requirements on non-Federal-aid projects as well. In the proposed rule, the first and second sentences under "Purpose" were meant to be taken together, thus indicating applicability to Federal-aid highway projects and recipients of Federal-aid highway funding. The language in the purpose section has been clarified to indicate that this final rule applies only to Federal-aid projects. Language has also been added to encourage application of this rule to non-Federal-aid projects as well.

One respondent argued that a primary intent of the rule is to get State DOTs and other agencies to ensure adequate funding to promote worker and road user safety in the work zone planning and design process. While acknowledging that FHWA and the Occupational Safety and Health Administration (OSHA) have different responsibilities, the respondent suggested that this rule should "strike a common ground between the two." The respondent went on to urge that FHWA take a more expansive view of worker safety, addressing safety within the work space as well as the interface between workers and motorized traffic. Another respondent suggested that the purpose statement should be changed to "establish requirements and provide guidance for addressing worker safety by limiting the exposure to hazards and risks inside the work zone as well as to hazards and risks from motorized traffic." This change would expand the scope of the rule to include worker safety inside the work zone, whether or not there is an intrusion. In response to the comments regarding worker safety from hazards and risks inside the work area, the FHWA agrees that worker safety related to internal operations is important, but believes that workplace safety requirements are outside the scope of this rulemaking effort and this subpart, and fall under the purview of OSHA.

Some respondents observed that the proposed rule would require changes to the Manual on Uniform Traffic Control Devices (MUTCD). The FHWA agrees that some of the provisions included in the regulation may be appropriate for consideration to be added to the MUTCD; the criteria and provisions for positive protection and law enforcement are, for the most part, good information that can be made more readily available by adding it as guidance or support to the MUTCD. Inclusion of such provisions in the MUTCD may be addressed by the FHWA in a separate and future rulemaking action.

Section 630.1104 Definitions

The FHWA made several changes to the terms used throughout the final rule to clarify the meaning of the term "positive protective measures." Changes have been made to the structure of the rule and definitions to strengthen and clarify the intent of the rule, based on the statutory language.

One respondent suggested that all definitions should be consistent with existing definitions in the MUTCD, while at the same time ensuring that new terms are not so similar to existing terms as to cause confusion. It was also suggested that any term not in the current MUTCD should be included in the next MUTCD. The FHWA generally agrees, and inclusion of appropriate terminology in the MUTCD may be addressed in a separate and future rulemaking action.

In reference to a term used elsewhere in the proposed rule, a respondent suggested that "[t]he term 'live travel lane' as referenced in section 630.1106 should be defined under this section." This wording has been revised in the final rule, now under section 630.1108, to read "travel lanes open to traffic" to better convey its meaning and as a result, the FHWA does not believe a definition is now required.

The terms appearing in the final rule are discussed below:

Agency. The definition for "Agency" was revised to include public authorities.

Exposure Control Measures. This definition was added to address concerns expressed by a number of respondents that terms as presented in the NPRM were somewhat confusing and potentially misleading. "Exposure Control Measures" was added in place of "Positive Protective Strategies" to reflect the fact that strategies were not aimed solely at preventing vehicles from entering the work space, but to reduce worker and road user exposure through a variety of strategies.

Federal-aid Highway Project. This definition was left unchanged.

Motorized Traffic. This definition was modified to clarify the reference to "construction or maintenance vehicles and equipment," and to emphasize that, while protection of workers and road users is equally important, the strategies used to address road users may be different from strategies primarily affecting construction vehicles and equipment, particularly when they are entering or exiting the protected area of the work zone. We declined to accept a comment suggesting that the term "motorized traffic" be expanded to include work vehicles in favor of describing in more detail the need to draw distinctions between vehicles passing through the work zone and vehicles operating within the work zone and its protected areas.

Other Traffic Control Measures. This definition was added to reflect structural changes in the rule that changed the nomenclature for different activities, and to underscore the distinction between the "exposure control measures," "positive protection devices," and any other strategies used to improve worker safety. The term "Intrusion Countermeasures" was eliminated because the measures listed were broader than simply reducing intrusion risk, and the term "Other Traffic Control Measures" is more descriptive of these measures.

Positive Protection Devices. A minor change in the wording was made to clarify that such devices may either contain or redirect vehicles, or perform both functions. The FHWA agrees that the term "contain and redirect" may be confusing, because some devices do not redirect impacting vehicles. Many types of crash cushions and arrestor nets contain vehicles, but do not redirect.

The terms "Positive Protective Strategies" and "Positive Protective Measures" were eliminated, based on the potential confusion involved in using three closely related terms with different meanings. While 23 U.S.C. 112(g)(4) refers to "Positive Protective Measures," the FHWA felt that the intent would be best served by using somewhat different terminology in the final rule.

Work Zone Safety Management. The term "Work Zone Safety Management" was added as an "umbrella" encompassing all actions taken by an agency to ensure the protection of workers and road users in work zones, including the development of policies, procedures, and guidelines for individual projects or programs. This term was added to respond to comments that the terminology in the NPRM was ambiguous and inconsistent with both current practice and the language of section 1110 of SAFETEA–LU.

Section 630.1106 Policy and Procedures for Work Zone Safety Management

Section 630.1106 was reorganized and refined from the proposed rule, largely in response to comments submitted to the docket. Material in the proposed rule was rearranged to separate elements related to overall policies and procedures to be developed by State DOTs from specifics related to particular traffic control strategies and the implementation of work zone safety measures.

Subsection (a) of section 630.1106 describes the nature of the required work zone safety measures and traffic control strategies, and encourages State DOTs to work in partnership with FHWA in developing policies and procedures. This use of the term "partnership" is consistent with existing language in Subpart J—Work Zone Safety and Mobility.

Subsection (b) refers to the MUTCD and the AASHTO Roadside Design Guide (RDG) as sources of information on work zone safety methods and traffic control strategies, and presents some of the project and highway characteristics and factors that the State DOTs should take into consideration when determining which measures and strategies should be employed.

Several respondents to the NPRM were concerned about the specificity of some of the language in the proposed rule, commenting that the proposed rule imposed requirements without any supporting research indicating that the proposed criteria were appropriate. The FHWA acknowledges that there is no definitive research supporting specific criteria. The language in the final rule has been modified to clarify the intent of the rule, which is to require appropriate consideration and management of worker and road user safety when planning highway construction, maintenance, and utility operations. The new language retains and expands the listing, previously located in subsection (a), of some of the characteristics and factors that should be considered when deciding what work zone safety measures should be used, while giving agencies flexibility in determining the criteria and thresholds that would affect decisions about the use of different strategies.

A comment relating to the specificity of the proposed rule noted that the original language "contains three specific requirements for the use of longitudinal barrier that cause significant concern, as they are restrictive and will have unintended negative consequences if applied unilaterally to all work zones. These requirements include: (1) Stationary work zones lasting two weeks or more; (2) with a design speed of 45 mph or higher; and (3) where workers are within one-lane-width of a live travel lane." In specifying these specific thresholds in the proposed rule, the intent was to use them as triggers for requiring an analysis on the need for positive protection devices rather than as direct requirements for the use of positive protection devices. These factors are now part of a more comprehensive set of considerations, and are not characterized as "requirements." As modified, the final rule still requires consideration of worker and road user safety, but provides more flexibility to agencies along with guidance on the factors that should be taken into account in selecting work zone safety measures.

Several respondents expressed concern about the term "project design speed." The FHWA concurs that "project design speed" is inappropriate. While the intended meaning of this term was the work zone design speed rather the design speed of the completed project, it may still not reflect the actual traffic speeds through the work zone. The language in the final rule has been modified to refer to anticipated traffic speeds through the work zone rather than the project design speed.

A respondent to the NPRM observed that "the material in the AASHTO Roadside Design Guide is intended to serve as guidance, not as requirements." The respondent indicated some discomfort with provisions that seem to suggest that the Guide is to be treated as a specific regulation (e.g., actions shall be "consistent with" or "in accordance with" that Guide). The commenter believes that such wording suggests that FHWA will be determining whether a State has acted in accordance with the Guide, even though the Guide itself is, as FHWA stated, a "resource document." Language in the final rule has been modified to make clear that guidance included in the AASHTO Roadside Design Guide is not, and should not be construed as a "regulation."

Another respondent expressed concern that the requirements in section 630.1106 are "arbitrary and overly prescriptive." The respondent believes that States should be required to develop policies that help protect highway worker safety and that they should begin by examining the application of strategies that would avoid or minimize worker exposure, even though in many, if not most cases, these strategies will not be practical. However, the respondent felt that section 630.1106(a) should be "softened," and that this section should be written more as recommendations rather than as requirements. The FHWA has modified the language in this section to emphasize that States have the flexibility to develop policies and procedures that are appropriate to the circumstances of a given project or program.

Subsection (c) deals with law enforcement, directing State DOTs and other agencies undertaking construction projects with Federal-aid funds to develop a policy addressing the use of uniformed law enforcement on such projects. The policy may consist of processes, procedures, and/or guidance, as appropriate.

Overall, there is good support and little or no opposition to the concept of agencies developing a policy for work zone law enforcement. The most significant concerns related to the manner of FHWA involvement in development of the policy, and some of the individual provisions to be included. One respondent argued that the language in the proposed rule, which "states that 'Each agency in cooperation with FHWA, shall develop a policy * * *' suggests a possible

interpretation of some type of joint authority for FHWA to decide how States utilize and pay for law enforcement. This would lead to FHWA involvement in a State's internal management, which is not appropriate." In response to this concern, the FHWA changed the term "cooperation" to "partnership." This is the same terminology currently used in Subpart J. Some respondents expressed concern that the proposed rule would have required operating agencies to take responsibility for an area over which they had no control—that is, the integration of law enforcement with work zone safety measures. Another respondent noted the difficulty of ensuring compliance due to the numerous entities involved in law enforcement, including State law enforcement agencies, sheriff departments in multiple counties, and a host of local agencies. The respondent suggested that the rule should include accommodations with numerous and widespread layers of law enforcement involved in safeguarding their roads.

The FHWA recognizes that some highway agencies do not have direct connections to law enforcement agencies. However, the FHWA does not believe that is a valid reason for not developing an agency enforcement policy and procedures as stated in the final rule under section 630.1106(c). The final rule does not impose specific requirements on the use of law enforcement and is not prescriptive. While section 630.1108(e) requires the agency to develop a law enforcement policy, it does not dictate what the policy is to contain. Each operating agency has the flexibility to develop a policy suitable for its situation in consideration of the factors listed. Numerous options can be used to acquire law enforcement services. The rule does not limit the required agency policy to consideration of only the State law enforcement agency. In fact, a number of State highway agencies currently have agreements in place with various local law enforcement agencies as well as State law enforcement agencies. Contractors can hire off-duty officers using contract funds as another alternative. Officer training is one of the issues that need to be addressed when developing whatever inter-agency accords may be needed to implement the agency policy.

A number of States have good policies and programs in place for use of law enforcement in work zones. For example, a comment by the California Highway Patrol (CHP) describes its approach. "California's work zone law enforcement program, the Construction/Maintenance Zone Enhanced Enforcement Program (COZEEP/MAZEEP), is based on CHP policy and interagency agreements between the California Department of Transportation (Caltrans) and the CHP. The current policy and agreements adequately meet the issues addressed in this proposed rulemaking. However, to improve communication and interaction, CHP and Caltrans are currently working toward joint training for CHP officers and Caltrans staff to clarify the roles and responsibilities of Caltrans and CHP at the COZEEP/MAZEEP details."

Section 630.1108 Work Zone Safety Management Measures and Strategies

Section 630.1108 is reorganized and refined in this final rule. One comment that was made repeatedly by respondents to the NPRM was that the proposed rule was arbitrary and too prescriptive, and that the proposed rule did not permit State DOTs and other affected agencies to make judgments about which work zone safety measures and traffic control strategies would be most appropriate for a given situation. Respondents generally supported a decision process based on an engineering study including consideration of specific work zone factors and existing guidance in the MUTCD and the RDG. An approach that appears to have support from both agencies and industry is to provide a clear listing of the available options, along with a discussion of the factors and existing guidelines that should be considered. Such an approach would also include the specific requirement that the agency policy developed in response to 23 CFR 630.1006 must address both worker and road user safety, and include consideration of the safety options presented in this final rule. FHWA agrees with these observations and has modified the language in the final rule to better reflect the intent of the rule, which is to require appropriate consideration and management of worker and road user safety when planning highway construction, maintenance, and utility operations, while giving agencies flexibility in determining the criteria and thresholds that would affect decisions about the use of different strategies. Throughout the final rule, many of the proposed "shall" statements were modified to emphasize that the proposed strategies or measures represented the types of actions that should be considered, and to make clear that the suggested actions were not being presented in a prescriptive priority order.

Comments from one group of respondents focused on the use of portable concrete barriers (PCB) as a form of positive protection. The respondents observed that, "According to the Roadside Design Guide, 'As with all types of traffic barriers, a median barrier should be installed only if striking the barrier is less severe than the consequences that would result if no barrier existed.' This is due to the fact that the PCB has such high Occupant Risk Values when impacted." The respondents continued, "Due to the fact that the Occupant Risk Values are much greater when impacting PCB than when impacting water-filled barriers, a significant margin of safety could be made available to the motoring public, if water-filled barriers were utilized in place of PCB.... Based on the serious and fatal injuries to vehicle occupants resulting from a number of crashes involving PCBs, we recommend that language be inserted in this section that would disallow PCBs from being installed on the NHS; or installed only in extreme situations. Instead of PCBs, we recommend that water ballast barriers be used exclusively according to accepted design guidelines and only where needed to shield work zone hazards." The FHWA does not agree with the comment or the suggested change. The FHWA does not believe that any significant overall advantage exists for water-filled barrier and it offers some disadvantages such as freezing and icing in cold temperatures. As worded, the rule allows agencies to select from any positive protection devices that meet the performance criteria set forth in NCHRP Report 350, "Recommended Procedures for the Safety Performance Evaluation of Highway Features."

Another respondent enumerated other concerns with respect to the use of PCBs as positive protection devices, expressing concern about the impact of strict requirements on primary roadway widening construction in their State. The respondent noted that in general, PCBs are utilized where there is a grade elevation change and where drop-offs (greater than two inches) adjacent to a travel lane are necessary, for a period of longer than one work day or work shift. The respondent felt that a literal reading of the proposed rule would necessitate placement of PCB at all edges of the roadway adjacent to construction activities. The PCB would occupy roadway width normally available for use as part of the adjacent travel lane, reducing the average 24-foot wide road to only 20 feet of available travel area. The respondent indicated that this

would eliminate opportunities for simultaneous construction on each side of the roadway. Currently, the agency submitting the comment requires construction of temporary pavement in locations adjacent to temporary concrete barrier wall to maintain 12 foot travel lanes. The requirements proposed in this rule would necessitate the construction of miles of temporary pavement to maintain 12 foot travel lanes. Without the temporary pavement, traffic would be restricted to 10 foot travel lanes with a longitudinal barrier on one side of the roadway. The respondent noted that such conditions could be especially hazardous on roadways with substantial truck traffic. Furthermore, the respondent noted that it would be necessary to install breaks in the temporary concrete barrier wall to maintain driveway access, and each break would require the installation of a portable terminal impact attenuator. The respondent felt that in areas with multiple driveways in close proximity to one another, maintenance of a safe installation of temporary concrete barrier wall would be problematic at best. The FHWA agrees that project characteristics need to be considered in decisions involving the use of barriers and language in the final rule requires that the need for positive protection devices be based on an engineering study.

Some respondents commented that the proposed rule did not go far enough, and suggested that the final rule should be strengthened to require minimum work zone safety measures or traffic control measures, based on specific criteria. Others proposed that the final rule should provide a "preference of controls," beginning with consideration of positive protection strategies, followed by consideration of positive protection devices, and then use of intrusion countermeasures. This runs counter to many other comments, which argued for greater flexibility in selection of appropriate work zone safety measures. FHWA concurs with the respondents who argued that there is no definitive research available to support highly prescriptive criteria for when specific work zone safety measures should be deployed. Neither is there evidence that there should be a rigid hierarchy or preference of controls. Instead, FHWA believes that the types of controls appropriate for any given work zone depend on the circumstances (location, volume and speed of adjacent traffic, availability of escape routes for workers, duration of the construction project) and the characteristics of the construction activity (drop-offs, proximity of workers to travel lanes, etc.). Agencies responsible for the construction project should determine the appropriate traffic control measures either on the basis of an engineering study for the individual project, or based on policies adopted by the agency for certain classes of projects. Traffic control strategies that provide for the safety of both workers and road users may be selected alone or in combination, after considering the characteristics and circumstances of the construction project.

One respondent argued that without permanent barriers, most maintenance workers are left unprotected from vehicle intrusions. The respondent expressed a preference that all work should be performed behind a permanent barrier, but acknowledged that this would not be possible. When permanent barriers could not be used, the respondent stated that the following measures should be mandated: Uniformed on-duty law enforcement officers in marked cars; marked law enforcement cars to pace traffic to reduce vehicular speeds adjacent to the work zone; buffer lanes between workers and the traveling public (Interstate highways with posted speed limits 55 mph or greater should have at least one buffer lane, and those in excess of 70 mph should have a minimum of two buffer lanes); water-filled barriers; and light towers around the work area to alert the public of highway work. FHWA does not agree, nor do most of the other commenters, that all work should be performed behind a permanent barrier. This is unrealistic and does not necessarily provide the best overall safety for all concerned. The suggestions of alternative measures that should be mandated would appear arbitrary in many respects and would limit an agency's ability to consider the entire range of safety treatments in order to obtain the best balance of worker and road user safety, mobility, constructability, and cost.

Another respondent suggested that FHWA should develop its own guidelines or reference non-proprietary products. The respondent also suggested that State agencies should be required to first look to deploy the most protective devices before being allowed to use a less protective measure. The FHWA strongly supports continued research to develop improved guidelines for application of the various treatments. However, the FHWA believes that such research is most appropriate under the National Cooperative Highway Research Program (NCHRP). In fact, NCHRP just recently released a study on the Design of Construction Work Zones on High-Speed Highways (NCHRP Report 581), which is an excellent example of the kind of emerging research that can guide agencies in designing work zones that will help ensure the safety of both road users and construction or maintenance workers. It appears that by "most protective," the commenter means temporary traffic barrier. The FHWA does not agree that this should always be the priority. The preferred approach is one that would provide the best overall management of safety, mobility, constructability, and cost. Requiring the highest level of positive protection does not necessarily result in the highest level of any of these objectives.

Some respondents provided extensive comments on such issues as the desirability of full road closures, and the need for Federal funding to encourage such actions; requiring "Type I and Type II barricades" in place of plastic or rubber cones and delineators; requiring the use of "pennant flagging or similar durable warning tape" to sequester sections of Portland concrete cement (PCC) that have been freshly laid; requiring the presence of an ATSSA Work Zone Supervisor-qualified person on projects; and to require training for contractors on the use of rolling road blocks. While some of these comments have merit, they are generally beyond the scope of this rulemaking action. However, it should be noted that Subpart J does require that both the contractor and State DOT designate a person responsible for implementing the project TMP and that said individual be properly trained in accordance with Subpart J.

The FHWA agrees with many of the suggestions offered by commenters and has substantially revised section 630.1108 as described below.

Section 630.1108(a) requires that agencies undertaking highway construction projects with Federal-aid funding determine the need for positive protection devices on the basis of an engineering study. This responds in part to comments from respondents that the term "engineering analysis" used in the proposed rule was not in common use among State DOTs and other agencies, but that the term "engineering study" is used in the MUTCD and is well-understood by such agencies. It also serves to address the language in 23 U.S.C. § 109(e)(2), which states that the "[i]nstallation and maintenance of the [proper temporary traffic control] devices shall be in accordance with the Manual of Uniform Traffic Control Devices." Section 630.1108(a) also emphasizes that the conditions enumerated in section 630.1106 should

be considered when agencies establish what work zone safety measures should be deployed, and identifies some circumstances under which the use of positive protection measures are required to be considered.

In section 630.1108(a), the FHWA also responds to concerns that undertaking an engineering study for every work zone, including situations where routine maintenance of facilities is to be undertaken, would be cost-prohibitive. The final rule notes that an engineering study "may be used to develop positive protection guidelines for the agency, or to determine the measures to be applied on an individual project." In other words, agencies may establish a policy, supported by an engineering study, that dictates the types of work zone safety measures and traffic control strategies that must be implemented at a minimum for certain types of work. Engineering studies could also be undertaken for a specific project based on characteristics of the project or of the circumstances surrounding the project. Factors to be considered in developing a policy for providing traffic control measures for different types of projects, or that might trigger an engineering study for a particular project, are enumerated in this subsection. Such characteristics and factors include duration of the construction zone, site characteristics that would provide workers no means of escape from motorized traffic (e.g., tunnels, bridges, etc.), operating speeds of traffic in lanes adjacent to the work zone, and other elements.

Section 630.1108(b) discusses the use of "Exposure Control Measures." This term was added in place of "Positive Protective Strategies" to reflect the fact that strategies were not aimed solely at preventing vehicles from entering the work space, but to reduce worker exposure through a variety of strategies. One respondent suggested that the use of the phrase "during work zone set up and removal" following "rolling road blocks" should be clarified to indicate that it only refers to rolling road blocks, and not to the other strategies suggested to minimize worker exposure in the proposed rule. Another respondent suggested adding off-peak or night work as another strategy to be considered. The FHWA agrees with these suggestions. Each suggested strategy has been itemized in the final rule for clarity and night or off-peak work, as well as accelerated construction techniques, have been added as additional strategies.

Section 630.1108(c) addresses "Other Traffic Control Measures," which are designed to reduce the number of work zone crashes or to minimize the risks and consequences of intrusion of motorized vehicles into the work space. Several respondents to the NPRM took exception to the use of the term "Intrusion Countermeasures" in the proposed rule. Several respondents noted that some of the measures or strategies included under the rubric of "Intrusion Countermeasures" did not have anything to do with preventing a vehicle from "intruding" or penetrating barriers into the work space. FHWA has changed the title of this section and the wording to reflect the fact that this class of measures or strategies includes actions that relate to increased driver awareness and alertness in work zones, as well as improvements in worker training, improved worker visibility, and the use of law enforcement personnel. This section clarifies that no single measure or strategy will be effective in all circumstances, and that strategies should be considered in combination in order to provide the maximum protection reasonably available to protect workers and road users alike.

With respect to specific measures, respondents expressed various levels of support (or opposition) for several strategies. One respondent encouraged FHWA to "strongly recommend automated speed enforcement rather than merely suggesting it." Automated speed enforcement is one of the available traffic control measures and is included in the list of strategies for consideration. However, the FHWA recognizes that implementation of this strategy would require legislative action by most States. Another respondent noted that "[a]utomated intrusion alarms present a concern due to problems in linking devices in miles-long, drum-protected work zones." FHWA agrees that intrusion alarms, like most of the other tools listed, may not be suitable for all situations. However, the wording in section 630.1108(c) simply lists it as a tool that may be considered. Several additional measures were added in response to comments, including public and traveler information, and temporary traffic signals.

Section 630.1108(d) provides guidance on the use of law enforcement personnel to increase work zone safety. This subsection emphasizes that, while the use of law enforcement personnel can be effective in increasing driver awareness of work zones and compliance with posted warnings, such law enforcement presence is not a substitute for temporary traffic control devices required by the MUTCD. This subsection describes a number of circumstances under which the use of law enforcement personnel may be appropriate, particularly "on projects with high traffic speeds and volumes, and where the work zone is expected to result in significant disruption to or changes in normal traffic flow patterns."

This subsection also addresses the issue of pay items for law enforcement, as required by 23 U.S.C. 112(g). Language from the proposed rule on Federal-aid participation in costs associated with the provision of law enforcement personnel for work zone safety is retained, including the stipulation that "law enforcement activities that would normally be expected in and around highway problem areas requiring routine or ongoing law enforcement traffic control and enforcement activities" are excluded from eligibility for Federal-aid.

Section 630.1108(e) was added to address concerns expressed by a number of respondents to the NPRM noting that there are hazards associated with the entry or exit of construction vehicles and equipment from the protected area of the work zone, whether for delivery of supplies and material or for other purposes. The new section 630.1108(e) acknowledges this situation, which poses risks to both workers and travelers, and states that agency processes, procedures, and/or guidance should "address safe means for work vehicles and equipment to enter and exit traffic lanes and for delivery of construction materials to the work space, based on individual project characteristics and factors."

Section 630.1108(f) addresses the issue of pay items. FHWA strongly supports the concept of providing appropriate payment for all work zone traffic control features needed to address both safety and mobility impacts of a highway project. Most highway agencies (but not all) and contractors also support this concept. However, the real issue is in how best to accomplish this. The FHWA believes that this issue arose because, even at this time, some agencies provide little or no specific payment for work zone safety features, and in extreme cases, provide only minimal information as to what features are required. Any payment provided is either incidental to other items of work, or is grouped into a single item for traffic control. This approach is unacceptable in that conscientious contractors are at a significant disadvantage because they provide more safety, without payment, than other contractors that choose to neglect safety to achieve a cost advantage. This problem gives rise to

the frequent complaint of the "lack of a level playing field." The FHWA believes that this is the issue that the wording in the Federal statute attempts to address, and the final rule requires that payment for work zone traffic control features and operations "shall not be incidental to the contract, or included in payment for other items of work not related to traffic control and safety". A related concern is that contractors may need to include a "contingency factor" in bids to make sure they cover the costs of safety requirements that are not clearly defined in project plans, specifications, and estimates (PS&Es), thus resulting in higher bid prices.

Many agencies include a range of pay items in their project PS&Es that provide adequate payment for traffic control, and provide a range of payment items (both lump sum and unit price) for the various safety features needed. Lump sum and unit price payments represent two different approaches to reimbursing contractors for costs associated with construction activities. In deciding whether to use unit price or lump sum payment methods, agencies generally consider the following:

- Unit price payment should be limited to those items where the quantity can either be quantified in advance, or closely controlled by the agency during construction. If the quantity cannot be predicted and controlled, it gives rise to the potential for unbalanced bidding. Both agencies and many responsible contractors realize these risks, and do not generally support unit price pay items where quantities cannot be predicted and controlled by the agency.
- Lump sum payment reduces the risks of unbalanced bids for features where the actual quantity is dependent upon the manner the contractor selects to accomplish the work. However, to reduce risks to contractors of uncontrolled costs (which may result in higher bids), allowance for contingency payments on lump sum items when the overall quantity or nature of the work changes is desirable and is provided by some agencies.

Section 112(g)(2) of title 23, United States Code, requires "separate pay items for the use of uniformed law enforcement officers, positive protective measures between workers and motorized traffic, and installation and maintenance of temporary traffic control devices", but does not require unit price pay items. In an attempt for clarity, "positive protective measures" was broken down into "positive protective devices" and "positive protective measures" in the proposed rule. The proposed rule addressed payment for positive protective devices and uniformed law enforcement officers, but did not require a separate pay item for the installation and maintenance of temporary traffic control devices because the FHWA felt that doing so would not be substantially different from current practice. Separate payment for positive protective strategies was not specifically addressed in the proposed rule as strategies ultimately translate to devices. Based on comments received and a broader interpretation of the language in section 112(g)(2), the final rule addresses pay items in a more comprehensive fashion by supplementing the requirements of 23 CFR 630.1012(d) with additional requirements as well as guidance. This includes the requirement that separate pay items be provided for major categories of traffic control devices, safety features, and work zone safety activities, including but not limited to positive protection devices, and uniformed law enforcement activities when funded through the project.

Section 630.1110 Maintenance of Temporary Traffic Control Devices

This section was relatively non-controversial, and retains most of the wording of the proposed rule. One recurring comment is worth mention again here—numerous suggestions called for use of the term "Guidelines" in lieu of "Standards," as stated in the language of the proposed rule. Some argued that "The term 'quality standards' will result in significant liability for State DOTs, leading to the need for constant inspection and maintenance." After further consideration, and recognizing that the ATSSA reference noted in the NPRM is a guideline, FHWA agrees that the use of the term "guidelines" in lieu of "standards" would be preferable.

One comment took exception to the use of the term "assure" in the proposed rule. The respondent contended that use of the term "assure" means to put beyond all doubt, and asserted that maintenance of quality standards to the level of certainty would be cost-prohibitive. The language in the final rule has been revised to eliminate use of the term "assure."

Several comments were made about the use of certain colors on warning signs. The FHWA believes that such recommendations are beyond the scope of the rule and the requirements of section 1110 of SAFETEA–LU.

National Congestion Initiative

The final rule includes measures that could further the goals of the Secretary of Transportation's National Strategy to Reduce Congestion on America's Transportation Network, announced on May 16, 2006.[1] By requiring the development and implementation of guidelines to help maintain the quality and adequacy of temporary traffic control devices on Federal-aid highway projects, the FHWA anticipates that the proposed rule will help reduce congestion by ensuring that road users are always provided with positive guidance while traveling through work zones.

Rulemaking Analysis and Notices

Executive Order 12866 (Regulatory Planning and Review) and U.S. DOT Regulatory Policies and Procedures

The FHWA has determined that this action would not be a significant regulatory action within the meaning of Executive Order 12866 or significant within the meaning of U.S. Department of Transportation regulatory policies and procedures. A recent synthesis of positive protection practices in highway work zones indicates that a wide range of positive protection devices and other safety treatments are already being used by State highway agencies.[2] This synthesis found that among positive protection devices, portable concrete barriers and shadow vehicles equipped with truck mounted attenuators (SV/TMAs) were being used by nearly every State highway agency. The final rule emphasizes the need to consider worker and road user safety as an integral part of each State highway agency's process for considering and managing the overall impacts due to work zones. As such, any additional usage of positive protection devices resulting from the proposed action would be incremental to what many State highway agencies are already using to address work zone safety. In addition, consideration of exposure control and other traffic control measures that would avoid or minimize worker exposure to motorized traffic may decrease the overall need for positive protection devices. Accordingly, it is anticipated that the

[1] Speaking before the National Retail Federation's annual conference on May 16, 2006, in Washington, DC, former U.S. Transportation Secretary Norman Mineta unveiled a new plan to reduce congestion plaguing America's roads, rail, and airports. The National Strategy to Reduce Congestion on America's Transportation Network includes a number of initiatives designed to reduce transportation congestion. The transcript of these remarks is available at the following URL: *http://www.dot.gov/affairs/minetasp051606.htm.*

[2] Transportation Research Board (TRB), National Cooperative Highway Research Program (NCHRP) Project 20–7(174), A Synthesis of Highway Practice—Positive Protection Practices in Highway Work Zones, June 17, 2005. Available in the docket.

economic impact of this rulemaking would be minimal.

The final rule is not anticipated to adversely affect, in a material way, any sector of the economy. In addition, the final rule is not likely to interfere with any action taken or planned by another agency or to materially alter the budgetary impact of any entitlements, grants, user fees, or loan programs.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (5 U.S.C. 601–612), the FHWA has evaluated the effects of these changes on small entities. This rule applies to all State and local highway agencies that use Federal-aid highway funding in the execution of their highway program. The final rule emphasizes the need to consider worker and road user safety as an integral part of each agency's process for considering and managing the overall impacts due to work zones on Federal-aid highway projects. As noted previously, a recent synthesis of positive protection practices in highway work zones indicates that a wide range of positive protection devices and other safety treatments are already being used by State highway agencies. This synthesis found that among positive protective devices, portable concrete barriers and SV/TMAs were being used by nearly every State highway agency. The FHWA believes that positive protection devices and other safety treatments are also widely used by many local agencies because the FHWA's research indicates that local agencies usually follow State practice with respect to MUTCD guidance. As such, any additional usage of positive protection devices resulting from the proposed action would be incremental to what many local highway agencies are already using to address work zone safety. In addition, consideration of exposure control and other traffic control measures that would avoid or minimize worker exposure to motorized traffic may decrease the overall need for positive protection devices. Accordingly, the FHWA has determined that the final rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

This final rule would not impose unfunded mandates as defined by the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, 109 Stat. 48, March 22, 1995). This action would not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $128.1 million or more in any one year period to comply with these changes. Additionally, the definition of "Federal mandate" in the Unfunded Mandate Reform Act excludes financial assistance of the type in which State, local or tribal governments have authority to adjust their participation in the program in accordance with changes made in the program by the Federal government. The Federal-aid highway program permits this type of flexibility to the States.

Executive Order 13132 (Federalism)

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 13132 dated August 4, 1999, and the FHWA has determined that this action will not have a substantial direct effect or sufficient federalism implications on States that would limit the policymaking discretion of the States and local governments. The FHWA has also determined that this final rule will not preempt any State law or State regulation or affect the States' ability to discharge traditional State governmental functions and does not have sufficient federalism implications to warrant the preparation of a federalism assessment. The amendments are in keeping with the Secretary of Transportation's authority under 23 U.S.C. 109(d), 315, and 402(a) to promulgate uniform guidelines to promote the safe and efficient use of highways.

Executive Order 13175 (Tribal Consultation)

The FHWA has analyzed this action under Executive Order 13175, dated November 6, 2000, and believes that it will not have substantial direct effects on one or more Indian tribes; will not impose substantial direct compliance costs on Indian tribal governments; and will not preempt tribal law. The purpose of this final rule is to improve worker and road user safety on Federal-aid highway projects, and will not impose any direct compliance requirements on Indian tribal governments and will not have any economic or other impacts on the viability of Indian tribes. Therefore, a tribal summary impact statement is not required.

Executive Order 13211 (Energy Effects)

The FHWA has analyzed this action under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. It has been determined that it is not a significant energy action under that order because it is not a significant regulatory action under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects under Executive Order 13211 is not required.

Executive Order 12372 (Intergovernmental Review)

Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.

Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501, et seq.), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct, sponsor, or require through regulations. The FHWA has determined that this action does not contain information collection requirements for purposes of the PRA.

Executive Order 12988 (Civil Justice Reform)

This action meets applicable standards in Sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Executive Order 13045 (Protection of Children)

The FHWA has analyzed this action under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. The FHWA certifies that this action would not cause an environmental risk to health or safety that may disproportionately affect children.

Executive Order 12630 (Taking of Private Property)

This action would not affect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

National Environmental Policy Act

The agency has analyzed this action for the purpose of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.) and has determined that it would not have any effect on the quality of the environment.

Regulation Identification Number

A regulation identification number (RIN) is assigned to each regulatory

action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document can be used to cross-reference this action with the Unified Agenda.

List of Subjects in 23 CFR Part 630

Government contracts, Grant programs—Transportation, Highway safety, Highways and roads, Project agreement, Traffic regulations, Incorporation by reference.

Issued on: November 29, 2007.

J. Richard Capka,

Federal Highway Administrator.

■ In consideration of the foregoing, the FHWA adds Subpart K to title 23, Code of Federal Regulations, Part 630, as follows:

Subpart K—Temporary Traffic Control Devices

Sec.

Authority: 23 U.S.C. 109(c) and 112; Sec. 1110 of Pub. L. 109–59; 23 CFR 1.32; and 49 CFR 1.48(b).

§ 630.1102 Purpose.

To decrease the likelihood of highway work zone fatalities and injuries to workers and road users by establishing minimum requirements and providing guidance for the use of positive protection devices between the work space and motorized traffic, installation and maintenance of temporary traffic control devices, and use of uniformed law enforcement officers during construction, utility, and maintenance operations, and by requiring contract pay items to ensure the availability of funds for these provisions. This subpart is applicable to all Federal-aid highway projects, and its application is encouraged on other highway projects as well.

§ 630.1104 Definitions.

For the purposes of this subpart, the following definitions apply:

Agency means a State or local highway agency or authority that receives Federal-aid highway funding.

Exposure Control Measures means traffic management strategies to avoid work zone crashes involving workers and motorized traffic by eliminating or reducing traffic through the work zone, or diverting traffic away from the work space.

Federal-aid Highway Project means highway construction, maintenance, and utility projects funded in whole or in part with Federal-aid funds.

Motorized Traffic means the motorized traveling public. This term does not include motorized construction or maintenance vehicles and equipment within the work space.

Other Traffic Control Measures means all strategies and temporary traffic controls other than Positive Protection Devices and Exposure Control Measures, but including uniformed law enforcement officers, used to reduce the risk of work zone crashes involving motorized traffic.

Positive Protection Devices means devices that contain and/or redirect vehicles and meet the crashworthiness evaluation criteria contained in National Cooperative Highway Research Program (NCHRP) Report 350, Recommended Procedures for the Safety Performance Evaluation of Highway Features, 1993, Transportation Research Board, National Research Council. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. This document is available for inspection and copying at FHWA, 1200 New Jersey Avenue, SE., Washington, DC 20590, as provided in 49 CFR part 7. You may also inspect a copy at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741 6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Work Zone Safety Management means the entire range of traffic management and control and highway safety strategies and devices used to avoid crashes in work zones that can lead to worker and road user injuries and fatalities, including Positive Protection Devices, Exposure Control Measures, and Other Traffic Control Measures.

§ 630.1106 Policy and Procedures for Work Zone Safety Management.

(a) Each agency's policy and processes, procedures, and/or guidance for the systematic consideration and management of work zone impacts, to be established in accordance with 23 CFR 630.1006, shall include the consideration and management of road user and worker safety on Federal-aid highway projects. These processes, procedures, and/or guidance, to be developed in partnership with the FHWA, shall address the use of Positive Protection Devices to prevent the intrusion of motorized traffic into the work space and other potentially hazardous areas in the work zone; Exposure Control Measures to avoid or minimize worker exposure to motorized traffic and road user exposure to work activities; Other Traffic Control Measures including uniformed law enforcement officers to minimize work zone crashes; and the safe entry/exit of work vehicles onto/from the travel lanes. Each of these strategies should be used to the extent that they are possible, practical, and adequate to manage work zone exposure and reduce the risks of crashes resulting in fatalities or injuries to workers and road users.

(b) Agency processes, procedures, and/or guidance should be based on consideration of standards and/or guidance contained in the Manual on Uniform Traffic Control Devices (MUTCD) and the AASHTO Roadside Design Guide, as well as project characteristics and factors. The strategies and devices to be used may be determined by a project-specific engineering study, or determined from agency guidelines that define strategies and approaches to be used based on project and highway characteristics and factors. The types of measures and strategies to be used are not mutually exclusive, and should be considered in combination as appropriate based on characteristics and factors such as those listed below:

(1) Project scope and duration;

(2) Anticipated traffic speeds through the work zone;

(3) Anticipated traffic volume;

(4) Vehicle mix;

(5) Type of work (as related to worker exposure and crash risks);

(6) Distance between traffic and workers, and extent of worker exposure;

(7) Escape paths available for workers to avoid a vehicle intrusion into the work space;

(8) Time of day (e.g., night work);

(9) Work area restrictions (including impact on worker exposure);

(10) Consequences from/to road users resulting from roadway departure;

(11) Potential hazard to workers and road users presented by device itself and during device placement and removal;

(12) Geometrics that may increase crash risks (e.g., poor sight distance, sharp curves);

(13) Access to/from work space;

(14) Roadway classification; and

(15) Impacts on project cost and duration.

(c) Uniformed Law Enforcement Policy. Each agency, in partnership with the FHWA, shall develop a policy

addressing the use of uniformed law enforcement on Federal-aid highway projects. The policy may consist of processes, procedures, and/or guidance. The processes, procedures, and/or guidance should address the following:

(1) Basic interagency agreements between the highway agency and appropriate law enforcement agencies to address work zone enforcement needs;

(2) Interaction between highway and law-enforcement agency during project planning and development;

(3) Conditions where law enforcement involvement in work zone traffic control may be needed or beneficial, and criteria to determine the project-specific need for law enforcement;

(4) General nature of law enforcement services to be provided, and procedures to determine project-specific services;

(5) Appropriate work zone safety and mobility training for the officers, consistent with the training requirements in 23 CFR 630.1008(d);

(6) Procedures for interagency and project-level communications between highway agency and law enforcement personnel; and

(7) Reimbursement agreements for law enforcement service.

§ 630.1108 Work Zone Safety Management Measures and Strategies.

(a) *Positive Protection Devices.* The need for longitudinal traffic barrier and other positive protection devices shall be based on an engineering study. The engineering study may be used to develop positive protection guidelines for the agency, or to determine the measures to be applied on an individual project. The engineering study should be based on consideration of the factors and characteristics described in section 630.1106(b). At a minimum, positive protection devices shall be considered in work zone situations that place workers at increased risk from motorized traffic, and where positive protection devices offer the highest potential for increased safety for workers and road users, such as:

(1) Work zones that provide workers no means of escape from motorized traffic (e.g., tunnels, bridges, etc.);

(2) Long duration work zones (e.g., two weeks or more) resulting in substantial worker exposure to motorized traffic;

(3) Projects with high anticipated operating speeds (e.g., 45 mph or greater), especially when combined with high traffic volumes;

(4) Work operations that place workers close to travel lanes open to traffic; and

(5) Roadside hazards, such as drop-offs or unfinished bridge decks, that will remain in place overnight or longer.

(b) *Exposure Control Measures.* Exposure Control Measures should be considered where appropriate to avoid or minimize worker exposure to motorized traffic and exposure of road users to work activities, while also providing adequate consideration to the potential impacts on mobility. A wide range of measures may be appropriate for use on individual projects, such as:

(1) Full road closures;

(2) Ramp closures;

(3) Median crossovers;

(4) Full or partial detours or diversions;

(5) Protection of work zone setup and removal operations using rolling road blocks;

(6) Performing work at night or during off-peak periods when traffic volumes are lower; and

(7) Accelerated construction techniques.

(c) *Other Traffic Control Measures.* Other Traffic Control Measures should be given appropriate consideration for use in work zones to reduce work zone crashes and risks and consequences of motorized traffic intrusion into the work space. These measures, which are not mutually exclusive and should be considered in combination as appropriate, include a wide range of other traffic control measures such as:

(1) Effective, credible signing;

(2) Changeable message signs;

(3) Arrow panels;

(4) Warning flags and lights on signs;

(5) Longitudinal and lateral buffer space;

(6) Trained flaggers and spotters;

(7) Enhanced flagger station setups;

(8) Intrusion alarms;

(9) Rumble strips;

(10) Pace or pilot vehicle;

(11) High quality work zone pavement markings and removal of misleading markings;

(12) Channelizing device spacing reduction;

(13) Longitudinal channelizing barricades;

(14) Work zone speed management (including changes to the regulatory speed and/or variable speed limits);

(15) Law enforcement;

(16) Automated speed enforcement (where permitted by State/local laws);

(17) Drone radar;

(18) Worker and work vehicle/equipment visibility;

(19) Worker training;

(20) Public information and traveler information; and

(21) Temporary traffic signals.

(d) *Uniformed Law Enforcement Officers.* (1) A number of conditions may indicate the need for or benefit of uniformed law enforcement in work zones. The presence of a uniformed law enforcement officer and marked law enforcement vehicle in view of motorized traffic on a highway project can affect driver behavior, helping to maintain appropriate speeds and improve driver alertness through the work zone. However, such law enforcement presence is not a substitute for the temporary traffic control devices required by Part 6 of the MUTCD. In general, the need for law enforcement is greatest on projects with high traffic speeds and volumes, and where the work zone is expected to result in substantial disruption to or changes in normal traffic flow patterns. Specific project conditions should be examined to determine the need for or potential benefit of law enforcement, such as the following:

(i) Frequent worker presence adjacent to high-speed traffic without positive protection devices;

(ii) Traffic control setup or removal that presents significant risks to workers and road users;

(iii) Complex or very short term changes in traffic patterns with significant potential for road user confusion or worker risk from traffic exposure;

(iv) Night work operations that create substantial traffic safety risks for workers and road users;

(v) Existing traffic conditions and crash histories that indicate a potential for substantial safety and congestion impacts related to the work zone activity, and that may be mitigated by improved driver behavior and awareness of the work zone;

(vi) Work zone operations that require brief stoppage of all traffic in one or both directions;

(vii) High-speed roadways where unexpected or sudden traffic queuing is anticipated, especially if the queue forms a considerable distance in advance of the work zone or immediately adjacent to the work space; and

(viii) Other work site conditions where traffic presents a high risk for workers and road users, such that the risk may be reduced by improving road user behavior and awareness.

(2) Costs associated with the provision of uniformed law enforcement to help protect workers and road users, and to maintain safe and efficient travel through highway work zones, are eligible for Federal-aid participation. Federal-aid eligibility excludes law enforcement activities that would normally be expected in and around highway problem areas requiring routine or ongoing law enforcement traffic control and enforcement

activities. Payment for the services of uniformed law enforcement in work zones may be included in the construction contract, or be provided by direct reimbursement from the highway agency to the law enforcement agency. When payment is included through the construction contract, the contractor will be responsible for reimbursing the law enforcement agency, and in turn will recover those costs through contract pay items. Direct interagency reimbursement may be made on a project-specific basis, or on a program-wide basis that considers the overall level of services to be provided by the law enforcement agency. Contract pay items for law enforcement service may be either unit price or lump sum items. Unit price items should be utilized when the highway agency can estimate and control the quantity of law enforcement services required on the project. The use of lump sum payment should be limited to situations where the quantity of services is directly affected by the contractor's choice of project scheduling and chosen manner of staging and performing the work. Innovative payment items may also be considered when they offer an advantage to both the highway agency and the contractor. When reimbursement to the law enforcement agency is made by interagency transfer of funds, the highway agency should establish a program-level or project-level budget that is adequate to meet anticipated program or project needs, and include provisions to address unplanned needs and other contingencies.

(e) *Work Vehicles and Equipment.* In addition to addressing risks to workers and road users from motorized traffic, the agency processes, procedures, and/or guidance established in accordance with 23 CFR 630.1006 should also address safe means for work vehicles and equipment to enter and exit traffic lanes and for delivery of construction materials to the work space, based on individual project characteristics and factors.

(f) *Payment for Traffic Control.* Consistent with the requirements of 23 CFR 630.1012, Project-level Procedures, project plans, specifications and estimates (PS&Es) shall include appropriate pay item provisions for implementing the project Transportation Management Plan (TMP), which includes a Temporary Traffic Control (TTC) plan, either through method or performance based specifications. Pay item provisions include, but are not limited to, the following:

(1) Payment for work zone traffic control features and operations shall not be incidental to the contract, or included in payment for other items of work not related to traffic control and safety;

(2) As a minimum, separate pay items shall be provided for major categories of traffic control devices, safety features, and work zone safety activities, including but not limited to positive protection devices, and uniformed law enforcement activities when funded through the project;

(3) For method based specifications, the specifications and other PS&E documents should provide sufficient details such that the quantity and types of devices and the overall effort required to implement and maintain the TMP can be determined;

(4) For method-based specifications, unit price pay items, lump sum pay items, or a combination thereof may be used;

(5) Lump sum payment should be limited to items for which an estimate of the actual quantity required is provided in the PS&E or for items where the actual quantity required is dependent upon the contractor's choice of work scheduling and methodology;

(6) For Lump Sum items, a contingency provision should be included such that additional payment is provided if the quantity or nature of the required work changes, either an increase or decrease, due to circumstances beyond the control of the contractor;

(7) Unit price payment should be provided for those items over which the contractor has little or no control over the quantity, and no firm estimate of quantities is provided in the PS&Es, but over which the highway agency has control of the actual quantity to be required during the project;

(8) Specifications should clearly indicate how placement, movement/relocation, and maintenance of traffic control devices and safety features will be compensated; and

(9) The specifications should include provisions to require and enforce contractor compliance with the contract provisions relative to implementation and maintenance of the project TMP and related traffic control items. Enforcement provisions may include remedies such as liquidated damages, work suspensions, or withholding payment for noncompliance.

§ 630.1110 Maintenance of Temporary Traffic Control Devices.

To provide for the continued effectiveness of temporary traffic control devices, each agency shall develop and implement quality guidelines to help maintain the quality and adequacy of the temporary traffic control devices for the duration of the project. Agencies may choose to adopt existing quality guidelines such as those developed by the American Traffic Safety Services Association (ATSSA) or other state highway agencies.[1] A level of inspection necessary to provide ongoing compliance with the quality guidelines shall be provided.

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DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 36

RIN 1076–AE51

Homeliving Programs

AGENCY: Bureau of Indian Education, BIA, Interior.

ACTION: Final Rule.

SUMMARY: Under the No Child Left Behind Act of 2001, the Secretary of the Interior is publishing final regulations addressing homeliving programs administered under the Bureau of Indian Education-funded school system.

DATES: *Effective Date:* January 4, 2008.

FOR FURTHER INFORMATION CONTACT: Kevin Skenandore, Director, Bureau of Indian Education, 1849 C Street NW., MS–3609, Washington, DC 20240, phone (202) 208–6123.

SUPPLEMENTARY INFORMATION:

I. Background

A. What Information Does This Section Address?

This section addresses:

—Requirements of the No Child Left Behind Act of 2001 (Pub. L. 107–110, enacted January 8, 2002; "NCLBA" or "the Act"), section 1122.

[1] The American Traffic Safety Services Association's (ATSSA) Quality Guidelines for Work Zone Traffic Contro! Devices uses photos and written descriptions to help judge when a traffic control device has outlived its usefulness. These guidelines are available for purchase from ATSSA through the following URL: *http://www.atssa.com/store/bc_item_detail.jsp?productId=1.* Similar guidelines are available from various State highway agencies. The Illinois Department of Transportation "Quality Standards for Work Zone Traffic Control Devices" is available online at *http://dot.state.il.us/workzone/wztcd2004r.pdf.* The Minnesota Department of Transportation "Quality Standards—Methods to determine whether the various traffic control devices are Acceptable, Marginal, or Unacceptable" is available online at *http://www.dot.state.mn.us/trafficeng/otepubl/fieldmanual2007/FM–2007–QualityStandards.pdf.*

—Overview of the negotiated rulemaking process.
—How public comments were handled.

B. What Are the Negotiated Rulemaking Requirements of the Act?

The Secretary of the Interior ("Secretary") established a negotiated rulemaking committee (Committee) to develop proposed regulations to implement several sections of the Act related to the Bureau of Indian Education (Bureau)-funded school system. The Act required that the committee be comprised only of representatives of the Federal Government and representatives of tribes served by Bureau-funded schools. The Act also required that, to the maximum extent possible, the tribal representative membership reflect the proportionate share of students from tribes served by the Bureau-funded school system. The Secretary chartered the committee under the Federal Advisory Committee Act (5 U.S.C. Appendix (FACA)) on May 1, 2003. The committee was comprised of Federal representatives and representatives of tribes served by Bureau-funded schools who met in February 2006 to negotiate recommendations for proposed regulations under Section 1122 of the Act, 25 CFR part 36, Minimum Academic Standards for the Basic Education of Indian Children and National Criteria for Dormitory Situations. As a basis for negotiations and for consensus, the committee used draft regulations proposed by the Bureau school and residential administrators.

C. What Was the Negotiated Rulemaking Process?

As required by the No Child Left Behind Act of 2001 (Pub. L. 107–110; enacted January 8, 2002, referred to in this preamble as "NCLB" or "the Act"), the Department of the Interior established a Negotiated Rulemaking Committee to develop proposed rules to implement several sections of the Act relating to the Bureau of Indian Education-funded school system. Negotiated Rulemaking is a process sanctioned by Subchapter III, or Chapter 5, Title 5, United States Code and the Federal Advisory Committee Act, 5 U.S.C. Appendix (FACA), that employs Federal representatives and members of the public who will be affected by rules to jointly develop proposed rules.

In this case, the Act required the Secretary of the Interior to select representatives of Indian tribes and Bureau-funded schools as well as Federal Government representatives to serve on the Committee. The Committee's task was to draft proposed rules to recommend to the Secretary. Upon the Secretary's approval, draft rules are published in the **Federal Register** for written public comments within a 120-day public comment period. After the close of the public comment period, the Committee will reconvene to review these comments and to recommend promulgation of final rules to the Secretary.

The Secretary chartered the Committee under the FACA on May 1, 2003. It is comprised of 19 members nominated by Indian tribes and tribally operated schools. The law required that, to the maximum extent possible, the tribal representative membership should reflect the proportionate share of students from tribes served by the Bureau-funded school system. The Secretary also appointed to the Committee six members from within the Department of the Interior. The Committee selected three tribal representatives and two Federal representatives as co-chairs. Six individuals were hired to facilitate all Committee meetings.

The Committee initially met in the months of June through October 2003 to develop regulations in six areas. Subsequently, the Department reconvened the Committee in February 2004 to develop regulations in the areas of closure and consolidation of schools and criteria for homeliving situations. The Committee met on several occasions and developed the proposed rules that were published on July 12, 2004 (69 FR 41770).

D. How Were Public Comments Handled?

The Secretary published proposed regulations on July 12, 2004, for public comment. The public comment period ended on November 9, 2004. We received comments on this proposed rule from nine commenters, including tribal leaders, educators, and administrators. We reviewed all comments. Summaries of individual public comments and our responses are noted below. The final regulations are organized, as were the proposed regulations, under three broad categories: homeliving staffing; homeliving programs; and homeliving privacy. The final regulations, published as 25 CFR part 36—Homeliving Situations, reflect the public comments that were accepted. The Department still has under consideration the regulations for school closure and consolidation. At this time, the Department has made no final decision on issuing these rules.

II. Public Comments

In this section we discuss the main public comments received. General comments are discussed first, followed by comments on specific sections of the rule. Our responses follow each comment.

Section 36.70 What Terms do I Need to Know?

Comment: Several commenters suggested that we clarify or define the term "supplemental services" in § 36.70 and several others suggested that we clarify what "actually receiving supplemental services" means in § 36.70(2)(ii).

Response: We considered these comments and removed the obsolete reference to "supplemental services."

Comment: Several commenters suggested we add definitions for the following terms: "behavioral health programs," "behavioral health services," and "behavioral health staff."

Response: We accepted the comments and have added definitions for the terms.

Comment: A commenter recommended clarifying the definitions of "homeliving manager" and "homeliving supervisor" by switching the definitions to more accurately reflect what each position is responsible for. In the alternative, if the manager is to be responsible for physically supervising students, the commenter recommended changing the name of the "homeliving supervisor" to "homeliving administrator."

Response: We considered this comment and made no change.

Section 36.71 What Is the Purpose of This Part?

Comment: A commenter recommended changing the definition for "homeliving situation" to: "Any program where education instruction and residential services are provided for students enrolled in Bureau-funded schools, who are housed at a Bureau-funded school facility, and who receive care, before and after school hours, in a manner in which they do not have to depend on family or guardianship."

Response: We considered this comment, but, determined no change was necessary.

Comment: A commenter suggested replacing the term "homeliving situations" with "homeliving programs."

Response: We considered the comment and revised § 36.71.

Section 36.75 What Qualifications Must Homeliving Staff Possess?

Comment: A commenter suggested that the competency or professional standards of homeliving personnel should not be compromised in § 36.75. The commenter stated that agreements to operate a quality program with quality staff is between BIE and the tribal governing body and should not be discretionary at the school staff level. The commenter stated that it may be appropriate to waive such qualifications only where the employee is a trainee under the supervision of a fully qualified supervisor, and it is a tribal decision, not a Federal one.

Response: We considered the comment, but determined that no change was necessary because a tribe can instruct the school supervisor if the school is a tribally operated school.

Comment: A commenter stated that requirements for improved criteria for homeliving staff in § 36.75 should not be unfunded mandates. The commenter supports a complete overhaul of the current funding formula in order to create a universal therapeutic model in all BIE-funded schools.

Response: While the Committee was aware of the funding needs for Indian education, the scope of the Committee was to draft regulations to implement the statute. Therefore, while the Committee notes the commenter's general comments about the need for additional funding and different funding priorities, these comments are outside of the scope of the rulemaking. Therefore, we made no change to the regulations.

Comment: A commenter suggested that substance abuse education and prevention training should be added to required training in § 36.75.

Response: This is already required in § 36.86(c)(2).

Comment: A commenter suggested: (1) that a determination of good cause in § 36.75(b)(2) should be made at the Education Line Officer level, (2) that guidelines or standards be provided for determining what good cause means, and (3) that a timeframe for waivers be added.

Response: We considered the comment and accepted it in part and rejected it in part. We rejected the part of the comment that raised issues the Committee considered in its deliberations. We accepted the part of the comment on adding a timeframe for waivers and revised § 36.75(b)(2).

Comment: A commenter recommended that in § 36.75 the delay of the effective date for higher standards for homeliving staff apply to current staff as a well as to new hires, and that the effective date depend on the Department's securing additional funding.

Response: The Committee considered the effective date of the higher standards for homeliving staff. The comment does not raise new issues that the Committee did not consider. Therefore, we considered the comment, but we made no change to the regulations.

Comment: A commenter suggested changing § 36.75 to allow the homeliving supervisor rather than the "school supervisor" to grant a waiver for a showing of good cause.

Response: We considered the comment, but we believed the proposed language provides for the entity with decision-making authority to decide whether to grant the waiver. Therefore, we made no change to the regulations.

Comment: Several commenters suggested that some homeliving program staff may not need the same level of educational standards as others because they work at night when students are sleeping and recommended changing the required standards in § 36.75(a).

Response: In adoptjng these regulations, the Committee considered that there are different levels of homeliving program staff. The Committee considered and did not adopt different standards for night-duty. Therefore, we considered the comment, but made no change to the regulations.

Comment: A commenter recommended that § 36.75 include a certificate program in lieu of the 32-hour post-secondary semester hour requirement since BIE-operated boarding schools are unique. Another commenter suggested that § 36.75 provide for development of a residential certificate of training including at least 80 hours in topics such as child development, behavior management, working with students at risk, special education students, social interaction skills, etc., as an option to requiring 32/48 hours of college credit. The certificate would be updated every 3 years with at least 10 hours of training.

A second commenter recommended that distance education and computer modules be available to staff.

A third commenter recommended that § 36.75 provide that each facility is responsible to set its own appropriate training requirements to fit its specific needs. This commenter further suggested that requiring 32 hours of post-secondary semester hours in a field related to child development and at least 1 year of relevant experience will cause a drop in the applicant pool and that a degree does not necessarily make an applicant competent for a position.

Response: We considered these comments and made no changes to the rule.

Comment: A commenter suggested that if the definitions for "homeliving manager" and "homeliving supervisor" are switched, the qualifications for the two positions should also be switched in § 36.75.

Response: We considered this comment and made no changes because the definitions were not switched.

Comment: A commenter recommended deleting § 36.75(b) "when this part is published in final" because it is unnecessary considering the 2009–2010 timeframe and could be interpreted to apply only to those persons employed at the time the rule becomes final.

Response: We accepted this comment and changed the text to delete the reference to the rule's publication date.

Comment: A commenter recommended that we clarify § 36.75(b)(2) by stating whether the supervisor empowered to grant waivers from new qualifications has procedural guidance to follow.

Response: We considered this comment and revised the paragraph to clarify the process. The paragraph now states that a person not meeting the qualifications, "may, upon showing good cause, petition the school supervisor (or the homeliving supervisor for peripheral dorms) for a waiver from the new qualifications."

Comment: A commenter stated that: (1) 32 hours of post-secondary semester hours for basic homeliving staff would dramatically reduce the applicant supply pool for those positions at the local level; (2) We should clarify whether new hires before SY 2009–2010 must meet the new requirements; (3) Funding should be made available for dormitory programs, for training and post-secondary credit hours for meeting the recommended qualification requirements, and for meeting the needs of the students being served.

Response: We considered the comment, but did not change the section. While the training requirement may reduce the number of applicants for these positions, dormitory staff must have more training because of new needs children are exhibiting in behavior, new diagnostic findings affecting learning skills, and changes in life styles affecting family concepts and step-parenting, among other issues.

Comment: A commenter stated that if "recreation staff" is included in "homeliving staff" that fact should be

stated and clarified in the definition of "homeliving staff."

Response: The committee considered this in its original deliberation and no new issues have been raised by this comment that were not already considered by the committee.

Section 36.76 Who Is in Charge of all Homeliving Operations?

Comment: A commenter stated that the purpose of § 36.76 is unclear. If the section means there will be clear lines of authority, the question should be revised to read: "Must there exist clear lines of authority?" and the answer should read: "Yes, clear lines of authority must be established through the development of an organizational chart approved by the local board * * *" Or, if this section means to make a point other than establishing the requirement that an organizational chart be developed; the section needs to be re-written for clarity.

Response: We accepted this comment and made corresponding changes to the rule.

Section 36.77 What Are the Homeliving Program Staffing Requirements?

Comment: Several commenters recommended that the delayed implementation of the homeliving staff-to-student ratios to school year 2009–10 in § 36.77 depend on the Department's securing the necessary funding to make the new ratios affordable.

Response: We considered this comment and revised the section title in response.

Comment: A commenter suggested that adult-to-child staffing ratios in dormitories for Native American children should be lower than 1:20–30 if other similar programs require lower adult-to-child staffing ratios.

Response: The Committee considered adult-to-child staffing ratios in drafting the regulations. The Committee discussed the pros and cons of changing staffing ratios and chose to adopt credentialing rather than changing staffing ratios. The comments raise no new issues to consider. Therefore, we made no change to the regulations.

Comment: A commenter recommended that § 36.77 should state what ratios will be effective until SY 2009–2010.

Response: We considered this comment, but made no changes to the regulation.

Comment: A commenter suggested that since § 36.75 requires higher quality staff, § 36.77 should provide that this staff be compensated appropriately, but questioned how positions will be funded if IRG is cut.

Response: The Committee in its original deliberations considered the impact of these requirements and balanced them with the needs of the students. No new issues are raised by the commenter that were not considered in the original deliberations. Therefore, we made no change to the rule.

Comment: A commenter suggested that § 36.77 state that existing staff-to-student ratios remain in effect until the new requirements are effective.

Response: The Committee considered this issue at the time it negotiated the regulations and the comment raises no new issues. Therefore, we made no change to the regulations.

Comment: A commenter questioned whether it is necessary in § 36.77(b) to have three different staff-to-student ratios on weekends because weekend staff is presumably supervising rather than conducting structured programs.

Response: The Committee considered this issue at the time it negotiated the regulations and the comment raises no new issues. Therefore, we made no change to the regulations.

Comment: A commenter recommended revising § 36.77 by revising the question to: "What is the minimum acceptable staffing supervisory requirements necessary to adequately supervise students and provide a safe environment?" and eliminating the introductory sentence.

Response: We considered this comment and changed the section title to read, "What are the homeliving program staffing requirements?"

Section 36.79 What Are the Homeliving Behavioral Staff/Student Ratio Requirements?

Comment: A commenter suggested that the regulations define the term "behavioral staff." Another commenter suggested clarifying whether a behavioral health professional is the same as a certified counselor, either school or MSW, in § 36.79.

Response: We accepted these comments and defined "behavioral staff" at § 36.79.

Comment: A commenter stated that the regulations at § 36.79(b) change "should" to "must" for providing one full-time behavioral health professional for off-reservation boarding schools.

Response: We considered the comment, but we did not accept it. This issue was raised during the original Committee deliberations. In order to reach consensus the Committee adopted the provision that the homeliving program "should" consider providing these services. This comment does not raise any new issues that were not considered by the committee when originally discussing this issue. Therefore, we made no change to the regulations.

Comment: A commenter recommended that § 36.79 be amended to delete a 20-hour minimum.

Response: We accepted this comment and added new paragraph (d) in response.

Comment: A commenter stated that funding increases are necessary to meet the criteria in § 36.79 for the number of and the educational level of behavioral health professionals who are necessary in homeliving programs to address issues such as abuse, neglect, trauma, cultural conflict, and lack of school success.

Response: Budget-related issues are fully addressed elsewhere in this preamble.

Comment: A commenter recommended revising § 36.79(b) to state "must," not "should" so that behavioral health may not be made optional and students who live off-reservation are not deprived of this requirement.

Response: This issue was raised during the original deliberations and, to reach consensus, the Committee adopted the provision that the homeliving program "should" consider providing these services. This comment does not raise any new issues that were not considered by the Committee when originally discussing this issue. Therefore, the comment is not accepted.

Section 36.80 If a School Has Separated Boys' and Girls' Homeliving Programs, May the Same Behavioral Staff Be Used for Each Program?

Comment: A commenter recommended clarifying the term "homeliving count period" in § 36.80.

Response: We considered the comment, but we are making no change to the regulations because the homeliving count period is defined in the funding formula regulations at 25 CFR 39.

Section 36.81 May a Homeliving Program Use Support Staff or Teachers to Meet Behavioral Health Staffing Requirements?

Comment: A commenter recommended revising the second sentence in § 36.81 to allow for flexibility in how a residential facility meets the behavioral health staffing requirements. The sentence is recommended to read: "The only exception is if the individual support staff employee or teacher has the appropriate behavioral health license or

certification or other appropriate training and supervision."

Response: We accepted this comment in part and revised the second sentence to read as follows: "The only exception is if the individual support staff employee or teacher has the appropriate behavioral health license or certification."

Comment: A commenter recommended eliminating the exception in § 36.81 or adding a requirement that the individual's contract provide that the teaching and behavioral health services are not to be provided simultaneously.

Response: We considered this comment in conjunction with other comments on this issue. If teachers have the requisite training, then they may be able to provide the service as long as the provisions of § 36.82 have been met. Therefore, we made no change to the rule.

Section 36.82 May Behavioral Health Staff Provide Services During the Academic School Day?

Comment: A commenter recommended adding a provision for maximizing time the behavioral health staff is working with students during the time students are in the dorms, especially on weekends. Another commenter stated that we should amend § 36.82 to require that behavioral health staff provide services outside the academic school day except in emergencies and provide that schools have the necessary staff to handle emergency situations. The commenter suggested that behavioral health staff may observe students in their academic environment.

Response: In response to these comments, we revised § 36.82.

Section 36.83 How Many Hours Can a Student be Taken Out of the Academic Setting to Receive Behavioral Health Services?

Comment: A commenter suggested that § 36.83 be clarified so that schools may not use behavioral health staff outside their intended services.

Response: We considered the comment and addressed the suggested changes in § 32.82.

Comment: A commenter recommended that we amend § 36.83 to provide that students not be taken out of the academic setting to receive behavioral health services unless it is an emergency and to provide that schools have their own behavioral health professionals. The commenter recommended that Licensed Practicing Counselors not have a caseload of students. Another commenter recommended revising § 36.83 to state: "should not spend more than" rather than "may spend no more than" in order to provide staff the needed flexibility to appropriately address each student's individual needs and provide necessary services.

Response: We considered these comments and made changes consistent with the other comments on this section.

Section 36.84 Can a Program Hire or Contract or Acquire by Other Means Behavioral Health Professionals to Meet Staffing Requirements?

Comment: A commenter recommended that § 36.84 provide that instructional time be guarded. Each student should be able to go through an initial screening provided by the counselors.

Response: We considered this comment, but no change to the rule is necessary.

Comment: A commenter recommended delaying implementation of behavioral staff license requirement until additional appropriations are obtained and recommended revising § 36.84, paragraph (b) by changing "and" to "or."

Response: We accepted this comment and changed the rule.

Comment: A commenter recommended that more instruction be provided so BIE-operated and grant/contract school programs can strategize with one another to maximize services to students and minimize the cost of services. In some locations distance is a factor and highly qualified people are in extreme demand and few agree to travel long distances and/or agree to provide services to a large number of identified students. Restrictions imposed by preferences of authority hinder meeting the needs of students. Schools must have strong working relationships.

Response: We revised this section to allow tribes and schools to work together to provide these services to students.

Section 36.85 Is a Nurse Required To Be Available in the Evenings?

Comment: A commenter recommended that we amend § 36.85 to require that nursing staff be on campus not only during the academic hours, but also outside of academic hours because more accidents are going to happen outside of academic hours. Another commenter recommended making the requirement in § 36.85 for having a RN or LPN available in the evenings when enrolment is over 300 mandatory.

Response: The committee considered the response but rejected it.

Section 36.86 Are There Staff Training Requirements?

Comment: A commenter agreed with the increase in educational requirements for new staff and homeliving managers and supervisors in § 36.86.

Response: We made no change to § 36.86 because the comment required no change.

Comment: A commenter stated that in § 36.86 (a)(4) confidentiality should follow the Family Education Right to Privacy Act, not just the Health Information Privacy Act.

Response: We considered the comment and revised § 36.86(a)(4).

Comment: A commenter recommended inserting "surrogate" before "parent training" in § 36.86(b)(4) because staff serves as surrogate parents in residential settings.

Response: We accepted the idea behind the comment and changed § 36.86(b)(4) to read:

(4) Parenting skills/child care.

Comment: A commenter recommended revising the question in § 36.86 as follows: "Are there homeliving staff training requirements?"

Response: We considered this comment and revised the section text, but not the title. To be more inclusive, the section states that all homeliving program staff and employees that supervise students participating in homeliving services and activities must have appropriate certification or requirements and receive annual training in specified topics.

Comment: A commenter suggested that the first paragraph in § 36.86, which applies to training that is "appropriate to the certification and licensing requirements," is erroneous since none of the required training will result in licensing or certification, except in First Aid or CPR. Homeliving staff is not required to be licensed or certified (§ 36.75). The commenter recommended that this section be revised to provide flexibility so that residential programs may determine the frequency and timing of training as appropriate to their situations, including providing for refresher sessions for returning staff and training that may be completed over a 2- or 3-year period (lessening the financial impact) or more frequently as new developments occur (such as new or revised policy).

Another commenter suggested correcting the cite to "Health Information Patient Privacy Act" to "Health Insurance Portability and Accountability Act of 1996" in § 36.86(a)(4).

A commenter suggested changing the title in § 36.86(a)(7) to "Child Abuse

Reporting Requirements and Protection Procedures."

Another commenter recommended that in § 36.86(b)(7) we clarify the term "child development" or make the terms applicable only to those residential programs with younger children in residence since some residential programs serve only high school age students. If paragraph (7) remains in this section, the commenter recommended adding "if appropriate to the student ages served."

Response: We considered these comments and made some changes based upon them. We did not change the section title because changes that we made in response to other comments made this unnecessary. Similarly, other changes we made regarding licensure eliminated the need to consider that suggestion. On the issue of training being only a refresher for returning staff, the committee considered this issue in its original deliberations and this comment raised no new issues.

Comment: A commenter suggested that § 36.86 include a recommendation that courses be provided on dealing with the tween, pre-teen, and teenage adolescent years.

Response: We considered this comment, but these various developmental stages are covered under the broader title of child development. We revised this section to clarify this.

Section 36.90 What Recreation, Academic Tutoring, Student Safety and Health Care Services Must Homeliving Programs Provide?

Comment: A commenter suggested clarifying in § 36.90 what a "homeliving program board" is and whether it applies to schools with peripheral dorms.

Response: We accepted the comment and changed § 36.90 to read: " * * * as deemed necessary by the local school board or homeliving program board."

Comment: A commenter suggested that if staff are required to provide these services in § 36.90, it should be required that students be assigned to participate in the service schedule.

Response: We considered this comment, but it is not something that should be addressed in regulations.

Comment: A commenter recommended that in § 36.90 we require that library and computer program requirements must be met in the dormitory facility because of the staff-to-student ratio, individual student needs, and academic needs in all subject areas and age/grade levels.

Response: These issues are addressed in § 36.102.

Section 36.91 What Are the Program Requirements for Behavioral Health Services?

Comment: A commenter suggested that requirements that a reiteration of the Intensive Residential Guidance program elements in § 36.91 is unnecessary because the IRG program was eliminated. Also, costs associated with some of the required services are prohibitive and not all students will require each of the enumerated services. The commenter recommended that this section be revised as follows: " * * * behavioral health program must include the following services as needed:"

Response: We considered this comment and clarified the rule to provide that the homeliving program should have the capacity to provide these services.

Section 36.92 Are There Any Activities That Must be Offered by a Homeliving Program?

Comment: A commenter recommended that we clarify § 36.92(a) by providing a requirement for one hour of scheduled, structured physical activity Monday through Thursday instead of through Friday since many residential programs dismiss students on Friday through Sunday. The commenter recommended requiring two hours total of physical or recreational activities for those present in the dorm on the weekend. Another commenter suggested revising § 36.92(b) to allow each tribe/school to decide whether to offer and to decide the content of any of these topics to ensure consistency with local community values.

Response: We accepted the comment regarding Monday through Thursday physical activity and changed the rule to reflect this. We partially accepted the suggestion regarding personal wellness, excluding the idea of consistency with tribal mores, since it is implicit in the ability to design a wellness program and some schools, such as off-reservation boarding schools, may not have local tribal mores.

Comment: A commenter recommended changing § 36.92(e) to refer to activities as "personal wellness," since mandating "character" and "sex education" may not be congruent with the local values or belief systems of the community.

Response: We accepted the comment and modified § 36.92(e).

Comment: A commenter recommended deleting the term "structures" in § 36.92 since it is not clear whether a lesson plan is required or students may pick from a choice of activities.

Response: We considered this comment, but did not modify the rule. The goal of the committee was to have a structured organized physical activity without a program goal or plan. We believe that the term "structure" adequately connotes this.

Section 36.93 Is a Homeliving Handbook Required?

Comment: A commenter suggested that in § 36.93 we add the terms "school board approval."

Response: We considered the comment and found the comment unpersuasive. Therefore, we made no change to the regulations.

Comment: A commenter recommended revising § 36.93 by requiring that the home living handbook be provided rather than referring to student rights and responsibilities and requiring that the handbook be provided during the first week the students are in residence rather than before the first day of school.

Response: We accepted this comment and revised the section accordingly.

Comment: A commenter recommended changing "school staff" to "homeliving staff" or "residential staff" in § 36.93(d).

Response: We considered limiting circulation of the handbook only to homeliving staff. However, we believe that all staff should receive a copy of the handbook.

Section 36.94 What Must a Homeliving Handbook Contain?

Comment: Commenters recommended the following changes to § 36.94: revise (i) to read "Personnel and position listing or a copy of the residential staff organizational chart"; revise (l) to "Transportation Policy and Procedures"; revise (o) to read "Drug, Alcohol and Tobacco Products Policy" and revise (q) to read: "Medication Administration Policy."

Response: We made several of the suggested changes, but did not require an organizational chart or transportation procedures. We do not see the need for requiring an organizational chart. The rule requires transportation policies, not procedures.

Comment: A commenter suggested that we add drug/alcohol policy and consequences and move up its priority in § 36.94.

Response: We accepted part of the comment and revised § 36.94(o) to read "drug/alcohol policy." We rejected the rest of the comment because the list is a list of all items that must be included in the handbook and is not a priority list. Therefore, we did not make the change to the regulations.

Section 36.95 What Sanitary Standards Must Homeliving Programs Meet?

Comment: A commenter recommended changing the term "rooms" to "dorm rooms" for clarification in § 36.95, and adding "unless need arises sooner" at the end of paragraph (c). A commenter recommended that § 36.95(d) and (e) be revised to read that linens and toiletries "may be provided as needed."

Response: We considered this change, but did not revise the rule because the existing is adequate.

Comment: A commenter recommended that § 36.95 require that dorms pass inspection by some entity, and that each site be visited at least once in five years to verify that health, safety and standards are met.

Response: We considered this comment and made no change because health and safety inspection requirements vary by locality.

Section 36.96 May Students Be Required to Assist With Daily or Weekly Cleaning?

Comment: A commenter noted that in § 36.96 students should be required to assist in cleaning the dorm.

Response: We considered the comment, but made no change because that rule already provides for students to assist with cleaning.

Comment: A commenter suggested we add a provision to § 36.96 for cleaning and maintaining a healthy environment by dorm staff as role models for students.

Response: We considered the comment and rejected it including any additional provisions on cleaning in § 36.96.

Section 36.97 What Basic Requirements Must a Program's Health Services Meet?

Comment: A commenter recommended revising § 36.97(a) to also allow for agreements between a tribe or tribal school board and IHS.

Response: We accepted this comment and changed the rule accordingly.

Section 36.98 Must the Homeliving Program Have an Isolation Room for Ill Children?

Comment: A commenter recommended modifying § 36.98 to require that a sickroom be available, but space does not have to be dedicated to this use only. Another commenter recommended rewriting the question in § 36.98 to read: "Must the homeliving program provide special accommodations for ill children?" Using the singular reference to "an isolation room," coupled with the first sentence and the second sentence could cause confusion as to whether one or two rooms are required.

Response: We considered these comments and made appropriate changes to the rule.

Section 36.100 Are There Minimum Requirements for Student Attendance Checks?

Comment: A commenter recommended revising § 36.100(d) to state that night time physical checks will be made once every hour, except high school student rooms which will be checked every two hours.

Response: We considered the comment, but did not change the rule. High school students are just as likely, or even more likely, to be out of their rooms at night.

Comment: A commenter recommended revising § 36.100(f) to make it applicable only when residential staff knows that a student will be absent from school.

Response: We accepted this comment and changed the rule accordingly.

Comment: A commenter suggested that § 36.100 provide that each child accepted into the dorm should agree to undergo drug and alcohol screening if needed.

Response: We considered the comment and made no change to the rule. Schools should develop their own drug and alcohol policies.

Section 36.102 What Student Resources Must be Provided by A Homeliving Program?

Comment: A commenter recommended that we clarify the terms "library resources" and "reasonable access" in § 36.102.

Response: We considered the comment, but found no change to the rule necessary.

Comment: A commenter recommended adding at the beginning of § 36.102(b): "To the extent the student does have their own * * *"

Response: We considered the comment, but made no change, as the committee believes it is in the best interest of students to have textbooks available after hours.

Section 36.110 Must Programs Provide Space for Storing Personal Effects?

Comment: A commenter recommended adding the following after the first sentence in § 36.110: "This requirement is met if a residential room door can be locked" because some residential facilities will have difficulty meeting the lockable storage space requirement due to space limitations and/or age of the facility.

Response: We considered this comment, but made no change. The committee wanted the students to have one lockable space, such as a drawer, closet, or storage bin.

Section 36.111 Can a Tribe, Tribal Governing Body, or Local School Board Waive the Homeliving Standards?

Comment: A commenter suggested that in § 36.111 we clarify how 60 days are calculated and recommended that a school board or tribal body submit a proposed waiver by January 1 of the year preceding implementation in order to provide time for revisions and for starting the year with alternative standards in place.

Response: We considered the comment and rejected it in part because the regulatory section is based on statutory language. We accepted some of the comment and made the following changes:

A tribal governing body or local school board may waive some or all of the standards established in this part by adopting a written resolution that determines that the standards are inappropriate for the needs of the tribe's students. The approved alternative standards are effective on the first day of the following school-year.

Section 36.112 What Are the Consequences for Failing to Meet the Requirements of This Part?

Comment: A commenter suggested adding a new question after § 36.112: "What happens to a school that does not meet these standards?"

Response: We considered the comment, but made no changes because this question is limited to whether the school can be closed or consolidated for failing to meet these standards and not for other reasons that are addressed in other regulations.

Section 36.120 What Type of Reporting Is Required to Ensure Accountability?

Comment: A commenter recommended that we identify a specific time for reporting enrolment figures in § 36.120.

Response: We accepted the comment and revised § 36.120(c) and (d).

Comment: A commenter recommended adding a requirement in § 36.120 that the report be filed 45 days after the end of the school year and a statement that the accountability report is the only report a residential program is required to file.

Response: We accepted the suggestions to add a 45-day filing period.

Comment: A commenter recommended adding a provision in § 36.120 to require that the report also be submitted to the Division of Residential Life in BIE.

Response: We did not accept this comment. The BIE already receives the report, and there is no reason to require in the rule that the report go to a particular division within the office.

III. Procedural Matters

A. Regulatory Planning and Review (E.O. 12866)

This document is a significant rule and the Office of Management and Budget (OMB) has reviewed the rule under Executive Order 12866.

(1) This rule will not have an effect of $100 million or more on the economy. It will not adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. The rule deals exclusively with homeliving programs and is not expected to have a significant effect on budgets.

(2) This rule will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency. This rule has been prepared in consultation with the U.S. Department of Education.

(3) This rule does not alter the budgetary effects of entitlements, grants, user fees, or loan programs or the rights or obligations of their recipients. This rule spells out student rights, the procedures for their dissemination, and the procedures for implementing them. The rule is not expected to have a significant effect on budgets.

(4) Office of Management and Budget has determined that this rule raises novel legal or policy issues. For this reason review is required under E.O. 12866.

B. Regulatory Flexibility Act

The Department of the Interior certifies that this document will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

C. Takings (E.O. 12630)

In accordance with Executive Order 12630, the rule does not have significant takings implications. Nothing in the rule proposes rules of private property rights, constitutional or otherwise, or invokes the Federal condemnation power or alters any use of Federal land held in trust. The focus of this rule is homeliving programs. A takings implication assessment is not required.

D. Federalism (E.O. 13132)

In accordance with Executive Order 13132, the rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment. Nothing in this rule has 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. This rule does not implicate State government. A Federalism Assessment is not required.

E. Consultation With Indian Tribes (E.O. 13175)

In accordance with Executive Order 13175, we have identified potential effects on federally recognized Indian tribes that will result from this rule. Accordingly: (1) We have consulted with the affected tribe(s) on a government-to-government basis. The consultations have been open and candid to allow the affected tribe(s) to fully evaluate the potential effect of the rule on trust resources. (2) We have fully considered tribal views in drafting this final rule. (3) We have consulted with the appropriate bureaus and offices of the Department about the political effects of this rule on Indian tribes. The BIE and the Office of the Assistant Secretary—Indian Affairs have been consulted.

F. Paperwork Reduction Act

This rulemaking requires information collection from 10 or more parties and a submission under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) is required. Accordingly, the Department prepared submissions on these collections for review and approval by OMB. Having reviewed the Department's submissions, along with any comments that were submitted by the reviewing public, OMB has approved the information collection requirements in this rulemaking and has assigned the OMB control number 1076–0164. In addition to this number, the information collections in part 39 are also covered by OMB control numbers 1076–0134 and 1076–0122.

The information collected will be used to enable the Bureau to better administer Bureau-funded schools subject to this rulemaking. In all instances, the Department has striven to lessen the burden on the public and ask for only information essential to administering the responsibility to federally recognized tribes. The public may make additional comments on the accuracy of our burden estimates (which are explained in detail in the preamble to the proposed rule published on February 25, 2004, at 69 FR 8752) and any suggestions for reducing this burden to the OMB Interior Desk Officer, Docket Number 1076–AE49, Office of Information and Regulatory Affairs, 202/395–6566 (facsimile); email: *OIRA_DOCKET@omb.eop.gov.*

G. National Environmental Policy Act

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the National Environmental Policy Act of 1969 is not required.

H. Civil Justice Reform (E.O. 12988)

In accordance with Executive Order 12988, the Department has determined that this rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order.

List of Subjects in 25 CFR Part 36

Indians—Education, Schools, Elementary and secondary education programs, grant programs—Indians, Government programs—education.

Dated: October 19, 2007.

Carl J. Artman,

Assistant Secretary—Indian Affairs.

■ For the reasons given in the preamble, part 36 of Title 25 of the Code of Federal Regulations is amended by revising subpart G to read as follows:

PART 36—MINIMUM ACADEMIC STANDARDS FOR THE BASIC EDUCATION OF INDIAN CHILDREN AND NATIONAL CRITERIA FOR DORMITORY SITUATIONS

Subpart G—Homeliving Programs

Sec.

Subpart G—Homeliving Programs

Authority: 25 U.S.C. 13; 25 U.S.C. 2008; Pub. L. 107–110 (115 Stat. 1425).

§ 36.70 What terms do I need to know?

The following definitions apply to this subpart:

Behavioral health professional means a State licensed or State certified Social Worker, School Counselor, Drug and Alcohol Counselor, School Psychologist, or School Psychometrist responsible for coordinating a broad range of needs including:

(1) Support groups;
(2) Individual counseling;
(3) Crisis intervention;
(4) Preventive activities; and
(5) Coordination of referrals and outside services with appropriate providers.

Behavioral Health Program means a homeliving based service designed to decrease barriers to learning or increase positive, personal well-being by:

(1) Providing early intervention services, coordinating crisis intervention and prevention services;
(2) Promoting a positive social and emotional environment;
(3) Reducing the incidence of problems; and
(4) Referring students with behavioral needs that require professional medical care to an appropriate residential care facility.

Behavioral health services means the services provided by a school behavioral health program as defined in this section.

Homeliving Manager means the employee responsible for direct supervision of the homeliving program staff and students.

Homeliving Program means a program that provides room and board in a boarding school or dormitory to residents who are either:

(1) Enrolled in and are current members of a public school in the community in which they reside; or

(2) Members of the instructional program in the same boarding school in which they are counted as residents and:

(i) Are officially enrolled in the residential program of a Bureau-operated or funded school; and

(ii) Are actually receiving a homeliving program provided to all students who are provided room and board in a boarding school or dormitory.

Homeliving Program Staff means the employee(s) responsible for direct supervision of students in the homeliving area.

Homeliving Supervisor means the employee with overall administrative responsibility for supervising students, programs, and personnel in the homeliving area.

§ 36.71 What is the purpose of this part?

The purpose of this part is to establish standards for homeliving programs.

Staffing

§ 36.75 What qualifications must homeliving staff possess?

(a) Homeliving staff must possess the qualifications shown in the following table:

Position	Required training
(1) Homeliving Supervisor	Must be qualified based on size and complexity of the school, but at minimum possess a bachelor's degree.
(2) Homeliving Manager	Must be qualified based on the size and complexity of the student body but must at a minimum have an associate's degree no later than 2008.
(3) Homeliving Program Staff	Must have at least 32 post-secondary semester hours (or 48 quarter hours) in an applicable academic discipline, including fields related to working with children, such as, child development, education, behavioral sciences and cultural studies.

(b) A person employed as a homeliving program staff:

(1) Should meet the requirements of paragraph (a) of this section by the 2009–2010 school year; and

(2) May, upon showing good cause, petition the school supervisor (or the homeliving supervisor for peripheral dorms) for a waiver from the new qualifications.

§ 36.76 Who is in charge of all homeliving operations?

One staff member who has the authority to ensure the successful functioning of all phases of the homeliving program should be designated as in charge of all homeliving operations. All staff should be advised of the lines of authority through an organizational chart approved by the local board responsible for operations of the homeliving program.

§ 36.77 What are the homeliving staffing requirements?

Homeliving programs must meet the staffing requirements of this section.

(a) Effective with the 2009–2010 school year, each homeliving program must maintain the following student minimum supervisory requirements on weekdays:

Grade level	Time of day	Ratio
Elementary (Grade 1–6).	Morning	1:20.
	During school	As school needs.
	Evening	1:20.
	Night	1:40.
High School (Gr. 7–12).	Morning	1:20.
	During school	As school needs.
	Evening	1:30.
	Night	1:50.

(b) The following staffing ratios apply on weekends:

Grade level	Time of day	Ratio
Elementary (Grade 1–6)	Morning/day	1:20.
	Evening	1:20.
	Night	1:40.
High School (Gr. 7–12)	Morning/day	1:40.
	Evening	1:40.
	Night	1:50.

§ 36.78 What are the staffing requirements for homeliving programs offering less than 5 nights service?

For homeliving programs providing less than 5 nights service, the staffing levels from § 36.77 apply. To fill this requirement, the program must use only employees who work a minimum of 20 hours per week.

§ 36.79 What are the homeliving behavioral professional staff/student ratio requirements?

Behavioral health professional(s) is necessary in homeliving programs to address issues, such as abuse, neglect, trauma, cultural conflict, and lack of school success. Each homeliving program must provide a minimum of one half-time behavioral health professional for every 50 students.

(a) The program may fill the staffing requirements of this section by using contract services, other agencies (including the Indian Health Service) or private/nonprofit volunteer service organizations.

(b) Off-reservation homeliving programs should consider providing one full-time behavioral health professional for every 50 students.

(c) For purposes of this section, a one half-time behavioral health professional is one that works for the homeliving program a minimum of 20 hours per week.

(d) For purposes of this section, in instances where the behavioral health services are obtained through other programs, the behavioral health professional must be available at the request of the homeliving program.

§ 36.80 If a school or dormitory has separated boys' and girls' homeliving programs, may the same behavioral professional be used for each program?

Yes, a program may use the same behavioral professional for both boys' and girls' programs. However, behavioral health staffing requirements are based on the combined enrollment during the homeliving count period.

§ 36.81 May a homeliving program use support staff or teachers to meet behavioral health staffing requirements?

No, a homeliving program must not use support staff or teachers to meet behavioral health staffing requirements. The only exception is if the individual support staff employee or teacher has the appropriate behavioral health license or certification.

§ 36.82 May behavioral health professional(s) provide services during the academic school day?

Behavioral health professional(s) must average at least 75 percent of their work hours with students in their dormitories. These work hours must occur outside of the academic school day, except in emergency situations as deemed by the administrative head of the homeliving program or designee. The purpose of this requirement is to maximize contact time with students in their homeliving setting.

§ 36.83 How many hours can a student be taken out of the academic setting to receive behavioral health services?

A student may spend no more than 5 hours per week out of the academic setting to receive behavioral health services from the homeliving behavioral health professional(s), except for emergency situations.

§ 36.84 Can a program hire or contract or acquire by other means behavioral health professionals to meet staffing requirements?

A program may hire or contract behavioral health professionals to meet staffing requirements or acquire such services by other means such as through a Memorandum of Understanding with other programs.

(a) At least one individual must be a licensed or certified school counselor or a social worker who is licensed/certified to practice at the location where the services are provided.

(b) For additional staffing, other individuals with appropriate certifications or licenses are acceptable to meet staffing requirements.

§ 36.85 Is a nurse required to be available in the evenings?

No, a program is not required to make a nurse (LPN or RN) available in the evenings. However, this is encouraged for homeliving programs with an enrollment greater than 300 or for programs that are more than 50 miles from available services.

§ 36.86 Are there staff training requirements?

(a) All homeliving program staff as well as all employees that supervise students participating in homeliving services and activities must have the appropriate certification or licensing requirements up to date and on file. Programs must provide annual and continuous professional training and development appropriate to the certification and licensing requirements.

(b) All homeliving program staff as well as all employees who supervise students participating in homeliving services and activities must receive annual training in the topics set out in this section before the first day of student occupancy for the year.

(1) First Aid/Safety/Emergency & Crisis Preparedness;

(2) CPR—Automated External Defibrillator;

(3) Student Checkout Policy;

(4) Confidentiality (Health Information Privacy Act and the Family Education Right to Privacy Act.);

(5) Medication Administration;

(6) Student Rights;

(7) Child Abuse Reporting Requirements and Protection Procedures; and

(8) Suicide Prevention.

(c) Homeliving staff as well as all employees that supervise students participating in homeliving services and activities must be given the following training annually:
(1) De-escalation/Conflict Resolution;
(2) Substance Abuse Issues;
(3) Ethics;
(4) Parenting skills/Child Care;
(5) Special Education and Working with Students with Disabilities;
(6) Student Supervision Skills;
(7) Child Development (recognizes various stages of development in the student population);
(8) Basic Counseling Skills; and
(9) Continuity of Operations Plan (COOP).

Program Requirements

§ 36.90 What recreation, academic tutoring, student safety, and health care services must homeliving programs provide?

All homeliving programs must provide for appropriate student safety, academic tutoring, recreation, and health care services for their students, as deemed necessary by the local school board or homeliving board.

§ 36.91 What are the program requirements for behavioral health services?

(a) The homeliving behavioral health program must make available the following services:
(1) Behavioral Health Screening/ Assessment;
(2) Diagnosis;
(3) Treatment Plan;
(4) Treatment and Placement;
(5) Evaluation; and
(6) Record of Services (if applicable, in coordination with the student's Individual Education Plan).
(b) Each homeliving behavioral health program must have written procedures for dealing with emergency behavioral health care issues.
(c) Parents or guardians may opt out of any non-emergency behavioral health services by submitting a written request.
(d) Parents or guardians must be consulted before a child is prescribed behavioral health.
(e) Medication in a non-emergency situation.

§ 36.92 Are there any activities that must be offered by a homeliving program?

Yes, a homeliving program must make available the following activities:
(a) One hour per day of scheduled, structured physical activity Monday through Thursday, and two hours of scheduled physical activities on the weekends for any students who are in residence on the weekends;
(b) One hour per day of scheduled, structured study at least four days per week for all students, and additional study time for students who are failing any classes;
(c) Tutoring during study time;
(d) Native language or cultural activities; and
(e) Wellness program that may include character, health, wellness, and sex education.

§ 36.93 Is a homeliving handbook required?

Yes, each program must publish a homeliving handbook, which may be incorporated into a general student handbook. During the first week the students and staff are in the dormitory, the homeliving program must:
(a) Provide each student with a copy of the handbook that contains all the provisions in § 36.94;
(b) Provide all staff, students, and parents or guardians with a current and updated copy of student rights and responsibilities;
(c) Conduct an orientation for all students on the handbook and student rights and responsibilities; and
(d) Ensure that all students, school staff, and to the extent possible, parents and guardians confirm in writing that they have received a copy of and understand the homeliving handbook.

§ 36.94 What must a homeliving handbook contain?

A homeliving handbook must contain all of the following, and may include additional information:
(a) Mission/Vision Statement;
(b) Discipline Policy;
(c) Parent/Student Rights and Responsibilities;
(d) Confidentiality;
(e) Sexual Harassment Policy;
(f) Violence/Bullying Policy;
(g) Homeliving Policies and Procedures;
(h) Services Available;
(i) Personnel and Position Listing;
(j) Emergency Procedures and Contact Numbers;
(k) Bank Procedures;
(l) Transportation Policy;
(m) Check-Out Procedures;
(n) Dress Code;
(o) Drug/Alcohol Policy;
(p) Computer Usage Policy;
(q) Medication Administration Policy and Procedure; and
(r) Isolation/Separation Policy.

§ 36.95 What sanitary standards must homeliving programs meet?

Each homeliving program must meet all of the following standards:
(a) Restrooms, showers, and common areas must be cleaned daily;
(b) Rooms must be cleaned daily;
(c) Linens must be changed and cleaned weekly;
(d) Linens are to be provided;
(e) Basic Toiletries must be provided; and
(f) Functional washing machines and dryers must be provided.

§ 36.96 May students be required to assist with daily or weekly cleaning?

Yes, students can be required to assist with daily or weekly cleaning. However, the ultimate responsibility of cleanliness rests with the homeliving supervisor and local law or rules regarding chemical use must be followed.

§ 36.97 What basic requirements must a program's health services meet?

(a) A homeliving program must make available basic medical, dental, vision, and other necessary health services for all students residing in the homeliving program, subject to agreements between the BIE and the Indian Health Service or between a tribally-operated homeliving program and the Indian Health Service or tribal health program.
(b) A homeliving program must have written procedures for dealing with emergency health care issues.
(c) Parents or guardians may opt out of any non-emergency services by submitting a written request.
(d) The homeliving supervisor or designee must act *in loco parentis* when the parent or guardian cannot be found.

§ 36.98 Must the homeliving program have an isolation room for ill children?

Yes, the homeliving program must have an isolation room(s) available for ill students. The isolation room (or rooms, if needed) must be made available for use by students with contagious conditions. Contagious boys and girls should have separate rooms. The isolation room(s) should have a separate access to shower and restroom facilities. Students isolated for contagious illness must be supervised as frequently and as closely as the circumstances and protocols require, but at least every 30 minutes.

§ 36.99 Are immunizations required for residential program students?

Each student must have all immunizations required by State, local, or tribal governments before being admitted to a homeliving program. Annual flu shots are not required, but are encouraged.

§ 36.100 Are there minimum requirements for student attendance checks?

Yes, there are minimum requirements for student attendance checks as follows:

(a) All students must be physically accounted for four times daily;

(b) Each count must be at least two hours apart;

(c) If students are on an off-campus activity, physical accounts of students must be made at least once every two hours or at other reasonable times depending on the activity;

(d) At night all student rooms should be physically checked at least once every hour;

(e) If a student is unaccounted for, the homeliving program must follow its established search procedures; and

(f) When homeliving staff is aware of a student who is going to be absent from school, the homeliving program is required to notify the school.

§ 36.101 How often must students who have been separated for emergency health or behavioral reasons be supervised?

Students who have been separated for emergency behavioral or health reasons must be supervised as frequently and as closely as the circumstances and protocols require. No student will be left unsupervised for any period until such factors as the student's health based on a medical assessment, the safety of the student, and any other applicable guidance for dealing with behavior or health emergencies are considered.

§ 36.102 What student resources must be provided by a homeliving program?

The following minimum resources must be available at all homeliving programs:

(a) Library resources such as access to books and resource materials, including school libraries and public libraries which are conveniently available;

(b) A copy of each textbook used by the academic program or the equivalent for peripheral dorms; and

(c) Reasonable access to a computer with Internet access to facilitate homework and study.

§ 36.103 What are the requirements for multi-purpose spaces in homeliving programs?

Homeliving programs must provide adequate areas for sleeping, study, recreation, and related activities.

Privacy

§ 36.110 Must programs provide space for storing personal effects?

Yes, students are entitled to private personal spaces for storing their own personal effects, including at least one lockable closet, dresser drawer, or storage space. However, all drawers, dressers, storage space, or lockable space are the property of the homeliving program and are subject to random search.

Waivers and Accountability

§ 36.111 Can a tribe, tribal governing body, or local school board waive the homeliving standards?

A tribal governing body or local school board may waive some or all of the standards established by this part if the body or board determines that the standards are inappropriate for the needs of the tribe's students.

(a) If a tribal governing body or school board waives standards under this section, it must, within 60 days, submit proposed alternative standards to the Director, BIE.

(b) Within 90 days of receiving a waiver and proposal under paragraph (a) of this section, the Director must either:

(1) Approve the submission; or

(2) Deliver to the governing body or school board a written explanation of the good cause for rejecting the submission.

(c) If the Director rejects a submission under paragraph (c) of this section, the governing body or school board may submit another waiver and proposal for approval. The standards in this part remain in effect until the Director approves alternative standards.

§ 36.112 Can a homeliving program be closed, transferred, consolidated, or substantially curtailed for failure to meet these standards?

No, a homeliving program cannot be closed, transferred to any other authority, consolidated, or its programs substantially curtailed for failure to meet these standards.

§ 36.120 What type of reporting is required to ensure accountability?

The homeliving program must provide to the appropriate local school board or alternative board such as a homeliving board, the tribal governing body, BIE, and the Secretary of the Interior, an annual accountability report within 45 days following the end of the school year consisting of:

(a) Enrollment figures identified by the homeliving count period;

(b) A brief description of programs offered;

(c) A statement of compliance with the requirements of this part and, if the program is not in compliance, recommendations for achieving compliance; and

(d) Recommendations to improve the homeliving program including identification of issues and needs.

[FR Doc. E7–23330 Filed 12–4–07; 8:45 am]
BILLING CODE 4310–6W–P

NATIONAL LABOR RELATIONS BOARD

29 CFR Part 102

Revisions of Regulations Concerning Procedures for Filing Appeals to Denial in Whole or Part of Initial FOIA Requests

AGENCY: National Labor Relations Board (NLRB).

ACTION: Final Rule.

SUMMARY: The National Labor Relations Board (NLRB) is amending regulations concerning the procedures for filing an appeal to adverse FOIA determinations. The revisions require that appeals be filed within 28 calendar days of the service of the notification of the adverse determination.

EFFECTIVE DATE: December 5, 2007.

FOR FURTHER INFORMATION CONTACT: Lester A. Heltzer, Executive Secretary, National Labor Relations Board, Room 11600, 1099 14th Street NW., Washington, DC 20570–0001, Telephone (202) 273–1067, e-mail address *Lester.Heltzer@nlrb.gov*.

SUPPLEMENTARY INFORMATION:

I. Current regulation

Section 102.117(c)(2)(v) provides in part that "An appeal from an adverse determination made pursuant to paragraph (c)(2)(iii) of this section must be filed within 20 working days of the receipt by the person making the request of the notification of the adverse determination where the request is denied in its entirety; or, in the case of a partial denial, within 20 working days of the receipt of any records being made available pursuant to the request."

II. Proposed revision

Since the Agency does not send such determinations on initial requests by certified mail, it has no objective means of determining when a requestor receives an adverse determination. Therefore, it is impossible to know from which date to compute time periods from adverse FOIA determinations.

Other agencies' practices support using the date of service rather than date of receipt as the appropriate date for computing timeliness of FOIA appeals. Under 28 CFR Ch. 1, Sec. 16.9, appeals from adverse Department of Justice FOIA determinations must be filed "within 60 days of the date of the letter denying" the request. See also, *Center for Biological Diversity v. Gutierrez*, 451 F. Supp.2d 57 (D.D.C. 2006)(Department of Commerce regulations provide that appeals from adverse determinations must be received by 5 p.m. EST on the

"thirtieth day after issuance of initial FOIA determination * * *" 15 CFR Sec. 410(a)); *Wilbur v.Central Intelligence Agency,* 355 F.3rd 675 (DC. Cir. 2004) (The CIA's FOIA regulations require that any administrative appeal "be received within 45 days of the agency's initial decision." 32 CFR Sec. 1900.42.)

III. Administrative Procedures Act

Because the change involves rules of agency organization, procedure or practice, the Agency is not required to publish it for comment under Section 553 of the Administrative Procedure Act (5 U.S.C. 553).

IV. Regulatory Flexibility Act

Because no notice of proposed rulemaking is required for procedural rules, the requirements of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) pertaining to regulatory flexibility analysis do not apply to these rules. However, even if the Regulatory Flexibility Act were to apply, the NLRB certifies that these changes will not have a significant economic impact on small business entities since the changes merely codify the actual practice under the existing rules.

V. Small Business Regulatory Enforcement Fairness Act

Because the rule relates to Agency procedure and practice and merely modifies the agency's existing filing procedures, the Board has determined that the Congressional review provisions of the Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801) do not apply.

VI. Paperwork Reduction Act

This revision does not impose any reporting or record keeping requirements under the Paperwork Reduction Act of 1995.

Lists of Subjects in 29 CFR Part 102

Administrative practice and procedure, Labor Management relations.

■ For the reasons set forth above, the NLRB proposes to amend 29 CFR part 102 as follows:

PART 102—RULES AND REGULATIONS

■ 1. The authority citation for 29 CFR part 102 continues to read as follows:

Authority: Section 6, National Labor Relations Act, as amended ((29 U.S.C. 151, 156). Section 102.117(c) also issued under Section 552(a)(4)(A) of the Freedom of Information Act, as amended (5 U.S.C. 552(a)(4)(A)). Sections 102.143 through 102.155 also issued under Section 504(c)(1) of the Equal Access to Justice Act, as amended (5 U.S.C. 504(c)(1)).

■ 2. Section 102.117(c)(2)(v) is revised to read as follows:

§ 102.117 Freedom of Information Act Regulations: Board materials and formal documents available for public inspection and copying; requests for described records; time limit for response; appeal from denial of request; fees for document search and duplication; files and records not subject to inspection.

* * * * *

(c) * * *

(2) * * *

(v) An appeal from an adverse determination made pursuant to paragraph (c)(2)(iii) of this section must be filed within 28 calendar days of the service of the notification of the adverse determination, in whole or in part. If the adverse determination was made in a Regional Office, a Subregional Office, or by the Freedom of Information Officer, Office of the General Counsel, the appeal shall be filed with the General Counsel in Washington, DC. If the adverse determination was made by the Executive Secretary of the Board or the Inspector General, the appeal shall be filed with the Chairman of the Board in Washington, DC. Within 20 working days after receipt of an appeal the General Counsel or the Chairman of the Board, as the case may be, shall make a determination with respect to such appeal and shall notify the person making the request in writing. If the determination is to comply with the request, the record shall be made promptly available to the person making the request upon receipt of payment of any charges due in accordance with the provisions of paragraph (d)(2) of this section. If on appeal the denial of the request for records is upheld in whole or in part, the person making the request shall be notified of the reasons for the determination, the name and title or position of each person responsible for the denial, and the provisions for judicial review of that determination under the provisions of 5 U.S.C. 552(4)(B). Even though no appeal is filed from a denial in whole or in part of a request for records by the person making the request, the General Counsel or the Chairman of the Board may, without regard to the time limit for filing of an appeal, sua sponte initiate consideration of an adverse determination under this appeal procedure by written notification to the person making the request. In such event the time limit for making the determination shall commence with the issuance of such notification. An adverse determination by the General Counsel or the Chairman of the Board, as the case may be, will be the final action of the Agency. If the requester wishes to seek review by a court of any adverse determination, the requester must first appeal it under this section.

* * * * *

Dated: Washington, DC, November 29, 2007.

By Direction of the Board.

Lester A. Heltzer,

Executive Secretary.

[FR Doc. E7–23521 Filed 12–4–07; 8:45 am]

BILLING CODE 7545–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD01–07–158]

Drawbridge Operation Regulations; Cheesequake Creek, Morgan, NJ

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, First Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the New Jersey Transit Rail Operation (NJTRO) Railroad Bridge across Cheesequake Creek, mile 0.2, at Morgan, New Jersey. Under this temporary deviation, the bridge may remain in the closed position from January 2, 2008 through March 31, 2008. Vessels that can pass under the draw without a bridge opening may do so at all times. This deviation is necessary to facilitate scheduled bridge maintenance.

DATES: This deviation is effective from January 2, 2008 through March 31, 2008.

ADDRESSES: Materials referred to in this document are available for inspection or copying at the First Coast Guard District, Bridge Branch Office, One South Street, New York, New York 10004, between 7 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (212) 668–7165. The First Coast Guard District Bridge Branch Office maintains the public docket for this temporary deviation.

FOR FURTHER INFORMATION CONTACT: Joe Arca, Project Officer, First Coast Guard District, at (212) 668–7069.

SUPPLEMENTARY INFORMATION: The NJTRO railroad bridge has a vertical clearance of 3 feet at mean high water, and 8 feet at mean low water in the closed position. The existing drawbridge operating regulations, listed at 33 CFR 117.709(b), require the bridge to open on signal; except that, at least

a four hour notice for bridge openings is required from January 1 through March 31 from 6 p.m. to 6 a.m.

The bridge owner, New Jersey Transit Rail Operations (NJTRO), requested a bridge closure to facilitate structural and mechanical rehabilitation at the NJTRO railroad bridge.

Under this temporary deviation, the NJTRO railroad bridge may remain closed to navigation from January 1, 2008 through March 31, 2008. Vessels that can pass under the bridge without an opening may do so at all times.

A small number of fishing boats are docked upstream from the NJTRO railroad bridge; however, Cheesequake Creek is predominantly a recreational waterway. From January through March, the recreational vessels are in winter storage and the waterway is normally not transited. The Coast Guard met with the mariners to discuss this bridge project and related closure. The mariners agreed with the closure dates since that is the time period the bridge seldom opens and the waterway is normally frozen.

In accordance with 33 CFR 117.35(e), the bridge must return to its regular operating schedule immediately at the end of the designated time period. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Should the bridge maintenance authorized by this temporary deviation be completed before the end of the effective period published in this notice, the Coast Guard will rescind the remainder of this temporary deviation, and the bridge shall be returned to its normal operating schedule. Notice of the above action shall be provided to the public in the Local Notice to Mariners and the **Federal Register**, where practicable.

Dated: November 26, 2007.

Gary Kassof,

Bridge Program Manager, First Coast Guard District.

[FR Doc. E7–23568 Filed 12–4–07; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. CGD01-07-150]

RIN 1625-AA00

Safety Zone: Wantagh Parkway 3 Bridge over the Sloop Channel, Town of Hempstead, New York

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is extending the effective period of a temporary safety zone previously established on the waters surrounding the Wantagh Parkway Number 3 Bridge across the Sloop Channel in Town of Hempstead, New York. The extended effective period of this zone is necessary to protect vessels transiting in the area from hazards imposed by construction barges and equipment that are being utilized to construct a new bascule bridge over the Sloop Channel. Entry into this zone is prohibited unless authorized by the Captain of the Port Long Island Sound, New Haven, Connecticut.

DATES: This rule is effective from January 4, 2008 until 11:59 p.m. June 30, 2008.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket CGD01-07-150 and will be available for inspection or copying.at Sector Long Island Sound, New Haven, CT, between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lieutenant D. Miller, Assistant Chief, Waterways Management Division, Coast Guard Sector Long Island Sound at (203) 468-4596.

SUPPLEMENTARY INFORMATION:

Regulatory History

We did not publish notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553 (b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. Any delay encountered in this regulation's effective date would be impracticable and contrary to public interest since immediate action to restrict and control maritime traffic transiting in the vicinity of the Sloop Channel under the Wantagh Parkway Number 3 Bridge in the Town of Hempstead, Nassau County, Long Island, New York is needed to ensure the safety of vessels transiting the area.

In 2003, the Coast Guard approved bridge construction and issued a permit for bridge construction for the Wantagh Parkway Number 3 Bridge over the Sloop Channel. Contractors began work constructing the two bascule piers for the new bridge in early June 2004. A safety zone was not deemed necessary at the inception of the construction, as this channel is primarily used by smaller recreational vessels, which could maneuver outside of the channel. However, bridge construction equipment that remains under the Wantagh Parkway Number 3 Bridge poses a potential hazard greater than originally anticipated. A safety zone was deemed necessary and was established on October 9, 2004 through December 31, 2004, the date when construction impacting the navigable channel was estimated to be complete. A second safety zone was implemented on January 1, 2005 and extended until December 31, 2005 due to delays in construction, requiring equipment to be in the channel in a manner that would leave the waterway unsafe to marine traffic. Due to continued significant delays in bridge construction, the safety zone was extended until December 31, 2006. Construction delays continued and the safety zone extended again to December 31, 2007. The contractor for this project continues to experience significant delays in bridge construction. In order to continue construction in a more rapid and safe manner, barges will need to continuously block the channel under the bridge. Accordingly, the New York State Department of Transportation (NYSDOT) has requested that a safety zone be put in place through June 30, 2008. At that time, the construction progress will allow the contractors to remove the equipment from the channel.

As the construction equipment is presently obstructing the navigable channel, immediate action is needed to prevent accidents by limiting vessel movement in the area with the construction equipment. Traffic exists in this area year round and increases significantly in the summer months with the return of recreational traffic.

Background and Purpose

Currently, there is a fixed bridge over the Wantagh Parkway Number 3 Bridge over the Sloop Channel in the Town of Hempstead, New York. New York Department of Transportation determined that a moveable bridge would benefit the boating community. In 2003, the Coast Guard approved bridge construction and issued a permit for bridge construction for the Wantagh Parkway Number 3 Bridge over the Sloop Channel. Contractors began work constructing the two-bascule piers for the new bridge in early June 2004. The equipment necessary for the construction of the bridge occupies the entire navigable channel. While there are side channels, which can be navigated, the equipment in the channel is extensive and poses a hazard to recreational vessels attempting to transit the waterway via the side channels under the bridge. Construction, requiring equipment in the navigable

channel, was originally scheduled to end on December 31, 2004. Numerous delays in the construction have required construction equipment to continue to occupy the navigable channel and have required three subsequent extensions of the established safety zone through December 31, 2005 and then through December 31, 2006 and most recently through December 31, 2007 when the contractor continued to experience significant delays. Due to continued construction delays, the NYSDOT has requested that a safety zone be in place through June 30, 2008. To ensure the continued safety of the boating community, the Coast Guard is extending the effective period of the safety zone that is currently in place in all waters of the Sloop Channel within 300-yards of the Wantagh Parkway Number 3 Bridge. This safety zone is necessary to protect the safety of the boating community who wish to utilize the Sloop Channel. Vessels may utilize the Goose Neck Channel as an alternative route to using the Sloop Channel, adding minimal additional transit time. Marine traffic may also transit safely outside of the safety zone during the effective dates of the safety zone, allowing navigation in the Sloop Channel, except the portion delineated by this rule.

Discussion of Rule

This regulation extends the effective period of a temporary safety zone on the waters of the Sloop Channel within 300-yards of the Wantagh Parkway Bridge. This action is intended to prohibit vessel traffic in a portion of the Sloop Channel in the Town of Hempstead, New York to provide for the safety of the boating community due to the hazards posed by significant construction equipment and barges located in the waterway for the construction of a new bascule bridge. The effective period of this safety zone is continued to 11:59 p.m. on June 30, 2008. Marine traffic may continue to transit safely outside of the safety zone during the effective dates of the safety zone, allowing navigation in the Sloop Channel, except the portion delineated by this rule. Entry into this zone is prohibited unless authorized by the Captain of the Port, Long Island Sound.

Any violation of the safety zone described herein is punishable by, among other things, civil and criminal penalties, in rem liability against the offending vessel, and the initiation of suspension or revocation proceedings against Coast Guard-issued merchant mariner credentials.

Regulatory Evaluation

This rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

This regulation may have some impact on the public, but the potential impact will be minimized for the following reasons: vessels may transit in all areas of the Sloop Channel other than the area of the safety zone, and may utilize other routes with minimal increased transit time.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), we have considered whether this rule will have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This rule may affect the following entities, some of which may be small entities: the owners or operators of vessels intending to transit or anchor in those portions of the Sloop Channel in the Town of Hempstead, New York covered by the safety zone. For the reasons outlined in the Regulatory Evaluation section above, this rule will not have a significant impact on a substantial number of small entities.

Assistance for Small Entities

Under subsection 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 [Pub. L. 104-121], the Coast Guard wants to assist small entities in understanding this rule so that they can better evaluate its effects on them and participate in the rulemaking. If this rule will affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call Lieutenant D. Miller Chief, Waterways Management Division, Coast Guard Sector Safety Office Long Island Sound at (203) 468-4596.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1-888-REG-FAIR (1-888-734-3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action fo the Coast Guard.

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531-1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this rule will not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and will not concern an environmental risk

to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, 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.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that order because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

The Coast Guard analyzed this rule under Commandant Instruction M16475.1D, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) 42 U.S.C. 4321-4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2-1, paragraph (34)(g), of the Instruction, from further environmental documentation. This rule fits the category selected from paragraph (34)(g), as it establishes a safety zone. An final "Environmental Analysis Check List" and a final "Categorical Exclusion Determination" will be available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting andrecordkeeping requirements, Security measures, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165--REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1225 and 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05-1, 6.04-1, 6.04-6, and 160.5; Pub. L. 107-295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Amend § 165.T01-132 by revising paragraph (b) to read as follows:

§ 165.T01-132 Safety Zone: Wantagh Parkway Number 3 Bridge over the Sloop Channel, Town of Hempstead, NY.

* * * * *

(b) *Effective date:* This rule is effective from 11:59 p.m. on January 22, 2007 until 11:59 p.m. June 30, 2008.

* * * * *

Dated: November 20, 2007.

D.A. Ronan,

Captain, U.S. Coast Guard, Captain of the Port, Long Island Sound.

[FR Doc. E7–23569 Filed 12–4–07; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[CGD09–07–127]

RIN 1625–AA11

Safety Zone, Chicago Harbor, Navy Pier East, Chicago, IL

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the Navy Pier East Safety Zone in Chicago Harbor on December 4, 2007. This action is necessary to protect vessels and people from the hazards associated with fireworks displays. This safety zone will restrict vessel traffic from a portion of the Captain of the Port Lake Michigan Zone.

DATES: Effective from 8:30 p.m. to 10 p.m. on December 4, 2007.

FOR FURTHER INFORMATION CONTACT: CWO Brad Hinken, Prevention Department, Coast Guard Sector Lake Michigan, Milwaukee, WI at (414) 747–7154.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the Safety Zone, Navy Pier East, Chicago Harbor, Chicago, IL, 33 CFR 165.933 for the following event:

(1) *Total Event Resources* on December 4, 2007 from 8:30 p.m. through 10 p.m.

All vessels must obtain permission from the Captain of the Port or his designated representative to enter, move within, or exit the safety zone. Vessels and persons granted permission to enter the safety zone shall obey all lawful orders or directions of the Captain of the Port or a designated representative. While within a safety zone, all vessels shall operate at the minimum speed necessary to maintain a safe course.

This notice is issued under authority of 33 CFR 165.933 Safety Zone, Navy Pier East, Chicago Harbor, Chicago, IL (72 FR 32525 (June 13, 2007)) and 5 U.S.C. 552(a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of these enforcement periods via broadcast Notice to Mariners and Local Notice to Mariners.

The Captain of the Port will issue a Broadcast Notice to Mariners notifying the public when enforcement of the safety zone established by this section is suspended. The Captain of the Port may be contacted via U.S. Coast Guard Sector Detroit on channel 16, VHF–FM.

Dated: November 20, 2007.

Sean R. Murtagh,

Commander, U.S. Coast Guard, Acting Captain of the Port Lake Michigan.

[FR Doc. E7–23570 Filed 12–4–07; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 3

RIN 2900–AM47

Extension of the Presumptive Period for Compensation for Gulf War Veterans

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document affirms an amendment to the Department of Veterans Affairs (VA) adjudication regulation regarding compensation for disabilities resulting from undiagnosed illnesses suffered by veterans who served in the Persian Gulf War. This amendment is necessary to extend the presumptive period for qualifying chronic disabilities resulting from undiagnosed illnesses that must become manifest to a compensable degree in order that entitlement for compensation be established. The intended effect of this amendment is to provide consistency in VA adjudication policy and preserve certain rights afforded to Persian Gulf War veterans and ensure fairness for current and future Persian Gulf War veterans.

DATES: *Effective Date:* December 5, 2007.

FOR FURTHER INFORMATION CONTACT: Rhonda F. Ford, Chief, Regulations Staff (211D), Compensation and Pension Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 273–7210. (This is not a toll-free number).

SUPPLEMENTARY INFORMATION: In response to the needs and concerns of veterans of the Persian Gulf War (Gulf War), Congress enacted the Persian Gulf War Veterans' Benefits Act, title I of the Veterans' Benefits Improvements Act of 1994, Public Law 103–446, which was codified in relevant part at 38 U.S.C. 1117. This law provided authority to the Secretary of Veterans Affairs (Secretary) to compensate Gulf War veterans with a chronic disability resulting from an undiagnosed illness that became manifest either during service on active duty in the Southwest Asia theater of operations during the Persian Gulf War or to a degree of 10 percent or more during a presumptive period determined by the Secretary. Section 1117 directs the Secretary to prescribe by regulation the presumptive period following service in the Southwest Asia theater of operations determined to be appropriate for the manifestation of an illness warranting payment of compensation. On December 18, 2006, we published an interim final rule extending the presumptive period in 38 CFR 3.317 to December 31, 2011 (71 FR 75669). We provided a 60-day comment period that ended February 16, 2007.

We received one comment from a concerned individual and one comment from The American Legion. The individual commented that it was important to acknowledge an undiagnosed illness as a real medical condition. We will make no change based on this comment. We note that both statute and regulation authorize payment of compensation for specific disabilities resulting from undiagnosed illnesses, thus recognizing the existence of undiagnosed illnesses for purposes of VA benefits. Moreover, we believe that the extension of the presumptive period and other existing regulations regarding disabilities and illnesses related to the Gulf War will continue to ensure that veterans with compensable disabilities due to undiagnosed illnesses that may be related to active service in the Southwest Asia theater of operations during the Persian Gulf War may qualify for benefits.

The American Legion commented that, because military operations continue in the Persian Gulf, research into Gulf War illnesses remains ongoing, and VA continues to receive disability claims for disabilities due to undiagnosed illnesses, the presumptive period should be extended indefinitely, not just to December 31, 2011. We will make no change based on this comment. Section 102(7) of the Persian Gulf War Veterans' Benefits Act states Congress' finding that further research must be undertaken to determine the causes of Gulf War veterans illnesses and that "pending the outcome of such research, veterans who are seriously ill as the result of such illnesses should be given the benefit of the doubt and be provided compensation to offset the impairment in earning capacities they may be experiencing." In 38 U.S.C. 1118, Congress has prescribed an ongoing process for investigating the nature and causes of Gulf War veterans' illnesses and for prescribing presumptions of service connection for specific conditions associated with Gulf War service. The statutory scheme reflects the hope that further research and the procedures mandated by section 1118 may eventually diminish the need for the presumptions in section 1117. Accordingly, we believe that extending the presumptive period for a significant, but not indefinite period to permit further investigation is consistent with the goals of this statutory scheme.

In 38 U.S.C. 1117(b), Congress provided the Secretary with discretion to prescribe a presumptive period based upon, among other things, a review of credible medical or scientific evidence. As stated in the interim final rule, the Secretary is extending the presumptive period to December 31, 2011 in order to provide more time for scientific and medical research regarding diseases and illnesses that may be related to service in the Southwest Asia theater of operations. Based on the current lack of scientific certainty surrounding the cause of illnesses suffered by Gulf War veterans, the Secretary's decision to extend the presumptive period until December 31, 2011, is within the discretion given to him by 38 U.S.C. 1117. Before the expiration of the presumptive period established by this rule, the Secretary may extend the presumptive period further if scientific uncertainty remains regarding the causes of Gulf War veterans illnesses.

We appreciate the comments submitted on the interim final rule. Based on the rationale-set forth in the interim final rule and in this document, we now affirm as a final rule the amendments made by the interim final rule.

Administrative Procedure Act

This document without any changes affirms amendments made by an interim final rule that is already in effect. Accordingly, we have concluded under 5 U.S.C. 553 that there is good cause for dispensing with a delayed effective date based on the conclusion that such procedure is impracticable, unnecessary, and contrary to the public interest.

Paperwork Reduction Act

This document contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521).

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. This final rule would not affect any small entities. Only VA beneficiaries could be directly affected. Therefore, pursuant to 5 U.S.C. 605(b), this final rule is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

Executive Order 12866

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select

regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Executive Order classifies a "significant regulatory action," requiring review by the Office of Management and Budget (OMB) unless OMB waives such review, as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

The economic, interagency, budgetary, legal, and policy implications of this final rule have been examined and it has been determined to be a significant regulatory action under the Executive Order.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532 that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any year. This final rule would have no such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance Numbers and Titles

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are 64.109, Veterans Compensation for Service-Connected Disability; and 64.110, Veterans Dependency and Indemnity Compensation for Service-Connected Death.

List of Subjects in 38 CFR Part 3

Administrative practice and procedure, Claims, Disability benefits, Health care, Pensions, Radioactive materials, Veterans, Vietnam.

Approved: August 27, 2007.

Gordon H. Mansfield,

Deputy Secretary of Veterans Affairs.

■ Accordingly, the interim final rule amending 38 CFR part 3 that was published at 71 FR 75669 on December 18, 2006, is adopted as a final rule without change.

[FR Doc. E7–23545 Filed 12–4–07; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2006–1021; FRL–8501–3]

Approval and Promulgation of Air Quality Implementation Plans; Minnesota

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving State Implementation Plan (SIP) revisions to sulfur dioxide (SO_2) requirements for Northern States Power Company, doing business as Xcel Energy, Inver Hills Generating Plant (Inver Hills), located in Inver Grove Heights, Dakota County, Minnesota. The revisions make the limits of the sulfur content in its fuel and its sulfur dioxide emissions more stringent, and prohibit the burning of residual fuel oil. The revisions allow the facility to use simpler methods to analyze the sulfur content of its fuel. Because the sulfur dioxide emission limits are being reduced, the air quality of Dakota County will be protected.

DATES: This direct final rule will be effective February 4, 2008, unless EPA receives adverse comments by January 4, 2008. If adverse comments are received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2006–1021, by one of the following methods:

1. *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
2. *E-mail: mooney.john@epa.gov.*
3. *Fax:* (312) 886–5824.
4. *Mail:* John M. Mooney, Chief, Criteria Pollutant Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.
5. *Hand Delivery:* John M. Mooney, Chief, Criteria Pollutant Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m. excluding Federal holidays.

Instructions: Direct your comments to Docket ID No. EPA–R05–OAR–2006–1021. 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.

Docket: All documents in the docket are listed in the 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 www.regulations.gov or in hard copy at the Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. This Facility is open from 8:30 am to 4:30 pm, Monday

through Friday, excluding legal holidays. We recommend that you telephone Matt Rau, Environmental Engineer, at (312) 886–6524 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT: Matt Rau, Environmental Engineer, Criteria Pollutant Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–6524, *rau.matthew@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever "we," "us," or "our" is used, we mean EPA. This supplementary information section is arranged as follows:

I. What is EPA Approving?

EPA is approving into the SO_2 SIP for Minnesota revised conditions from the Inver Hills joint Title I/Title V document. The revisions lower the allowable sulfur content of its fuel and reduce the allowable limits of its SO_2 emissions. The revisions also allow a simplified method to analyze fuel sulfur content. EPA is also removing from the SIP any non-SIP related Title I conditions that were previously mistakenly incorporated into the SIP for Inver Hills.

EPA is incorporating only the conditions in the joint Title I/Title V document labeled as "Title I Condition: State Implementation Plan for SO_2 NAAQS" into the Minnesota SIP. The joint Title I/Title V document is the Minnesota Air Emission Permit Number 03700015–003.

II. What is the Background for This Action?

A. What are the Revisions to the SIP?

Xcel Energy's Inver Hills facility is a 440 Megawatt peak demand electrical generation plant. The plant has six generation units, turbines EU 001–EU 006, which can fire both natural gas and distillate fuel oil. The facility is located in the Pine Bend portion of the Minneapolis-Saint Paul SO_2 maintenance area.

The SIP revisions reduce the limit for SO_2 emissions from the six turbines from 0.67 pounds per million British Thermal Units (lb/MMBTU) to 0.50 lb/MMBTU. This emission reduction is achieved by requiring the reduction of the sulfur content in the fuel from 0.64 percent by weight to 0.48 percent by weight. The SIP revision prohibits the use of residual fuel oil. If Inver Hills uses low sulfur fuel having a sulfur content of 0.10 percent by weight or less, Inver Hills can use a guarantee from a supplier as to the sulfur content of the fuel, and can use a simple fuel analysis option (ASTM Method D–1552) at the time of delivery.

B. What Prior SIP Actions Are Pertinent to This Action?

In 1980, Inver Hills was identified by the state of Minnesota as a culpable source in the Pine Bend area's nonattainment plan for the SO_2 National Ambient Air Quality Standards (NAAQS). On July 28, 1992, the Minnesota Pollution Control Agency (MPCA) issued an Administrative Order for Inver Hills to address the source's contribution to the nonattainment problem. The SIP revision contained in the Administrative Order was approved by EPA into the SIP on April 14, 1994. The most recent SIP action was taken when the MPCA submitted the Title I SIP conditions in the original Title V permit, Air Emission Permit 03700015–001, to EPA in August 2002. EPA approved those Title I SIP conditions into the SIP as of July 2, 2004 (69 FR 31891). However, the materials incorporated by reference into the SIP included all Title I conditions, including certain conditions that were unrelated to the SIP.

C. Has Public Notice Been Provided?

Minnesota published public notice of the Inver Hills revisions on September 7, 2006. No comments were received during the comment period which ended on October 9, 2006. In the public notice, Minnesota stated it would hold a public hearing if one were requested during the comment period. This follows the alternative public participation process EPA approved on June 5, 2006 (71 FR 32274). For limited types of SIP revisions that the public has shown little interest in, a public hearing is not automatically required. If anyone requests a public hearing during the comment period, Minnesota will hold a public hearing. Because no one requested a public hearing, Minnesota did not hold a public hearing for this SIP revision.

D. What Are Title I Conditions and Joint Title I/Title V Documents?

SIP control measures were contained in permits issued to culpable sources in Minnesota until 1990 when EPA determined that limits in state-issued permits are not federally enforceable because the permits expire. Minnesota then issued permanent Administrative Orders to culpable sources in nonattainment areas from 1991 to February of 1996.

Minnesota's consolidated permitting regulations, approved into the state SIP on May 2, 1995 (60 FR 21447), includes the term "Title I condition" which was written, in part, to satisfy EPA requirements that SIP control measures remain permanent. A "Title I condition" is defined as "any condition based on source-specific determination of ambient impacts imposed for the purposes of achieving or maintaining attainment with the national ambient air quality standard and which was part of the state implementation plan approved by EPA or submitted to the EPA pending approval under section 110 of the act * * *" The rule also states that "Title I conditions and the permittee's obligation to comply with them, shall not expire, regardless of the expiration of the other conditions of the permit." Further, "any Title I condition shall remain in effect without regard to permit expiration or reissuance, and shall be restated in the reissued permit."

Minnesota has initiated using joint Title I/Title V documents as the enforceable document for imposing emission limitations and compliance requirements in SIPs. The SIP requirements in joint Title I/Title V documents submitted by MPCA are cited as "Title I conditions," therefore ensuring that SIP requirements remain permanent and enforceable. EPA reviewed the State's procedure for using joint Title I/Title V documents to implement site-specific SIP requirements and found it to be acceptable under both Titles I and V of the Act (July 3, 1997 letter from David Kee, EPA, to Michael J. Sandusky, MPCA). Further, a June 15, 2006, letter from EPA to MPCA clarifies procedures to transfer requirements from Administrative Orders to joint Title I/Title V documents.

III. What Is EPA's Analysis of the State Submission?

Xcel Energy is receiving more stringent SO_2 limits on the generation units at the Inver Hills facility. However, it can take advantage of simplified methods of meeting fuel sulfur content and analysis requirements. The use of low sulfur fuel will ensure the tightened emission limits are met.

A modeling analysis was not conducted for the Inver Hills revision because its emission limits will be more stringent. The actual emissions may not decrease, but the potential to emit will decrease with the SO_2 limit reductions.

Modeling uses potential to emit in determining the impact on ambient air. Minnesota has noted that a July 2006 modeling analysis for the Pine Bend area showed that ambient SO_2 levels will remain below the standards and thus the area's air quality is protected. All significant sources of SO_2 emissions in the Pine Bend area including Inver Hills were in the July 2006 modeling analysis.

IV. What Are the Environmental Effects of This Action?

Sulfur dioxide causes breathing difficulties and aggravation of existing cardiovascular disease. It is also a precursor of acid rain and fine particulate matter formation. Sulfate particles are a major cause of visibility impairment in America. Acid rain damages lakes and streams impairing aquatic life and causes damage to buildings, sculptures, statues, and monuments. Sulfur dioxide also causes the loss of chloroform leading to vegetation damage. Ambient SO_2 levels are expected to be unchanged or to decrease because of the SIP revisions. Thus, the Pine Bend area of Dakota County, Minnesota is expected to remain in attainment of the SO_2 NAAQS.

V. What Action Is EPA Taking?

EPA is approving into the Minnesota SIP revised Title I conditions from the Inver Hills joint Title I/Title V document. EPA is also removing from the SIP for Inver Hills any non-SIP related Title I conditions that were previously mistakenly incorporated into the SIP.

We are publishing this action without prior proposal because we view this as a noncontroversial amendment and anticipate no adverse comments. However, in the proposed rules section of this **Federal Register** publication, we are publishing a separate document that will serve as the proposal to approve the state plan if relevant adverse written comments are filed. This rule will be effective February 4, 2008 without further notice unless we receive relevant adverse written comments by January 4, 2008. If we receive such comments, we will withdraw this action before the effective date by publishing a subsequent document that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on the proposed action. The EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. If we do not receive any comments, this action will be effective February 4, 2008.

VI. Statutory and Executive Order Reviews

Executive Order 12866: Regulatory Planning and Review

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.

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

Because it is not a "significant regulatory action" under Executive Order 12866 or a "significant energy action," 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).

Regulatory Flexibility Act

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.).

Unfunded Mandates Reform Act

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).

Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

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 (59 FR 22951, November 9, 2000).

Executive Order 13132: Federalism

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 Clean Air Act.

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

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 approves a State rule implementing a Federal Standard.

National Technology Transfer Advancement Act

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.

Paperwork Reduction Act

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.).

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).

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 February 4, 2008. 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, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: November 20, 2007.

Bharat Mathur,

Acting Regional Administrator, Region 5.

■ 40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

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

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

Subpart Y—Minnesota

■ 2. In § 52.1220 the table in paragraph (d) is amended by revising the entry for "Xcel Energy, Inver Hills Generating Plant" to read as follows:

§ 52.1220 Identification of plan.

* * * * *

(d) * * *

EPA-APPROVED MINNESOTA SOURCE-SPECIFIC PERMITS

Name of source	Permit No.	State effective date	EPA approval date	Comments
* * * * * * *				
Xcel Energy—Inver Hills Generating Plant.	03700015–003	10/27/06	12/5/07, [Insert page number where the document begins].	Only conditions cited as "Title I condition: SIP for SO_2 NAAQS."
* * * * * * *				

* * * * *

[FR Doc. E7–23496 Filed 12–4–07; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2007–0479; FRL–8500–9]

Approval and Promulgation of Air Quality Implementation Plans; Virginia; Amendments Extending the Applicability of Four Consumer and Commercial Product Regulations to the Fredericksburg Volatile Organic Compound (VOC) Emissions Control Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is approving a State Implementation Plan (SIP) revision submitted by the Commonwealth of Virginia. This revision consists of amendments to extend the geographic applicability of four consumer and commercial product regulations—Portable Fuel Container Spillage, Mobile Equipment Repair and Refinishing Operations, Architectural and Industrial Maintenance Coatings, and Consumer Products—to the Fredericksburg VOC Emissions Control Area. These amendments are necessary to implement VOC contingency measures within the Fredericksburg Area. The revision also incorporates by reference two additional test methods and procedures needed for Virginia's Architectural and Industrial Maintenance Coatings Rule. EPA is approving this revision to the Virginia SIP in accordance with the requirements of the Clean Air Act (CAA).

DATES: *Effective Date:* This final rule is effective on January 4, 2008.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA–R03–OAR–2007–0479. All documents in the docket are listed in the *www.regulations.gov* Web site. Although listed in the electronic docket, some information is not publicly available, i.e., confidential business information (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 through *www.regulations.gov* or in hard copy for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Virginia Department of Environmental Quality, 629 East Main Street, Richmond, Virginia, 23219.

FOR FURTHER INFORMATION CONTACT: Ellen Wentworth, (215) 814–2034, or by e-mail at *wentworth.ellen@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On September 12, 2007 (72 FR 52028), EPA published a notice of proposed rulemaking (NPR) for the Commonwealth of Virginia. The NPR proposed the approval of amendments extending the geographic applicability of four consumer and commercial product regulations to the Fredericksburg VOC Emissions Control Area. The formal SIP revision was submitted by the Commonwealth of Virginia on May 14, 2007.

II. Summary of the SIP Revision

The May 14, 2007 SIP revision contained regulation amendments to 9 VAC 5 Chapter 40 that extended the geographic applicability of four consumer and commercial product regulations—Portable Fuel Container Spillage, Mobile Equipment Repair and Refinishing, Architectural and Industrial Maintenance Coatings, and Consumer Products—into the new Fredericksburg VOC Emissions Control Area established in 9 VAC 5–20–206 (March 2, 2007, 72 FR 9441). These regulations had formerly applied only in the Northern Virginia VOC Emissions Control Area, and were based on the Ozone Transport Commission (OTC) model rules. The OTC developed control measures into model rules for a

number of source categories and estimated emission reduction benefits from implementing those model rules. These regulations are necessary to implement VOC contingency measures within the Fredericksburg VOC Emissions Control Area. The revision also adds six additional specialty coatings to the Architectural and Industrial Maintenance Coatings regulation. Other specific requirements of Virginia's SIP revision and the rationale for EPA's proposed action are explained in the NPR and will not be restated here. No public comments were received on the NPR.

III. General Information Pertaining to SIP Submittals From the Commonwealth of Virginia

In 1995, Virginia adopted legislation that provides, subject to certain conditions, for an environmental assessment (audit) "privilege" for voluntary compliance evaluations performed by a regulated entity. The legislation further addresses the relative burden of proof for parties either asserting the privilege or seeking disclosure of documents for which the privilege is claimed. Virginia's legislation also provides, subject to certain conditions, for a penalty waiver for violations of environmental laws when a regulated entity discovers such violations pursuant to a voluntary compliance evaluation and voluntarily discloses such violations to the Commonwealth and takes prompt and appropriate measures to remedy the violations. Virginia's Voluntary Environmental Assessment Privilege Law, Va. Code Sec. 10.1–1198, provides a privilege that protects from disclosure documents and information about the content of those documents that are the product of a voluntary environmental assessment. The Privilege Law does not extend to documents or information (1) that are generated or developed before the commencement of a voluntary environmental assessment; (2) that are prepared independently of the assessment process; (3) that demonstrate a clear, imminent and substantial danger to the public health or environment; or (4) that are required by law.

On January 12, 1998, the Commonwealth of Virginia Office of the Attorney General provided a legal opinion that states that the Privilege law, Va. Code Sec. 10.1–1198, precludes granting a privilege to documents and information "required by law," including documents and information "required by Federal law to maintain program delegation, authorization or approval," since Virginia must "enforce Federally authorized environmental programs in a manner that is no less stringent than their Federal counterparts* * * * *." The opinion concludes that "[r]egarding § 10.1–1198, therefore, documents or other information needed for civil or criminal enforcement under one of these programs could not be privileged because such documents and information are essential to pursuing enforcement in a manner required by Federal law to maintain program delegation, authorization or approval."

Virginia's Immunity law, Va. Code Sec. 10.1–1199, provides that "[t]o the extent consistent with requirements imposed by Federal law," any person making a voluntary disclosure of information to a state agency regarding a violation of an environmental statute, regulation, permit, or administrative order is granted immunity from administrative or civil penalty. The Attorney General's January 12, 1998 opinion states that the quoted language renders this statute inapplicable to enforcement of any Federally authorized programs, since "no immunity could be afforded from administrative, civil, or criminal penalties because granting such immunity would not be consistent with Federal law, which is one of the criteria for immunity."

Therefore, EPA has determined that Virginia's Privilege and Immunity statutes will not preclude the Commonwealth from enforcing its program consistent with the Federal requirements. In any event, because EPA has also determined that a state audit privilege and immunity law can affect only state enforcement and cannot have any impact on Federal enforcement authorities, EPA may at any time invoke its authority under the CAA, including, for example, sections 113, 167, 205, 211 or 213, to enforce the requirements or prohibitions of the state plan, independently of any state enforcement effort. In addition, citizen enforcement under section 304 of the Clean Air Act is likewise unaffected by this, or any, state audit privilege or immunity law.

IV. Final Action

EPA is approving a revision to the Commonwealth of Virginia SIP, extending the geographic applicability of four consumer and commercial product regulations—Portable Fuel Container Spillage, Mobile Equipment Repair and Refinishing Operations, Architectural and Industrial Maintenance Coatings, and Consumer Products—to the Fredericksburg VOC Emissions Control Area. EPA is also approving the incorporation by reference of two additional test methods and procedures needed for Virginia's architectural and Industrial Maintenance Coatings Rule.

V. Statutory and Executive Order Reviews

A. General Requirements

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 requirement, 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 approves a state rule implementing a Federal standard.

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.*).

B. Submission to Congress and the Comptroller General

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

C. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by *February 4, 2008*. 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, expanding the geographic applicability of four consumer and commercial product regulations to the Fredericksburg VOC Emissions Control Area, 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, Incorporation by reference, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: November 20, 2007.

Donald S. Welsh,

Regional Administrator, Region III.

■ 40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for 40 CFR part 52 continues to read as follows:

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

Subpart VV—Virginia

■ 2. In § 52.2420, the table in paragraph (c) is amended by revising the entries for Chapter 40, Part II, Sections 5–40–5700, 5–40–5720, 5–40–5750, 5–40–6970, 5–40–7050, 5–40–7120, 5–40–7130, 5–40–7140, 5–40–7210, 5–40–7240, 5–40–7250, 5–40–7260, 5–40–7270, 5–40–7300, 5–40–7330, and 5–40–7360. The table in paragraph (e) is amended by adding an entry for Documents Incorporated by Reference after the eighth existing entry for Documents Incorporated by Reference. The amendments read as follows:

§ 52.2420 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED VIRGINIA REGULATIONS AND STATUTES

State citation (9 VAC 5)	Title/subject	State effective date	EPA approval date	Explanation [former SIP citation]
*	*	*	*	*
Chapter 40 Existing Stationary Sources (Part IV)				
*	*	*	*	*
Part II Emissions Standards				
*	*	*	*	*
Article 42 Portable Fuel Container Spillage (Rule 4–42)				
5–40–5700	Applicability and designation of affected facility.	10/04/06	12/05/07 [Insert page number where the document begins].	Revision extends the applicability to include the Fredericksburg VOC Emissions Control Area.
*	*	*	*	*
5–40–5720	Standard for volatile organic compounds.	10/04/06	12/05/07 [Insert page number where the document begins].	
*	*	*	*	*
5–40–5750	Compliance schedules	10/04/06	12/05/07 [Insert page number where the document begins].	

EPA-APPROVED VIRGINIA REGULATIONS AND STATUTES—Continued

State citation (9 VAC 5)	Title/subject	State effective date	EPA approval date	Explanation [former SIP citation]
* * * * * * *				
Article 48 Mobile Equipment Repair and Refinishing Operations (Rule 4–48)				
5–40–6970	Applicability and designation of affected facility.	10/04/06	12/05/07 [Insert page number where the document begins].	Revision extends the applicability to include the Fredericksburg VOC Emissions Control Area
* * * * * * *				
5–40–7050	Compliance schedule	10/04/06	12/05/07 [Insert page number where the document begins].	
* * * * * * *				
Article 49 Architectural and Industrial Maintenance Coatings (Rule 4–49)				
5–40–7120	Applicability and designation of affected facility.	10/04/06	12/05/07 [Insert page number where the document begins].	Revision extends the applicability to include the Fredericksburg VOC Emissions Control Area.
5–40–7130	Definitions	10/04/06	12/05/07 [Insert page number where the document begins].	Revision adds definitions for the following: ASTM, Calcimine recoater,Concrete surface retarder, Conversion varnish, Impacted immersion coating, Nuclear coatings, and Thermoplasftic rubber coating and mastic.
5–40–7140	Standard for volatile organic compounds.	10/04/06	12/05/07 [Insert page number where the document begins].	Revision adds standards for the following categories: Calcimine recoaters, Conversion varnishes, Concrete surface retarder, Impacted immersion coatings, Nuclear coatings, and Thermoplastic rubber coating and mastic.
* * * * * * *				
5–40–7210	Compliance schedules	10/04/06	12/05/07 [Insert page number where the document begins].	
* * * * * * *				
Article 50 Consumer Products (Rule 4–50)				
5–40–7240	Applicability	10/04/06	12/05/07 [Insert page number where the document begins].	Revision extends the applicability to include the Fredericksburg VOC Emissions Control Area.
5–40–7250	Exemptions	10/04/06	12/05/07 [Insert page number where the document begins].	
5–40–7260	Definitions	10/04/06	12/05/07 [Insert page number where the document begins].	
5–40–7270	Standard for volatile organic compounds.	10/04/06	12/05/07 [Insert page number where the document begins].	
* * * * * * *				
5–40–7300	Administrative requirements	10/04/06	12/05/07 [Insert page number where the document begins].	
* * * * * * *				
5–40–7330	Compliance schedules	10/04/06	12/05/07 [Insert page number where the document begins].	
* * * * * * *				
5–40–7360	Notification, records and reporting	10/04/06	12/05/07 [Insert page number where the document begins].	

(e) * * *

* * * * * *

Name of non-regulatory SIP revision	Applicable geographic area	State submittal date	EPA approval date	Additional Explanation
*	*	*	*	*
Documents Incorporated by Reference (9 VAC 5–20–21, Paragraphs E.4.a. (21) and (22))..	Fredericksburg VOC Emissions Control Area Designated in 9 VAC 5–20–206.	05/14/07	12/05/07 [Insert page number where the document begins].	State effective date is 10/04/06.
*	*	*	*	*

[FR Doc. E7–23386 Filed 12–4–07; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 97

[EPA–R05–OAR–2007–0390; FRL–8501–1]

Approval of Implementation Plans; Ohio; Clean Air Interstate Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of direct final rule.

SUMMARY: Due to the receipt of an adverse comment, the EPA is withdrawing the October 16, 2007 (72 FR 58546), direct final rule approving the State of Ohio's September 26, 2007, request to revise the Ohio State Implementation Plan (SIP) by incorporating provisions related to the implementation of EPA's Clean Air Interstate Rule (CAIR). In the direct final rule, EPA stated that if adverse comments were submitted by November 15, 2007, the rule would be withdrawn and not take effect. On November 9, 2007, EPA received a comment. EPA believes this comment is adverse and, therefore, EPA is withdrawing the direct final rule. EPA will address the comment in a subsequent final action based upon the proposed action also published on October 16, 2007 (72 FR 58571). EPA will not institute a second comment period on this action.

DATES: The direct final rule published at 72 FR 58546 on October 16, 2007, is withdrawn as of December 5, 2007.

FOR FURTHER INFORMATION CONTACT: John Paskevicz, Engineer, Criteria Pollutant Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–6084, *paskevicz.john@epa.gov.*

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Electric utilities, Incorporation by reference, Intergovernmental relations, Nitrogen oxides, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur dioxide.

40 CFR Part 97

Environmental protection, Administrative practice and procedure, Air pollution control, Electric utilities, Intergovernmental relations, Nitrogen oxides, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur dioxide.

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

Dated: November 23, 2007.

Gary Gulezian,

Acting Regional Administrator, Region 5.

■ Accordingly, the amendments to 40 CFR 52.1870 and part 97 which were published in the **Federal Register** on October 16, 2007 (72 FR 58546) on pages 58552–58553 are withdrawn as of December 5, 2007.

[FR Doc. E7–23504 Filed 12–4–07; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 81

[EPA–R03–OAR–2006–0353; EPA–R03–OAR–2007–0476; EPA–R03–OAR–2005–VA–0007; EPA–R03–OAR–2005–VA–0013; EPA–R03–OAR–2005–0548; EPA–R03–OAR–2006–0485; EPA–R03–OAR–2006–0682; EPA–R03–OAR–2006–0692; EPA–R03–OAR–2006–0817; FRL–8500–8]

Approval and Promulgation of Air Quality Implementation Plans; Maryland, Pennsylvania, Virginia, West Virginia; Redesignation of 8-Hour Ozone Nonattainment Areas to Attainment and Approval of the Areas' Maintenance Plans and 2002 Base-Year Inventories; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correcting amendment.

SUMMARY: This document corrects an error in the part 81 tables of a series of final rules pertaining to EPA's approval of ozone redesignation requests for Kent and Queen Anne, Erie, Fredericksburg, Shenandoah, Charleston, Parkersburg-Marietta, Steubenville-Weirton, Wheeling, and Huntington-Ashland 8-hour ozone nonattainment areas. The requests to redesignate the areas from nonattainment to attainment were submitted by Maryland, Pennsylvania, Virginia, and West Virginia.

EFFECTIVE DATE: December 5, 2007.

FOR FURTHER INFORMATION CONTACT: Irene Shandruk, (215) 814–2166 or by e-mail at *shandruk.irene@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document wherever "we" or "our" are used we mean EPA. The following table is a summary of the dates on which we published final rulemaking documents announcing our approval of three simultaneous actions for nine areas: (1) Redesignation from nonattainment to attainment of 8-hour ozone national ambient air quality standard (NAAQS); (2) approval of the areas' maintenance plans, and (3) approval of the emissions 2002 base-year inventories and mobile budgets. The effective dates for the three actions were announced in the **DATES** section as being 30 days from the date of publication.

State	Nonattainment area	Date of publication	FRN	Effective date
Maryland	Kent & Queen Anne's	December 22, 2006	71 FR 76920	January 22, 2007.
Pennsylvania	Erie	October 9, 2007	72 FR 57207	November 8, 2007.
Virginia	Fredericksburg	December 23, 2005	70 FR 76165	January 23, 2006.
	Shenandoah	January 3, 2006	71 FR 24	February 2, 2006.
West Virginia	Charleston	July 11, 2006	71 FR 39001	August 10, 2006.
	Huntington-Ashland	September 15, 2006	71 FR 54421	October 16, 2006.
	Parkersburg-Marietta	May 8, 2007	72 FR 25967	June 7, 2007.
	Steubenville-Weirton	May 14, 2007	72 FR 27060	June 13, 2007.
	Wheeling	May 15, 2007	72 FR 27247	June 14, 2007.

The corresponding effective dates in the 40 CFR part 81 tables for each nonattainment area should have also been 30 days from date of publication, but were inadvertently established as the dates of publication. This action corrects the erroneous effective date in part 81 for each of the above listed areas.

In the rule documents published in the **Federal Register** on the effective dates given in the above table, the part 81 tables for the nonattainment areas listed in the above table are corrected by revising the entry for the effective designation date for these areas from the date of publications given in the above table to the effective dates given in the above table (for example, for Kent & Queen Anne, corrected from December 23, 2006 to January 22, 2007).

Section 553 of the Administrative Procedure Act, 5 U.S.C. 553(b)(B), provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary or contrary to the public interest, the agency may issue a rule without providing notice and an opportunity for public comment. We have determined that there is good cause for making today's rule final without prior proposal and opportunity for comment because this rule is not substantive and imposes no regulatory requirements, but merely corrects a citation in a previous action. Thus, notice and public procedure are unnecessary. We find that this constitutes good cause under 5 U.S.C. 553(b)(B).

Statutory and Executive Order Reviews

Under Executive Order (E.O.) 12866 (58 FR 51735, October 4, 1993), this action is not a "significant regulatory action" and is therefore not subject to review by the Office of Management and Budget. 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)). Because the agency has made a "good cause" finding that this action is not subject to notice-and-comment requirements under the Administrative Procedures Act or any other statute as indicated in the Supplementary Information section above, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), or to sections 202 and 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). In addition, this action does not significantly or uniquely affect small governments or impose a significant intergovernmental mandate, as described in sections 203 and 204 of UMRA. This rule also does 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), nor will it 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 governments, as specified by Executive Order 13132 (64 FR 43255, August 10, 1999). This rule also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it approves a state rule implementing a Federal standard.

This technical correction action does not involve technical standards; 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. The rule also does not involve special consideration of environmental justice related issues as required by Executive Order 12898 (59 FR 7629, February 16, 1994). In issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct, as required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996). EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1998) by examining the takings implications of the rule in accordance with the "Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings" issued under the executive order. This rule does not impose an information collection burden under 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. Section 808 allows the issuing agency to make a rule effective sooner than otherwise provided by the CRA if the agency makes a good cause finding that notice and public procedure is impracticable, unnecessary or contrary to the public interest. This determination must be supported by a brief statement. 5 U.S.C. 808(2). As stated previously, EPA had made such a good cause finding, including the reasons therefore, and established an effective date of December 5, 2007. 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**. These corrections to the tables in 40 CFR 81.321, 81.339, 81.347 and 81.349 for Maryland, Pennsylvania, Virginia and West Virginia are not "major rules" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 81

Air pollution control, National parks, Wilderness areas.

Dated: November 20, 2007.

Donald S. Welsh,

Regional Administrator, Region III.

■ 40 CFR part 81 is amended as follows:

PART 81—[AMENDED]

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

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

■ 2. In § 81.321, the table entitled "Maryland—Ozone (8-Hour Standard)" is amended by revising the entry for Kent and Queen Anne's Area to read as follows:

§ 81.321 Maryland.

* * * * *

MARYLAND—OZONE (8-HOUR STANDARD)

Designated Area	Designation [a]		Category/Classification	
	Date [1]	Type	Date [1]	Type
* * * * * * *				
Kent and Queen Anne's Area				
Kent County	January 22, 2007	Attainment		
Queen Anne's County	January 22, 2007	Attainment		
* * * * * * *				

[a] Includes Indian County located in each county or area, except otherwise noted.
[1] This date is June 15, 2004, unless otherwise noted.

■ 3. In § 81.339, the table entitled "Pennsylvania-Ozone (8-Hour Standard)" is amended by revising the entry for Erie, PA: Erie County to read as follows:

§ 81.339 Pennsylvania.

* * * * *

PENNSYLVANIA—OZONE (8-HOUR STANDARD)

Designated Area	Designation [a]		Category/Classification	
	Date [1]	Type	Date [1]	Type
* * * * * * *				
Erie, PA: Erie County	11/8/2007	Attainment		
* * * * * * *				

[a] Includes Indian County located in each county or area, except otherwise noted.
[1] This date is June 15, 2004, unless otherwise noted.

■ 4. In § 81.347, the table entitled "Virginia—Ozone (8-Hour Standard)" is amended by revising the entries for Fredericksburg, VA and Madison and Page Cos. (Shenandoah NP), VA Area to read as follows:

§ 81.347 Virginia.

* * * * *

VIRGINIA—OZONE (8-HOUR STANDARD)

Designated Area	Designation [a]		Category/Classification	
	Date [1]	Type	Date [1]	Type
* * * * * * *				
Fredericksburg, VA:				
City of Fredericksburg	January 23, 2006	Attainment		
Spotsylvania County	January 23, 2006	Attainment		
Stafford County	January 23, 2006	Attainment		
Madison and Page Cos. (Shenandoah NP), VA area:				
Madison County (part)	February 2, 2006	Attainment		
Page County (part)	February 2, 2006	Attainment		
* * * * * * *				

[a] Includes Indian County located in each county or area, except otherwise noted.
[1] This date is June 15, 2004, unless otherwise noted.

■ 5. In § 81.349, the table entitled "West Virginia—Ozone (8-Hour Standard)" is amended by revising the entries for Charleston, WV; Huntington-Ashland, WV-KY; Parkersburg-Marietta WV-OH Area; Wheeling, WV-OH Area; and Steubenville-Weirton, OH-WV Area to read as follows:

§ 81.349 West Virginia.

* * * * *

WEST VIRGINIA—OZONE (8-HOUR STANDARD)

Designated Area	Designation [a]		Category/Classification	
	Date [1]	Type	Date [1]	Type
* * * * * * *				
Charleston, WV:				
Kanawha County	August 10, 2006	Attainment		
Putnam County	August 10, 2006	Attainment		
Huntington-Ashland, WV-KY				
Cabell County	October 16, 2006	Attainment		
Wayne County	October 16, 2006	Attainment		
Parksburg-Marietta, WV-OH Area:				
Wood County	June 7, 2007	Attainment		
Wheeling, WV-OH area:				
Marshall County	June 14, 2007	Attainment		
Ohio County	June 14, 2007	Attainment		
Steubenville-Weirton, OH-WV area:				
Brooke County	June 13, 2007	Attainment		
Hancock County	June 13, 2007	Attainment		
* * * * * * *				

[a] Includes Indian County located in each county or area, except otherwise noted.
[1] This date is June 15, 2004, unless otherwise noted.

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[FR Doc. E7–23498 Filed 12–4–07; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 94

[EPA–HQ–OAR–2007–0120; FRL–8502–6]

RIN 2060–A026

Change in Deadline for Rulemaking to Address the Control of Emissions From New Marine Compression-Ignition Engines at or Above 30 Liters per Cylinder

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: A February 2003 final rule established the first U.S. emission standards for new compression-ignition Category 3 marine engines, those with a per-cylinder displacement at or above 30 liters. It also established a deadline of April 27, 2007 for EPA to promulgate a second set of emission standards for these engines. This rulemaking schedule was intended to allow time to consider the state of technology for deeper emission reductions and the status of international action for more stringent standards. Since 2003 we have continued to gain a greater understanding of technical issues and assess the continuing efforts of manufacturers to apply advanced emission control technologies to these engines. In addition, we have continued to work with and through the International Maritime Organization toward more stringent emission standards that would apply to all new marine diesel engines on ships engaged in international transportation. Much of the information necessary to develop more stringent Category 3 marine diesel engines standards has become available only recently and we expect more information to come to light in the course of the current negotiations underway as part of the international process. EPA is therefore adopting a new deadline for the rulemaking to consider the next tier of Category 3 marine diesel engine standards. Under this new schedule, EPA would adopt a final rule by December 17, 2009. EPA has started this rulemaking process by publishing an Advance Notice of Proposed Rulemaking elsewhere in today's **Federal Register**.

DATES: This rule is effective on January 4, 2008.

ADDRESSES: All documents in the docket are listed in the www.regulations.gov index under Docket ID No. EPA-HQ-OAR–2007–0120. Some information listed in the index is not publicly available, such as confidential business information or other information for which 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 www.regulations.gov or in hard copy at the EPA Docket Center, EPA/DC, EPA West, Room 3334, 1301 Constitution Avenue, 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: Michael Samulski, Assessment and Standards Division, Office of Transportation and Air Quality, 2000 Traverwood Drive, Ann Arbor, MI 48105; telephone number: (734) 214–4532; fax number: (734) 214–4050; e-mail address: *samulski.michael@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Does This Action Apply to Me?

This action will affect companies that manufacture, sell, or import into the United States new marine compression-ignition engines for use on vessels flagged or registered in the United States; companies and persons that make vessels that will be flagged or registered in the United States and that use such engines; and the owners or operators of such U.S. vessels. This action may also affect companies and persons that rebuild or maintain these engines. Affected categories and entities include the following:

Category	NAICS Code [a]	Examples of potentially affected entities
Industry	333618	Manufacturers of new marine diesel engines.

Category	NAICS Code[a]	Examples of potentially affected entities
Industry	336611	Manufacturers of marine vessels.
Industry	811310	Engine repair and maintenance.
Industry	483	Water transportation, freight and passenger.

[a] North American Industry Classification System (NAICS).

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. To determine whether particular activities may be affected by this action, you should carefully examine the regulations. You may direct questions regarding the applicability of this action as noted in **FOR FURTHER INFORMATION CONTACT.**

I. Background

EPA published the intended change in the rulemaking schedule for Category 3 marine diesel engines as a direct final rule (72 FR 20948, April 27, 2007). We received adverse comments from six state and non-governmental organizations. As a result, we retracted the direct final rule and are proceeding with the rulemaking based on the proposal that was published concurrent with the direct final rule. Comments received on the direct final rule are therefore considered to be comments on the concurrent proposed rule. In this action we are announcing our decision to change the regulatory deadline as intended and responding to those comments.

II. Summary of the Rule

In this final rule we are extending the regulatory deadline for issuing a final rule setting more stringent standards for Category 3 marine diesel engines to December 17, 2009. This additional time will allow us to better address significant remaining concerns about the emission control technologies and create a compliance program that ensures proper implementation of new standards. This approach will allow us to set standards that achieve the maximum emission reductions from these engines. We do not believe this extension will delay emission reductions from Category 3 marine diesel engines beyond what could be achieved by setting standards sooner. Instead, it creates the opportunity for the development and implementation of a more effective program for the longer term. Finally, this delay will allow us to take advantage of information that is being prepared for consideration by the International Maritime Organization as part of the ongoing negotiations to amend MARPOL Annex VI under the International Convention for the Prevention of Pollution from Ships.

III. Basis for the Rule

A. History of EPA's Category 3 Standards

In February 2003, we adopted standards for new marine diesel engines with per-cylinder displacement at or above 30 liters per cylinder (also called Category 3 marine diesel engines; see 68 FR 9746, February 28, 2003). The program consisted of a two-part approach. First, we adopted near-term Tier 1 standards that went into effect in 2004 and were based on readily available control technology. Those standards are identical to the international standards adopted at the International Maritime Organization in MARPOL Annex VI. Second, we adopted regulations that set a schedule for a future rulemaking to assess and adopt an appropriate second tier of standards. We explained that it was appropriate to defer a final decision on the longer-term Tier 2 standard to a future rulemaking because there were several outstanding technical issues concerning the widespread commercial use of advanced control technologies on engines of this size. We highlighted the following concerns in the 2003 final rule:

- Selective catalytic reduction has been widely used in stationary applications and there are now efforts underway to use this technology for marine applications. We expressed concerns that these systems may not be capable of working effectively during the low-speed and light-load operation typical of operation closest to port areas where emission control is most important. We also noted that this approach could lead to increased emissions of PM, especially direct sulfate PM. There was also a concern that high fuel sulfur levels could lead to premature wear of catalyst materials.
- Various approaches for adding water to the combustion event were also cited as possible approaches to reduce NO_X emissions by 50 to 80 percent. There were concerns that adding water could increase engine wear with its low lubricity and increase PM emissions (by decreasing combustion temperatures). We also noted that new approaches to adding water—humidification and steam injection—held promise for substantially greater control of NO_X emissions.
- We raised several questions related to implementation and compliance provisions that would be appropriate with a new set of standards. For example, we need to develop an effective approach to address off-cycle emissions and uncertainties related to test-fuel specifications and PM measurement methods relative to the high sulfur concentrations typical of in-use fuels. We also raised the possible need to create a compliance program that would allow for emission controls to be disabled for operation on the open ocean and restored upon entry into some defined boundary representing U.S. coastal waters. These issues are complicated and need time for resolution.

We expected new information to become available with respect to (1) new developments as manufacturers continue to make various improvements with respect to emission aftertreatment; (2) data or experience from recently initiated in-use installations using advanced technologies; and (3) information from longer-term in-use experience that would be helpful for evaluating the long-term durability of emission controls.

The revision of the deadline for Tier 2 of the standards for new Category 3 marine diesel engine standards is permitted by the Clean Air Act. Clean Air Act section 213(a)(3) requires EPA to adopt and periodically revise regulations that contain standards concerning certain pollutants reflecting the greatest degree of emission reductions achievable through the application of technology that will be available, taking into consideration the availability and costs of the technology, and noise, energy, safety factors and existing motor vehicle standards. EPA's strategy toward achieving the maximum level of emission control from Category 3 marine diesel engines is consistent with those statutory requirements. See *Bluewater Network* v. *EPA*, 372 F. 3d 404 D.C. Cir. (2004).

B. Need for Revised Schedule

Deferring the Tier 2 standards to a second rulemaking has allowed us to obtain more information on the implementation of advanced technologies. Toward that end, we are publishing an Advance Notice of Proposed Rulemaking elsewhere in

today's **Federal Register** in which we describe the new information and our current thinking with regard to potential new requirements for Category 3 marine diesel engines. This new information comes from field experiences related to the continuing pilot projects to test new technologies, several recently published technical papers, and ongoing negotiations in the context of developing MARPOL Annex VI standards. This includes a better understanding of the capabilities and constraints associated with selective catalytic reduction, the potential for seawater scrubbers to control PM emissions, and the possibility of relying on the use of distillate fuel as a part of the overall approach to reducing emissions. For example, it appears that selective catalytic reduction can be quite tolerant of high fuel sulfur levels, but reactors would need to be physically larger to avoid sulfur-related problems. Also, pairing selective catalytic reduction with oxidation catalysts allows for reactivity at substantially lower exhaust temperatures. This would help to address the concern for controlling emission at light engine loads.

As we prepare a proposed rule to set standards based on advanced emission control technologies, we intend to resolve remaining questions for crafting a complete set of requirements. This will include consideration of testing requirements that reflect the need for engines using selective catalytic reduction to control emissions at light engine loads typical of operation in port areas. We will also consider whether further technological developments with selective catalytic reduction and water-based technologies will allow us to pursue PM emission standards more stringent than we are currently contemplating.

Control of PM and SO_X emissions depends on a combination of using distillate fuel and adding seawater scrubbers for removing emissions from engines that burn residual fuel. EPA will be separately pursuing the appropriate designations under MARPOL Annex VI such that all vessels would need to either use distillate fuel or achieve an equivalent level of emission control with seawater scrubbers. We intend to address certification requirements for seawater scrubbers in the rulemaking proposal for setting emission standards for Category 3 marine diesel engines. In addition, the proposal will address remaining questions for applying such standards to the current fleet in addition to new vessels, and for disposing of emissions removed from the exhaust gases, including the possible negative impacts on water quality for discharged wastewater.

The proposed rule will also rely on development and use of new analytic tools to assess the costs and benefits of alternative emission control strategies, especially related to at-sea emissions and how they are transported to shore.

Additional time will also allow us to take advantage of the ongoing negotiations for amendments to MARPOL Annex VI. When we finalized our Tier 1 standards in 2003, we anticipated that negotiations for the next round of international standards would begin shortly thereafter. Due to many delays, Members of the Convention did not agree to begin negotiations until July 2006, and the first round of negotiations did not occur until November 2006. These negotiations are expected to conclude in October 2008. These negotiations provide a key forum for sharing information on the performance of current installations. In addition, the IMO Secretary General has commissioned an experts group to examine control alternatives for PM and SO_X emissions; this information will also be important for developing the national standards. EPA is involved in these negotiations as a member of the U.S. delegation to IMO.

All these rulemaking issues are described in more detail in the Advance Notice of Proposed Rulemaking published elsewhere in today's **Federal Register**. This Advance Notice initiates the rulemaking process for adopting a more stringent set of standards for Category 3 marine diesel engines.

C. New Schedule

EPA remains committed to developing and proposing Tier 2 emission standards for Category 3 marine diesel engines. Advanced technology solutions are available or under development for these engines. However, it is necessary to resolve the questions described above before we are ready to propose a program with appropriate Tier 2 emission standards for these engines.

Our commitment to Tier 2 standards is evidenced by our position at the IMO and in the Advance Notice of Proposed Rulemaking. Specifically, as part of the process for setting new emission standards under IMO, the United States submitted a paper to the April 2007 BLG Sub-Committee meeting (called BLG–11) setting out an approach for substantially reducing emissions from marine diesel engines.[1] If adopted, these standards could achieve significant reductions in NO_X, particulate matter (PM), and oxides of sulfur (SO_X) emissions from marine vessels.[2] This framework formed the basis of the approach we are currently pursuing for an EPA rulemaking under the Clean Air Act to establish Tier 2 standards for Category 3 marine diesel engines, as described in the Advance Notice of Proposed Rulemaking. We expect the information we receive during this international process and as comments on the Advance Notice to provide very useful information in addressing our remaining concerns.

We do not believe this extension will delay emission reductions from Category 3 marine diesel engines beyond what could be achieved by setting standards sooner. If we would adopt emission standards earlier, we would need to allow several years of lead time to give manufacturers opportunity to work out remaining technological issues in designing engines with advanced emission control technologies for all sizes and types of vessels. Manufacturers have continued to make progress in developing these technologies in the meantime, which will help us tailor requirements to what emission reductions are achievable and should allow us to adopt a program with shorter lead time relative to the final rule setting these emission standards. Any foregone emission reductions from delaying the implementation of emission standards would likely be offset by our ability to set more stringent standards based on the additional information that is available by setting standards at the later date.

In sum, the delay in issuing the final rule for more stringent emission standards for Category 3 marine diesel engines is reasonable given the need to address certain technical issues and collect further information. We believe there will be no significant foregone emission reductions resulting from the delayed rulemaking schedule. In contrast, the additional time allows the opportunity to develop and implement a more effective program for the longer term.

In recognition of the current situation, we are taking this action to establish a new rulemaking deadline that will

[1] "Revision of the MARPOL Annex VI, the NO_X Technical Code and Related Guidelines; Development of Standards for NO_X, PM, and SO_X," subitted by the United States, BLG 11/5, Sub-Committee on Bulk Liquids and Gases, 11th Session, Agenda Item 5, February 9, 2007, Docket ID EPA–HQ–OAR–2007–0121–0034. This document is also available on our *Web site: http://www.epa.gov/otaq/oceanvessels.com.*

[2] "Revision of MARPOL Annex VI, the NO_X, PM, and SO_X," Submitted by the United States to the Sub-Committee on Bulk Liquids and Gases, 11th Session, 2007.

facilitate our ability to adopt emission standards consistent with the statutory directive, while advocating adoption of the same controls as part of the international process. In this action we are adopting a new deadline of December 17, 2009 for a final rule that will address additional emission standards for Category 3 marine diesel engines as appropriate under section 213(a)(3) of the Clean Air Act.

IV. Summary and Analysis of Comments

A. Summary of Comments

Commenters pointed out that Category 3 marine diesel engines are significant and growing contributors to air pollution in the United States. This included reference to various EPA estimates and was supplemented by several estimates for specific areas. Several commenters pointed out the acute need for reduced emissions from these engines in California, particularly in the South Coast Air Basin. For example, over half of current or projected levels of SO_x and diesel PM emissions in the South Coast Air Basin are estimated to come from marine vessels (or all port-related sources). SO_x emissions from marine vessels in particular would need to be reduced by about 90 percent in the next few years for the South Coast Air Basin to reach timely attainment of the air quality standard for $PM_{2.5}$. The South Coast Basin is also home to the Ports of Los Angeles and Long Beach, which are claimed to be the entry point for 40 percent of the nation's goods, with cargo throughput projected to triple by 2025. Santa Barbara County, California was noted as another particular concern, where 75 percent of local NO_X emissions are projected to come from marine vessels, even though there are no commercial ports within county boundaries. One commenter referenced a finding that 70 percent of global shipping emissions occur within 400 kilometers of shore, where pollution transport may range from 400 to 1200 kilometers inland.

Commenters emphasized that the emissions from Category 3 marine diesel engines contribute to serious public health and environmental problems. Commenters cited the EPA finding that diesel exhaust is a likely human carcinogen. Diesel particulate matter, ozone, SO_x, and air toxic emissions were identified as substantial causes of environmental degradation, illness, and/or death. Commenters noted that emissions from marine diesel engines also raise concerns for environmental justice, since the pollution effects fall disproportionately on the relatively low-income residential areas surrounding ports and transportation corridors.

Commenters cited Clean Air Act section 213 and EPA's 1994 and 1998 findings to establish the significance of emissions from nonroad engines in general and Category 3 marine diesel engines specifically as demonstration that EPA had a mandatory duty to set technology-forcing emission standards for these engines. Commenters further maintained that missing the regulatory deadline violated EPA's repeated statements committing to take final action on the schedule reflected in the regulation. Commenters noted that in similar circumstances the District Court of the District of Columbia compelled EPA to take a final action based on a regulatory deadline EPA had earlier adopted as part of the effort to address hazardous air pollutants from motor vehicles. Commenters further reasoned that the court decision upholding the sufficiency of the Tier 1 standards adopted in February 2003 depended on EPA's commitment to adopt more stringent emission standards for these engines by the established deadline.

Commenters claimed that delaying implementation of emission standards based on the need for more time to evaluate potential emission controls is without merit and outside the scope of EPA's rulemaking authority. Rather, commenters view Clean Air Act section 213 as requiring EPA to establish technology-forcing standards based on projected future advances in pollution control capabilities. Commenters further argue that the necessary advances for low-emission technologies for these engines have already occurred and these technologies are widely used in commercial applications today, and that EPA has provided no reasoned basis describing why the originally adopted schedule was not sufficient to address any remaining technical concerns related to emission control technologies. For example, commenters cited EPA's report of more than 300 marine engines operating worldwide with selective catalytic reduction, including oceangoing vessels. Some commenters also disagreed with the logic of EPA's argument that setting intermediate-stringency standards would prevent more effective long-term standards, noting Congress's intent for periodic review and update of nonroad emission standards to reflect the evolutionary nature of emission control technology. Commenters also pointed out that more stringent emission controls are urgently needed, given the large number of ships expected to be built over the coming years and the difficulty of retrofitting vessels to reduce emissions.

Commenters also posit that it is impermissible and inappropriate for EPA to allow international negotiations to nullify its obligations under the Clean Air Act. Commenters point out that Clean Air Act section 213 does not allow for foreign-policy considerations to serve as the basis for determining whether or how to set emission standards for nonroad engines, and that the Supreme Court recently reinforced this principle in the decision related to greenhouse gas emissions. This was presented as an inappropriate means of shifting power from the Congress to the Executive Branch. Commenters further maintain that EPA has failed to explain how emission standards adopted for the United States under the Clean Air Act would hamper international negotiations (or how the specific and feasible standards EPA has recommended for consideration at IMO lack information needed for pursuing standards under U.S. law). They emphasized other examples of international agreements that followed implementation of domestic regulations in the United States, and argued that the delays in adoption of international standards for marine diesel engines were in fact a basis for EPA to pursue separate requirements. Aside from a general skepticism that the IMO process would lead to meaningful emission reductions from these engines, commenters promoted the contrary view that rigorous U.S. emission standards would provide the political and technical foundation for international action regarding Category 3 marine diesel engines, and that EPA has missed out on an opportunity to demonstrate to the IMO that the United States is serious about reducing emissions from large marine vessels and will act unilaterally if the IMO does not. Commenters recommended that EPA pursue emission standards based on the recent U.S. proposal for consideration under the IMO process.

Commenters noted that the decision to delay the deadline for setting new emission standards also postpones EPA's promised decision regarding the authority to apply U.S. emission standards to engines on foreign-flagged vessels. Commenters also made the following arguments to emphasize that EPA should decide affirmatively to apply emission standards to engines on foreign-flagged vessels:

- Clean Air Act section 213 requires EPA to set emission standards for all classes of nonroad engines that contribute to air pollution in the United

States, without distinguishing between domestic and foreign engines.

- EPA has repeatedly acknowledged that foreign-flagged vessels account for the clear majority of emissions from Category 3 marine diesel engines.
- Court decisions have established that foreign-flagged vessels in U.S. ports and water are subject to U.S. regulations other than those pertaining to a ship's "internal management and affairs."
- International law explicitly protects the right of the U.S. to regulate foreign-flagged ships in U.S. ports and waters.
- As described above for emission standards, the court upheld EPA's refusal to decide whether to regulate foreign flagged vessels on the basis that EPA promised to address the issue in its 2007 rulemaking.

Commenters concluded by emphasizing their interest in seeing EPA establish and commit to a firm and timely deadline to develop and implement stringent emission standards for Category 3 marine diesel engines, with rulemaking and implementation schedules expedited as much as possible to address EPA's legal obligations and the compelling air quality needs associated with these standards.

B. Analysis of Comments

We are mindful of the extent to which Category 3 marine diesel engines contribute to air pollution in coastal and inland areas of the United States. We do not disagree with the general characterization of the emission contribution or health and environmental impacts described by commenters.

However, we believe that amending the regulatory deadline to allow more time to address several remaining technical issues and collect some additional information is reasonable and consistent with our authority under the statute. The February 2003 final rule fulfilled our statutory obligation under Clean Air Act section 213 to set standards for Category 3 marine diesel engines. In *Bluewater Network* v. *EPA*, 372 F. 3d 404 D.C. Cir. (2004), the Court upheld EPA's rulemaking as having met the statutory requirement to establish standards that achieve the greatest degree of emission reduction. As a result, we disagree with the comments suggesting that we have failed to meet our mandatory statutory duty to set initial emission standards.

We have an additional obligation to periodically revise the emission standards to ensure that they reflect the greatest degree of emission control considering various statutory factors. We set a schedule for producing a new rulemaking to adopt these more stringent emission standards by April 2007 but have found that this did not allow sufficient time for completion, as described above. The delay rulemaking schedule we are adopting in this notice is reasonable in light of these issues and is consistent with Congress' intent that EPA consider the availability of technologies that can achieve the desired reductions, as well as the necessary lead time, cost, noise, energy and safety issues with adopting such standards.

As part of the process for setting new emission standards under IMO, the United States submitted a paper to the April 2007 BLG Sub-Committee meeting (called BLG–11) setting out an approach for substantially reducing emissions from marine diesel engines.[3] In parallel with this development toward a new set of international standards, we are initiating a rulemaking under the Clean Air Act to adopt these standards for the United States by publishing an Advance Notice of Proposed Rulemaking elsewhere in today's **Federal Register**.

We believe there has been great progress toward establishing the feasibility of controlling NO_X, SO_X, and PM emissions from these engines. Laboratory and in-field pilot demonstrations have significantly advanced the development of emission control technologies and allowed for relatively near-term projections for deploying these technologies in commercial service. These developments have allowed us to advocate specific emission targets as participating members of IMO in the effort to adopt more stringent emission standards. These targets are also the basis of our Advance Notice of Proposed Rulemaking. As described in the Advance Notice, we are still concluding resolution of the technological issues described above. We also expect to receive information through the international process and as comment on the Advance Notice of Proposed Rulemaking to help us address these remaining concerns.

While we are supporting the efforts in an international forum to set global emission standards, we are not deferring to that process in pursuing emission standards under the Clean Air Act. By initiating our own rulemaking to set new emission standards, we are pursuing an approach in which harmonized U.S. and global standards would be developed in parallel. While we are mindful of the timing of the international process and the state of these negotiations, the reasons described above for taking additional time to adopt a new round of emission standards hinge on the factors specified by Congress for considering the timing for implementing new emission standards, especially for the feasibility, lead time, and costs associated with new emission controls.

Regarding the question of applying emission standards to foreign-flagged vessels, we understand the positions expressed by commenters, as well as the contrary views expressed by commenters in previous rulemaking activity, and will be taking these concerns into account as we pursue a decision on this issue, which we will describe with supporting rationale in the proposal for setting emission standards for these engines.

The Advance Notice of Proposed Rulemaking is the next step toward developing more stringent emission standards for Category 3 marine diesel engines under the Clean Air Act. We intend to pursue these aggressive emission reductions, both in the EPA rulemaking and in the international process. The revised regulatory deadline included in this final rule indeed reflects a delay from the original April 2007 target, but we believe the revised schedule will allow for a thorough consideration of a wide range of important issues that need to be addressed before we can adopt an appropriate set of requirements for these engines. We continue to believe that pursuing resolution of these issues in an EPA rulemaking in parallel with the ongoing international negotiations will be the best path to leverage the most effective program for reducing the emissions impact from Category 3 marine diesel engines on U.S. air quality.

V. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under section (3)(f)(1) Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of this Executive Order. This final rule has been sent to OMB for review under Executive Order 12866 and any changes

[3] "Revision of the MARPOL Annex VI, the NO_X Technical Code and Related Guidelines; Development of Standards for NO_X, PM, and SO_X," submitted by the United States, BLG 11/5, Sub-Committee on Bulk Liquids and Gases, 11th Session, Agenda Item 5, February 9, 2007, Docket ID EPA–HQ–OAR–2007–0121–0034. This document is also available on our Web site: *http://www.epa.gov/otaq/oceanvessels.com.*

made in response to OMB recommendations have been documented in the docket for this action.

B. Paperwork Reduction Act

This action does not impose any new information collection burden. This final rule merely changes the regulatory schedule for a rulemaking to address emissions from Category 3 marine diesel engines. However, the Office of Management and Budget (OMB) has previously approved the information collection requirements contained in the existing regulations in 40 CFR part 94 under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* and has assigned OMB control number 2060–0287, EPA ICR number 1684.10. A copy of the 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 Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedures 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 final rule on small entities, a small entity is defined as: (1) A small business that meets the definition for business based on SBA size standards at 13 CFR 121.201; (2) a small 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 this final rule on small entities, I certify 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 rule on small entities." 5 U.S.C. 603 and 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 regulatory burden, or otherwise has a positive economic effect on all of the small entities subject to the rule.

This final rule merely changes the regulatory schedule for a rulemaking to address emissions from Category 3 marine engines. We have therefore concluded that this final rule will relieve regulatory burden for all affected small businesses.

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 to 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 of why such an alternative was 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 rule contains no Federal mandates for State, local, or tribal governments, or the private sector as defined by the provisions of Title II of the UMRA. The rule imposes no enforceable duties on any of these governmental entities. This rule contains no regulatory requirements that would significantly or uniquely affect small governments. EPA has determined that this rule contains no Federal mandates that may result in expenditures of more than $100 million to the private sector in any single year. This final rule merely changes the regulatory schedule for a rulemaking to address emissions from Category 3 marine engines. This rule is not subject to the requirements of sections 202 and 205 of 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" are 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."

Under Section 6 of Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute,

unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law, unless the Agency consults with State and local officials early in the process of developing the regulation.

Section 4 of the Executive Order contains additional requirements for rules that preempt State or local law, even if those rules do not have federalism implications (*i.e.*, the rules 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). Those requirements include providing all affected State and local officials notice and an opportunity for appropriate participation in the development of the regulation. If the preemption is not based on express or implied statutory authority, EPA also must consult, to the extent practicable, with appropriate State and local officials regarding the conflict between State law and Federally protected interests within the agency's area of regulatory responsibility.

This 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 final rule merely changes the regulatory schedule for a rulemaking to address emissions from Category 3 marine diesel engines. Thus, Executive Order 1312 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" (59 FR 22951, November 6, 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." "Policies that have tribal implications" is defined in the Executive Order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes."

This rule does not have tribal implications. It 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. This rule does not uniquely affect the communities of Indian Tribal Governments. Further, no circumstances specific to such communities exist that would cause an impact on these communities beyond those discussed in the other sections of this rule. This final rule merely changes the regulatory schedule for a rulemaking to address emissions from Category 3 marine engines. 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, "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, Section 5–501 of the Order directs the Agency to evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This rule is not subject to 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 final rule merely changes the regulatory schedule for a rulemaking to address emissions from Category 3 marine diesel engines.

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

This 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 final rule merely changes the regulatory schedule for a rulemaking to address emissions from Category 3 marine engines.

I. 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 doing so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (such as materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This final rule does not involve technical standards. This final rule merely changes the regulatory schedule for a rulemaking to address emissions from Category 3 marine engines. Therefore, EPA did not consider 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 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 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 final rule merely changes the regulatory schedule for a rulemaking to address emissions from Category 3 marine diesel engines.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as amended 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 Congress and the Comptroller General of the United States. We 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 before 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 final rule is effective on January 4, 2008.

L. Statutory Authority

The statutory authority for this action comes from section 213 of the Clean Air Act as amended (42 U.S.C. 7547). This action is a rulemaking subject to the provisions of Clean Air Act section 307(d). See 42 U.S.C. 7607(d).

List of Subjects in 40 CFR Part 94

Environmental protection, Administrative practice and procedure, Air pollution control, Confidential business information, Imports, Penalties, Reporting and recordkeeping requirements, Vessels, Warranties.

Dated: November 29, 2007.

Stephen L. Johnson,

Administrator.

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

PART 94—CONTROL OF AIR POLLUTION FROM MARINE COMPRESSION-IGNITION EMISSIONS

■ 1. The authority citation for part 94 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

■ 2. Section 94.8 is amended by revising paragraph (a)(2)(ii) to read as follows:

§ 94.8 Exhaust emission standards.

(a) * * *

(2) * * *

(ii) EPA has not finalized Tier 2 standards for Category 3 engines. EPA will promulgate final Tier 2 standards for Category 3 engines on or before December 17, 2009.

* * * * *

[FR Doc. E7–23557 Filed 12–4–07; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[EPA–HQ–OPP–2007–0574; FRL–8340–5]

Bacillus Thuringiensis Vip3Aa20 Protein and the Genetic Material Necessary for its Production in Corn; Extension of Temporary Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extends the temporary exemption from the requirement of a tolerance for residues of *Bacillus thuringiensis* Vip3Aa20 protein in corn when applied or used as a plant-incorporated protectant. Syngenta Seeds, Inc., submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting that the temporary tolerance exemption be extended. This regulation eliminates the need to establish a maximum permissible level for residues of the *Bacillus thuringiensis* Vip3Aa20 protein in corn when applied or used as a plant-incorporated protectant on field corn, sweet corn, and popcorn. The temporary tolerance exemption expires on October 31, 2009.

DATES: This regulation is effective December 5, 2007. Objections and requests for hearings must be received on or before February 4, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2007–0574. To access the electronic docket, go to *http://www.regulations.gov*, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (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 in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Mike Mendelsohn, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8715; e-mail address: *mendelsohn.mike@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this "**Federal Register**" document electronically through the EPA Internet under the "**Federal Register**" listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of 40 CFR part 174 through the Government Printing

Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr.*

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, as amended by FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2007–0574 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before February 4, 2008.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2007–0574, by one of the following methods.

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of August 8, 2007 (72 FR 44521) (FRL–8139–7), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7F7212) by Syngenta Seeds, Inc., 3054 Cornwallis Rd., P.O. Box 12257, Research Triangle Park, NC 27709. The petition requested that 40 CFR 174.458 (now 40 CFR 174.528, see the **Federal Register** issue of April 25, 2007 (72 FR 20431) (FRL–7742–2) be amended such that the temporary tolerance exemption for *Bacillus thuringiensis* Vip3Aa20 protein and the genetic material necessary for its production in corn when applied/used as a plant-incorporated protectant on field corn, sweet corn, and popcorn expires on October 31, 2009.

This notice included a summary of the petition prepared by Syngenta Seeds, Inc., the registrant. There were no comments received in response to the notice of filing.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(2)(A)(ii) of FFDCA defines "safe, " to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to section 408(c)(2)(B) of FFDCA, in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C) of FFDCA, which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...." Additionally, section 408(b)(2)(D) of FFDCA requires that the Agency consider "available information concerning the cumulative effects of a particular pesticide's residues" and "other substances that have a common mechanism of toxicity."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with section 408(c)(2)(B) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Data have been submitted demonstrating a lack of mammalian toxicity at high levels of exposure to the pure (microbially expressed) Vip3Aa20 protein. These data demonstrate the safety of Vip3Aa20 at well above maximum possible exposure levels that are reasonably anticipated in the crops. This is similar to the Agency position regarding toxicity and the requirement of residue data for the microbial *Bacillus thuringiensis* products from which this plant-incorporated protectant was derived (see 40 CFR 158.740(b)(2)(i)). For microbial products, the need for Tier II and III toxicity testing and residue data to verify the observed effects and clarify the source of these effects is triggered only by significant acute effects in studies such as the mouse oral toxicity study.

In order to clarify the discussion that follows in the remainder of this final rule, it is necessary to distinguish the various Vip3A designations that are used. Vip3Aa20 is the designation applicable to Vip3A protein expressed in corn. Vip3Aa19 is the designation applicable to Vip3A protein expressed in cotton. Because the Agency has determined that both Vip3Aa19 and Vip3Aa20 are functionally equivalent, the Agency in amending this temporary tolerance exemption for Vip3Aa20 expressed in corn has relied on data and analysis specifically developed for Vip3Aa20, as well as on data and analysis specifically developed for Vip3Aa19. A separate temporary exemption from the requirement of tolerance already has been established for Vip3Aa19 as expressed in cotton (72 FR 40754; 40 CFR 174.501).

An acute oral toxicity study was submitted for the Vip3Aa19 protein. Male and female mice (16 of each) were dosed with 3,675 milligrams/kilograms bodyweight (mg/kg bwt) of Vip3Aa19 protein. All mice survived the study, gained weight, had no test material-related clinical signs, and had no test material-related findings at necropsy. This acute oral toxicity data also supports the prediction that the Vip3Aa20 protein would be non-toxic to humans.

When proteins are toxic, they are known to act via acute mechanisms and at very low-dose levels (Sjoblad, Roy D., et al. 1992). Therefore, since no effects

were shown to be caused by the plant-incorporated protectants, even at relatively high-dose levels, the Vip3Aa20 protein is not considered toxic. Amino acid sequence comparisons showed no similarity between the Vip3Aa20 protein and known toxic proteins available in public protein data bases. According to the Codex Alimintarius guidelines, the assessment of potential toxicity also includes stability to heat Food and Agriculture Organization of the United Nations/World Health Organization Standards Programme, 2001. A heat lability study demonstrated that Vip3Aa19 is inactivated against fall army worm, when heated to 55 °C for 30 minutes.

Since Vip3Aa20 is a protein, allergenic sensitivities were considered. Currently, no definitive tests exist for determining the allergenic potential of novel proteins. Therefore, EPA uses a weight of the evidence approach where the following factors are considered: source of the trait; amino acid sequence similarity with known allergens; prevalence in food; and biochemical properties of the protein, including *in vitro* digestibility in simulated gastric fluid, and glycosylation. Current scientific knowledge suggests that common food allergens tend to be resistant to degradation acid and proteases; may be glycosylated; and present at high concentrations in the food.

Data have been submitted that demonstrate that the Vip3A from recombinant maize (LPPACHA–0199) and *E. coli* (VIP3A-0100) proteins are rapidly degraded by gastric fluid *in vitro*. (VIP3A–0100 refers to a microbially expressed Vip3A that has been shown to be the equivalent of the plant-expressed Vip3A protein.) In a solution of simulated gastric fluid (containing pepsin) and either 80 microLiter (µL) of LPPACHA–0199 or 320 µL of VIP3A–0100 test protein, both were shown to be susceptible to pepsin degradation. These data support the conclusion that Vip3A proteins expressed in transgenic plants will be readily digested as a conventional dietary protein under typical mammalian gastric conditions. Further data demonstrate that Vip3Aa20 is not glycoslylated and a comparison of amino acid sequences of known allergens uncovered no evidence of any homology with Vip3Aa20, even at the level of 8 contiguous amino acid residues. Preliminary data of the quantification of Vip3Aa20 protein in various maize tissues were also submitted. This data demonstrated that mean Vip3Aa20 concentrations in corn kernels ranged from circa (*ca*). 24.6–40.3 microgram (µg) Vip3Aa20/gram (g) dry weight, representing *ca*. 0.003% of the total protein in grain (assuming that corn grain contains 10% total protein by weight). Therefore, Vip3Aa20 is present in low levels in corn tissue and the protein expression is much lower than the amounts of allergen protein found in commonly allergenic foods. In those foods, the allergens can be 10 to 50% of the total protein found.

Therefore, the potential for the Vip3Aa20 protein to be a food allergen is minimal. As noted in grams/kilogram (gm/kg), toxic proteins typically act as acute toxins with low-dose levels. Therefore, since no effects were shown to be caused by this plant-incorporated protectant, even at relatively high-dose levels, the Vip3Aa20 protein is not considered toxic.

IV. Aggregate Exposures

In examining aggregate exposure, section 408 of FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens; lawns, or buildings (residential and other indoor uses).

The Agency has considered available information on the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances. These considerations include dietary exposure under the tolerance exemption and all other tolerances or exemptions in effect for the plant-incorporated protectant chemical residue, and exposure from non-occupational sources. Exposure via the skin or inhalation is not likely since the plant-incorporated protectant is contained within plant cells, which essentially eliminates these exposure routes or reduces these exposure routes to negligible. The amino acid homology assessment revealed no similarities to known aeroallergens, indicating that Vip3A has a low potential to be an inhalation allergen. It has been demonstrated that there is no evidence of occupationally related respiratory symptoms, based on a health survey on migrant workers after exposure to *Bacillus thuringiensis* pesticides (Berstein et al. 1999), which provides further evidence of the negligible respiratory risks of *Bacillus thuringiensis* plant-incorporated protectants. Exposure via residential or lawn use to infants and children is also not expected because the use sites for the Vip3Aa20 protein are all agricultural for control of insects. Oral exposure, at very low levels may occur from ingestion of processed corn products and, theoretically, drinking water.

However, oral toxicity testing done at a dose in excess of 3 grams/kilogram showed no adverse effects. Furthermore, the expected dietary exposure from both cotton and corn are several orders of magnitude lower than the amounts of Vip3Aa20 protein shown to have no toxicity. Therefore, even if negligible aggregate exposure should occur, the Agency concludes that such exposure would present no harm due to the lack of mammalian toxicity and the rapid digestibility demonstrated for the Vip3Aa20 proteins.

V. Cumulative Effects

Pursuant to FFDCA section 408(b)(2)(D)(v), EPA has considered available information on the cumulative effects of such residues and other substances that have a common mechanism of toxicity. These considerations include the cumulative effects on infants and children of such residues and other substances with a common mechanism of toxicity. Because there is no indication of mammalian toxicity, the Agency concludes that there are no cumulative effects arising from Vip3Aa20 protein residues in corn.

VI. Determination of Safety for U.S. Population, Infants and Children

A. Toxicity and Allergenicity Conclusions

The data submitted and cited regarding potential health effects for the Vip3Aa20 protein include the characterization of the expressed Vip3Aa20 protein in corn, as well as the acute oral toxicity, heat stability, and *in vitro* digestibility of the proteins. The results of these studies were determined applicable to evaluate human risk, and the validity, completeness, and reliability of the available data from the studies were considered.

Adequate information was submitted to show that the Vip3A protein test material derived from microbial cultures (designated VIP3A–0100) was biochemically and functionally similar to the Vip3Aa20 protein expressed in corn. Microbially produced protein was chosen in order to obtain sufficient material for testing.

The acute oral toxicity data submitted support the prediction that the Vip3Aa20 protein would be non-toxic to humans. As mentioned above, when proteins are toxic, they are known to act via acute mechanisms and at very low-

dose levels (Sjoblad, Roy D., et al. 1992). Since no effects were shown to be caused by Vip3Aa20 protein, even at relatively high-dose levels (3,675 mg Vip3Aa19/kg bwt), the Vip3Aa20 protein is not considered toxic. This is similar to the Agency position regarding toxicity and the requirement of residue data for the microbial *Bacillus thuringiensis* products from which this plant-incorporated protectant was derived. Moreover, Vip3Aa20 showed no sequence similarity to any known toxin.

Protein residue chemistry data for Vip3Aa20 were not required for a human health effects assessment of the subject plant-incorporated protectant ingredients because of the lack of mammalian toxicity. However, preliminary data (that were submitted with administrative materials for an Experimental Use Permit (EUP) application for corn expressing the Vip3Aa20 protein) demonstrated low levels of Vip3Aa20 in corn tissues with less than 40 µg Vip3Aa20 protein/g dry weight in kernels and less than 75 µg Vip3Aa20 protein/g dry weight of whole corn plant.

Since Vip3Aa20 is a protein, its potential allergenicity is also considered as part of the toxicity assessment. Information considered as part of the allergenicity assessment included data demonstrating that the Vip3Aa20 protein came from a *Bacillus thuringiensis* which is not a known allergenic source, showed no sequence similarity to known allergens, was readily degraded by pepsin, and was not glycosylated when expressed in the plant. Therefore, there is a reasonable certainty that the Vip3Aa20 protein will not be an allergen.

Neither available information concerning the dietary consumption patterns of consumers (and major identifiable subgroups of consumers including infants and children), nor safety factors that are generally recognized as appropriate for the use of animal experimentation data were evaluated. The lack of mammalian toxicity at high levels of exposure to the Vip3Aa20 protein, as well as the minimal potential to be a food allergen, demonstrate the safety of Vip3Aa20 at levels well above possible maximum exposure levels anticipated in the crop.

The genetic material necessary for the production of the plant-incorporated protectant active ingredients are the nucleic acids (DNA, RNA) which comprise genetic material encoding these proteins and their regulatory regions. The genetic material (DNA, RNA) necessary for the production of Vip3Aa20 protein already are exempted from the requirement of a tolerance under a blanket exemption for all nucleic acids (40 CFR 174.507).

B. Infants and Children Risk Conclusions

Section 408(b)(2)(C) of FFDCA provides that EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues, and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity.

In addition, FFDCA section 408(b)(2)(C) also provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base, unless EPA determines that a different margin of safety will be safe for infants and children.

In this instance, based on all the available information, the Agency concludes that there is a finding of no toxicity for the Vip3Aa20 protein and the genetic material necessary for its production in corn. Because there are no threshold effects of concern, the Agency has determined that the additional tenfold margin of safety is not necessary to protect infants and children. Further, the provisions of consumption patterns, special susceptibility, and cumulative effects do not apply.

C. Overall Safety Conclusion

There is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of the Vip3Aa20 protein and the genetic material necessary for its production in corn, when it is applied/used in accordance with good agricultural practices on field corn, sweet corn, and popcorn. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion because, as previously discussed, no toxicity to mammals has been observed, nor has there been any indication of allergenicity potential for this plant-incorporated protectant.

VII. Other Considerations

A. Endocrine Disruptors

The pesticidal active ingredient is a protein, derived from sources that are not known to exert an influence on the endocrine system. Therefore, the Agency is not requiring information on the endocrine effects of the plant-incorporated protectant at this time.

B. Analytical Method(s)

A method for extraction and Enzyme Linked Immunosorbent (ELISA) Analysis of Vip3Aa20 protein in corn has been submitted and is under review by the Agency.

C. Codex Maximum Residue Level

No Codex maximum residue levels exist for the plant-incorporated protectant *Bacillus thuringiensis* Vip3Aa20 protein and the genetic material necessary for its production in corn.

VIII. Statutory and Executive Order Reviews

This final rule extends the exemption from the requirement of a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866, 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) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national

government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000) do not apply to this rule. In addition, This rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

IX. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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 this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 174

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

Dated: November 19, 2007,

Janet L. Andersen,

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

■ Therefore, 40 CFR chapter I is amended as follows:

PART 174—[AMENDED]

■ 1. The authority citation for part 174 continues to read as follows:

Authority: 7 U.S.C. 136–136y; 21 U.S.C. 346a and 371.

■ 2. Section 174.528 is revised to read as follows:

§ 174.528 Bacillus thuringiensis Vip3Aa20 protein in corn; temporary exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Vip3Aa20 protein in corn are temporarily exempt from the requirement of a tolerance when used as a plant-incorporated protectant in the food and feed commodities; corn, field; corn, sweet; and corn, pop. This temporary exemption from the requirement of tolerance will permit the use of the food commodities in this section when treated in accordance with the provisions of the experimental use permit 67979–EUP–6, which is being amended and extended in accordance with the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136). This temporary exemption from the requirement of a tolerance expires and is revoked October 31, 2009; however, if the experimental use permit is revoked, or if any experience with or scientific data on this pesticide indicate that the temporary tolerance exemption is not safe, this temporary exemption from the requirement of a tolerance may be revoked at any time.

[FR Doc. E7–23308 Filed 12–4–07; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0195; FRL–8342–2]

Ethalfluralin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of ethalfluralin in or on dill, dried leaves; dill, fresh leaves; mustard, seed; potato; and rapeseed, seed. It also removes the current tolerance for residues of ethalfluralin on canola seed since residues on canola are covered by the rapeseed tolerance, thus making the canola tolerance unnecessary. Interregional Research Project Number 4 (IR–4) requested the new tolerances and removal of the canola tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 5, 2007. Objections and requests for hearings must be received on or before February 4, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2005–0195. To access the electronic docket, go to *http://www.regulations.gov*, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (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 in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; e-mail address: *stanton.susan@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers;

greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2005–0195 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before February 4, 2008.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2005–0195, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Tolerance

In the **Federal Register** of August 31, 2005 (70 FR 51797) (FRL–7730–4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petitions (PP 1E6326, PP 2E6360 and PP2E6466) by Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201 W, Princeton, NJ 08540–6635. The petitions requested that 40 CFR 180.416 be amended by establishing tolerances for residues of the herbicide ethalfluralin, [N-ethyl-N-(2-methyl-2-propenyl)-2,6-dinitro-4-(trifluoromethyl)benzenamine], in or on dill (PP 1E6326); rapeseed, canola, crambe and mustard seed (PP2E6466); and potato (PP 2E6360) at 0.05 parts per million (ppm). That notice included a summary of the petitions prepared by Dow AgroSciences LLC, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

EPA has modified the tolerances proposed in PP 1E6326 (rapeseed, canola, crambe and mustard). The reason for these changes is explained in Unit V.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...." These provisions were added to FFDCA by the Food Quality Protection Act (FQPA) of 1996.

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerance for residues of ethalfluralin on dill, dried leaves; dill, fresh leaves; mustard, seed; potato; and rapeseed, seed at 0.05 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by ethalfluralin as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document *Ethalfluralin: Human Health Risk Assessment for (IR–4) Proposed Uses on Dill and Potato*. The referenced document is available in the docket established by this action, which is described under **ADDRESSES**, and is identified as document number EPA–HQ–OPP–2005–0195–0001 in that docket.

The toxicity database for ethalfluralin is complete and indicates it has low acute toxicity by oral, dermal, and inhalation routes of exposure. It is moderately irritating to the eye and produces moderate to severe skin irritation. In one study ethalfluralin was negative for dermal sensitization, but in another, it was considered positive.

In general, subchronic and chronic feeding studies in rats, mice, and dogs

indicate the liver as the target organ, with consistent effects of enzymatic changes, liver weight increases, and histopathology (chronic mouse). A combined chronic/carcinogenicity study in rats showed no non-neoplastic effects at the highest dose tested (32 milligrams/kilogram/day ((mg/kg/day). However, mammary gland fibroadenomas were increased in a dose-related manner. The mouse carcinogenicity study showed no increase in tumor incidence. Ethalfluralin was classified as a possible human carcinogen in 1994 and, pursuant to that classification, cancer risk is assessed using quantitative linear low-dose extrapolation.

Ethalfluralin does not produce developmental toxicity in rats at doses up to 1,000 mg/kg/day. There are several rabbit developmental toxicity studies available; together, these studies indicate the potential for ethalfluralin to induce skeletal malformations at doses of >150 mg/kg/day. Maternal toxicity was observed at similar doses. Ethalfluralin did not produce reproductive or offspring effects in the 3-generation reproduction studies; the parental effects consisted of decreased body weight gains.

There is no evidence of neurotoxicity in the submitted toxicity studies for ethalfluralin.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the LOC to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for ethalfluralin used for human risk assessment can be found at *http://www.regulations.gov* in document *Ethalfluralin: Human Health Risk Assessment for (IR–4) Proposed Uses on Dill and Potato* at pages 13–17 in docket ID number EPA–HQ–OPP–2005–0195.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to ethalfluralin, EPA considered exposure under the petitioned-for tolerances as well as all existing ethalfluralin tolerances in (40 CFR 180.416). EPA assessed dietary exposures from ethalfluralin in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure. No such effect was identified for the general population, including infants and children, in the toxicological studies for ethalfluralin. However, EPA identified potential acute effects (increased number of resorptions and increased sternal and cranial variations seen in the rabbit developmental toxicity study) for the population subgroup females, 13 to 49 years old. In estimating acute dietary exposure of females, 13 to 49 years old, EPA used food consumption information from the U.S. Department of Agriculture (USDA) 1994–1996 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA relied on anticipated residues derived from field trial data for certain commodities (dry bean, peanuts, dry peas, soybeans and sunflower seed) and assumed tolerance level residues for the remaining commodities, including dill and potato. EPA assumed 100 percent crop treated (PCT) for all commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the 1994–1996 and 1998 CSFII. As to residues in food, EPA relied on the same anticipated residues and tolerances as in the acute exposure assessment and assumed 100 PCT for all commodities.

iii. *Cancer.* EPA has classified ethalfluralin as a possible human carcinogen, based on a dose-related increase in mammary gland fibroadenomas observed in the rat carcinogenicity study. EPA evaluated cancer risk using a quantitative approach based on a cancer potency factor, or $Q1^*$, of 8.9×10^{-2} $(mg/kg/day)^{-1}$. As to residues in food, EPA relied on the same estimates used in the acute and chronic exposure assessments for all commodities except soybean, watermelon and potato. For soybean and watermelon, EPA relied on anticipated residues derived from the USDA Pesticide Data Program monitoring data. The anticipated residue for potatoes was derived from field trial data. EPA assumed 100 PCT for all commodities.

iv. *Anticipated residue and PCT information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must pursuant tosection 408(f)(1) of FFDCA require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by section 408(b)(2)(E) of FFDCA and authorized under section 408(f)(1) of FFDCA. Data will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

EPA did not use any information on the actual percent of crops treated with ethalfluralin, but rather assumed 100% of each crop would be treated and contain residues of ethalfluralin.

2. *Dietary exposure from drinking water.* Drinking water monitoring data collected by USDA's Pesticide Data Program (PDP) are available for ethalfluralin for the years 2003, 2004 and 2005. During this time period, a total of 1,253 water samples were collected and found to contain no detectable residues of ethalfluralin. The limit of detection (LOD) of the method used to collect the data was 45.4 parts per trillion (ppt). EPA used a value equal to ½ the LOD or 22.7 ppt (0.023 parts per billion (ppb)) to assess cancer risk from residues of ethalfluralin in drinking water.

The PDP drinking water monitoring data were considered to be appropriate to assess cancer risk from the established and new uses of ethalfluralin for the following reasons:

i. Application rates for both existing and new uses are similar; while peak drinking water estimates differ slightly from one crop to another, the Agency's modeled drinking water numbers for the average of yearly means did not differ significantly by crop, supporting the notion that the existing monitoring data can support new uses;

ii. The drinking water monitoring data were collected over multiple years from a variety of states which include potential ethalfluralin use areas;

iii. The lack of findings of detectable residues is supported by modeled drinking water estimates and by the environmental fate properties of ethalfluralin (e.g., 6–hour half-life for aqueous photolysis).

EPA did not use the PDP data to evaluate acute or chronic risk from residues of ethalfluralin in drinking water. PDP drinking water monitoring data are not appropriate for use in acute dietary exposure assessments, because the frequency of sample collection may not accurately capture peak drinking water values. However, for the purpose of chronic and cancer assessments, multiple years of data over multiple seasons and reflecting a variety of sampling regions are considered to provide an additional level of refinement over the use of modeled drinking water estimates. In the case of ethalfluralin, since estimated chronic risks based on more conservative modeled estimates are below the Agency's LOC, the additional refinement provided by the PDP data is not necessary. Therefore, for both the acute and chronic dietary exposure assessments EPA relied on estimates of ethalfluralin residues in drinking water developed through simulation or modeling taking into account data on the environmental fate characteristics of ethalfluralin. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated environmental concentrations (EECs) of ethalfluralin for acute exposures are estimated to be 11 ppb for surface water and 0.02 ppb for ground water. The EECs for chronic exposures are estimated to be 0.4 ppb for surface water and 0.02 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 11 ppb was used to access the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 0.4 ppb was used to access the contribution to drinking water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Ethalfluralin is not registered for use on any sites that would result in residential exposure.

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

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to ethalfluralin and any other substances and ethalfluralin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that ethalfluralin has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of FFDCA provides that EPA shall apply an additional ("10X") tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional FQPA safety factor value based on the use of traditional UFs and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* The prenatal and postnatal toxicology database for ethalfluralin includes a rat developmental toxicity study, several rabbit developmental toxicity studies and a 3–generation reproduction toxicity study in rats. There was no quantitative or qualitative evidence of increased prenatal or postnatal sensitivity in the rat developmental toxicity study or 3–generation reproduction toxicity study in rats. The rabbit developmental toxicity studies indicate the potential for ethalfluralin to induce skeletal malformations at doses of ≥ 150 mg/kg/day. These effects were seen in the presence of maternal toxicity.

Although there is evidence of increased qualitative susceptibility in young in the developmental toxicity studies in rabbits, there are no residual uncertainties and the degree of concern is low. The developmental effects seen at the LOAEL of 150 mg/kg/day are slight (mainly sternal variations in one or two fetuses, incomplete cranial development in 2 fetuses and a slight increase in resorptions). There is a clear NOAEL for these effects and the effects occurred in the presence of maternal toxicity. Additionally, the dose used for risk assessment purposes is 75 mg/kg/day, the NOAEL from the developmental studies in rabbits. Use of this NOAEL for risk assessment is protective of any potential developmental effects.

3. *Conclusion.* EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X. That decision is based on the following findings:

i. The toxicity database for ethalfluralin is complete.

ii. There is no indication that ethalfluralin is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. Although there is qualitative evidence of increased susceptibility in the prenatal developmental studies in rabbits, the risk assessment team did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment of ethalfluralin. The degree of concern for prenatal and/or postnatal toxicity is low.

iv. There are no residual uncertainties identified in the exposure databases.

The dietary food exposure assessments were performed based on 100 PCT and tolerance-level or anticipated residues derived using reliable field trial data. Conservative ground and surface water modeling estimates were used to assess threshold acute and chronic risks. These assessments will not underestimate the exposure and risks posed by ethalfluralin.

E. Aggregate Risks and Determination of Safety

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the aPAD and cPAD. The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to ethalfluralin will occupy less than 1% of the aPAD for females 13 to 49 years old, the population group of concern for acute exposure to ethalfluralin.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to ethalfluralin from food and water will utilize less than 1% of the cPAD for children, 1 to 2 years old, the population group with the greatest estimated exposure. There are no residential uses for ethalfluralin that result in chronic residential exposure to ethalfluralin.

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Ethalfluralin is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Ethalfluralin is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's LOC.

5. *Aggregate cancer risk for U.S. population.* Using the exposure assumptions described in this unit for the cancer risk assessment, EPA has concluded that exposure to ethalfluralin from food and water will result in a lifetime cancer risk of 2×10^{-6} for the U.S. population. This risk estimate is based, in part, on the conservative assumption that 100% of all crops for which ethalfluralin is registered or proposed for registration are treated. Additional refinement using PCT estimates would result in a lower estimate of dietary cancer risk.

EPA generally considers cancer risks in the range of 10^{-6} or less to be negligible. The precision which can be assumed for cancer risk estimates is best described by rounding to the nearest integral order of magnitude on the log scale; for example, risks falling between 3.16×10^{-7} and 3.16×10^{-6} are expressed as risks in the range of 10^{-6}. Considering the precision with which cancer hazard can be estimated, the conservativeness of low-dose linear extrapolation, and the rounding procedure described above, cancer risk should generally not be assumed to exceed the benchmark LOC of the range of 10^{-6} until the calculated risk exceeds approximately 3×10^{-6}. Since the calculated cancer risk for ethalfluralin falls below this level, estimated cancer risk is considered to be negligible.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to ethalfluralin residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression. Two gas chromatograph (GC) methods, Methods I and II, both with electron capture detection (ECD) are listed in the Pesticide Analytical Manual (PAM, Vol. II, section 180.416). Methods I and II are applicable for the analysis of ethalfluralin residues in/on plant and animal commodities, respectively. The limits of detection (LODs) are 0.01 and <0.01 ppm for methods I and II, respectively.

B. International Residue Limits

There are currently no Codex, Canadian, or Mexican Maximum Residue Limits (MRLs) established on the commodities associated with these petitions.

V. Conclusion

EPA has determined that the proposed tolerance on crambe is unnecessary, since, pursuant to 40 CFR 180.1(g), the tolerance being established for rapeseed also applies to residues of ethalfluralin on crambe. The rapeseed tolerance also covers residues of ethalfluralin in or on canola seed. Since there is no longer a need for the canola tolerance, EPA is removing this tolerance as requested in IR–4's petition.

Therefore, tolerances are established for residues of ethalfluralin, N-ethyl-N-(2-methyl-2-propenyl)-2,6-dinitro-4-(trifluoromethyl)benzenamine, in or on dill, dried leaves; dill, fresh leaves; mustard, seed; potato; and rapeseed, seed at 0.05 ppm. The current tolerance of 0.05 ppm on canola is removed.

VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866, 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) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments,

on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000) do not apply to this rule. In addition, This rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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 this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: November 26, 2007.

Donald R. Stubbs,

Acting Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.416 is amended by removing the current tolerance on "Canola, seed" and alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

§180.416 Ethalfluralin; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* *
Dill, dried leaves	0.05
Dill, fresh leaves	0.05
Mustard, seed	0.05
* * *	* *
Potato	0.05
Rapeseed, seed	0.05
* * *	* *

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[FR Doc. E7–23578 Filed 12–4–07; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0310; FRL–8339–8]

Spinosad; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of spinosad in or on spice, subgroup 19B, except black pepper; pineapple; and pineapple, process residue. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 5, 2007. Objections and requests for hearings must be received on or before February 4, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2007–0310. To access the electronic docket, go to *http://www.regulations.gov*, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (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 in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; e-mail address: *stanton.susan@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2007–0310 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before January 4, 2008.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2007–0310, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Tolerance

In the **Federal Register** of May 9, 2007 (72 FR 26375) (FRL–8128–1), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 6E7148) by Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201 W, Princeton, NJ 08540–6635. The petition requested that 40 CFR 180.495 be amended by establishing a tolerance for residues of the insecticide spinosad, in or on Spice crop subgroup 19B, except black pepper at 1.7 parts per million (ppm); pineapple at 0.02 ppm; and pineapple, process residue at 0.08 ppm. Spinosad is a fermentation product of *Saccharopolyspora spinosa*, consisting of two related active ingredients: Spinosyn A (Factor A; CAS # 131929–60–7) or 2-[(6-deoxy-2,3,4-tri-*O*-methyl-α-*L*-manno-pyranosyl)oxy]-13-[[5-(dimethylamino)-tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-14-methyl-1H-as-Indaceno[3,2-d]oxacyclododecin-7,15-dione; and Spinosyn D (Factor D; CAS # 131929–63–0) or 2-[(6-deoxy-2,3,4-tri-*O*-methyl-α-*L*-manno-pyranosyl)oxy]-13-[[5-(dimethyl-amino)-tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-4,14-methyl-1H-as-Indaceno[3,2-d]oxacyclododecin-7,15-dione. That notice referenced a summary of the petition prepared by Dow AgroSciences LLC, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. Comments were received on the notice of filing from a private citizen. EPA's response to these comments is discussed in Unit IV.C. below.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...." These provisions were added to FFDCA by the Food Quality Protection Act (FQPA) of 1996.

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerances for residues of spinosad on spice, subgroup 19B, except black pepper at 1.7 ppm; pineapple at 0.02 ppm; and Pineapple, process residue at 0.08 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by spinosad as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in the final rule published in the **Federal Register** of September 27, 2002 (67 FR 60923) (FRL–7199–5), available on-line at *http://www.epa.gov/fedrgstr/EPA-PEST/2002/September/Day-27/p24484.htm*.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the LOC to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the

human population as well as other unknowns. Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

The Agency has concluded that spinosad should be considered toxicologically identical to another pesticide, spinetoram. This conclusion is based on the following: (1) Spinetoram and spinosad are large molecules with nearly identical structures; and (2) the toxicological profiles for each are similar (generalized systemic toxicity) with similar doses and endpoints chosen for human-health risk assessment. Spinosad and spinetoram should be considered toxicologically identical in the same manner that metabolites are generally considered toxicologically identical to the parent.

Although, as stated above, the doses and endpoints for spinosad and spinetoram are similar, they are not identical due to variations in dosing levels used in the spinetoram and spinosad toxicological studies. EPA compared the spinosad and spinetoram doses and endpoints for each exposure scenario and selected the lower of the two doses for use in human risk assessment. A summary of the toxicological endpoints for spinosad and spinetoram used for human risk assessment can be found at *http://www.regulations.gov* in the document *Spinosad and Spinetoram. Human-Health Risk Assessment for Application of Spinosad to Pineapple and the Spice Subgroup (19B, except black pepper)* at page 11 in docket ID number EPA–HQ–OPP–2007–0310.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to spinosad, EPA considered exposure under the petitioned-for tolerances as well as all existing spinosad tolerances in 40 CFR 180.495. Since spinosad and spinetoram are toxicologically identical, EPA considered exposure to both in assessing aggregate risk. EPA assessed dietary exposures from spinosad and spinetoram in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure. No such effects were identified in the toxicological studies for spinosad and spinetoram; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* Spinosad and spinetoram are registered for use on the same crops; however, EPA has concluded it would overstate exposure to assume that residues of both spinosad and spinetoram would appear on the same crop. It is unlikely that both will be applied to the same crop, since spinosad and spinetoram control the same pest species. Rather, EPA aggregated exposure from residues of spinosad and spinetoram by assuming that spinosad residues would be present in all commodities, because side-by-side spinosad and spinetoram residue data indicated that spinetoram residues were less than or equal to spinosad residues. EPA assumed that 100 percent of each food crop commodity would be treated with spinosad. For feed crop commodities, EPA summed the percentage of the crop that would be treated with spinosad and the percentage expected to be treated with spinetoram and used this estimate in conjunction with spinosad residue data to develop anticipated residues for livestock commodities.

The chronic dietary exposure assessment was conducted using the Dietary Exposure Evaluation Model - Food Consumption Intake Database (DEEM™-FCID), Version 2.03, which incorporates food consumption data from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Continuing Surveys of Food Intakes by Individuals (CSFII). In addition to the Percent Crop Treated (PCT) assumptions described above, EPA, in estimating chronic exposure, relied upon average field trial residues for apple, leafy vegetables (except Brassica), citrus and fruiting vegetables; tolerance level residues for the remaining food crop commodities; average feed crop residues for feed commodities from the following crops: Sweet corn forage, leaves of root and tuber vegetables and aspirated grain fractions; average residues from animal feeding and dermal magnitude of residue studies; and DEEM™ (Version 7.81) default processing factors for all commodities, excluding field corn (meal, starch, flour and oil), grape juice and wheat (flour and germ), where processing factors based on the results of processing studies were assumed.

iii. *Cancer.* Based on the results of carcinogenicity studies in rats and mice, spinosad has been classified as "Not likely to be carcinogenic to humans." Preliminary results of a carcinogenicity study in mice indicate that spinetoram is not carcinogenic to mice at doses up to 37.5 milligram/kilogram/day (mg/kg/day). Based on these preliminary results and spinetoram's structural and toxicological similarity to spinosad, spinetoram is also considered to be "Not likely to be carcinogenic to humans." Consequently, a quantitative cancer exposure and risk assessment is not appropriate for spinosad or spinetoram.

iv. *Anticipated residue and PCT information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must pursuant to FFDCA section 408(f)(1) require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

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

a. The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue.

b. The exposure estimate does not underestimate exposure for any significant subpopulation group.

c. Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency

must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information as follows:

One-hundred percent crop treated was assumed for all food crop commodities and some feed crop commodities (aspirated grain fractions, sugarbeet molasses and cottonseed). For certain feed crop commodities, the Agency summed the projected PCT for spinosad and spinetoram and used the combined estimates in conjunction with average field trial residues to calculate cattle dietary burdens and anticipated residues of spinosad in meat and milk. The following combined projected PCT estimates were used: sweet corn forage (39%), sorghum grain (5%), soybean seed meal (5%) and leaves of root and tuber vegetables (50%).

Spinetoram is a new, recently registered pesticide. EPA estimates an upper bound of projected percent crop treated (PPCT) for a new pesticide use by assuming that its actual PCT during the initial 5 years of use on a specific use site will not exceed the recent PCT of the market leader (i.e., the one with the greatest PCT) on that site. EPA calls this the market leader PPCT estimate. In this specific case, the new use to be estimated is the combined use of spinosad together with that of spinetoram since the most new use of spinetoram will likely replace previous use of spinosad. An average market leader PCT, based on three recent surveys of pesticide usage, if available, is used for chronic risk assessment. The average market leader PCT may be based on one or two survey years if three are not available. Also, with limited availability of data, the average market leader PCT may be based on a cross-section of state PCTs. Comparisons are only made among pesticides of the same pesticide type (i.e., the leading insecticide on the use site is selected for comparison with the new insecticide), or, for refined estimates, among pesticides targeting the same pests. The market leader PCTs used to determine the average may be each for the same pesticide or for different pesticides for any year since the same or different pesticides may dominate for each year. Typically, EPA uses U.S. Department of Agriculture/National Agricultural Statistics Service (USDA/NASS) as the source for raw PCT data because it is publicly available. When a specific use site is not surveyed by USDA/NASS, EPA uses other sources including proprietary data.

An estimated PPCT, based on the average PCT of the market leaders, is appropriate for use in chronic dietary risk assessment. This method of estimating PPCT for a new use of a registered pesticide or a new pesticide produces a high-end estimate that is unlikely, in most cases, to be exceeded during the initial 5 years of actual use. Predominant factors that bear on whether the PPCT could be exceeded may include PCTs of similar chemistries, pests controlled by alternatives, pest prevalence in the market and other factors. All relevant information currently available for predominant factors has been considered for the combined use of spinetoram and spinosad on each of these several crops. It is the Agency's opinion that it is unlikely that actual combined PCTs for spinetoram and spinosad will exceed the corresponding estimated PPCTs during the next 5 years.

The PPCTs for the combined use of spinosad and spinetoram for chronic risk assessment were determined using the market leader approach for the feed commodities of sweet corn, grain sorghum, soybeans and turnip greens. For turnip greens, the PCTs of market leaders were averaged over states rather than years because only 1–year of data was available.

The Agency believes that the three conditions listed in this Unit have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which spinosad may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring data to complete a comprehensive dietary exposure analysis and risk assessment for spinosad in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the environmental fate characteristics of spinosad. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated environmental concentrations (EECs) of spinosad for acute exposures are estimated to be 34.5 parts per billion (ppb) for surface water and 1.1 ppb for ground water. The EECs for chronic exposures are estimated to be 10.5 ppb for surface water and 1.1 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. As explained above, an acute dietary risk assessment was not conducted for spinosad and spinetoram. For chronic dietary risk assessment, the water concentration of value 10.5 ppb was used to access the contribution to drinking water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

The Agency has concluded that spinosad and spinetoram are toxicologically equivalent; therefore, residential exposure to both spinosad and spinetoram was evaluated. Spinosad is currently registered for the following residential non-dietary sites: Homeowner application to turf grass and ornamentals to control a variety of worms, moths, flies, beetles, midges, thrips, leafminers and fire ants (granular formulation). Spinetoram is registered for homeowner applications to gardens, lawns/ornamentals and turf grass for control of lepidopterous larvae (worms or caterpillars), dipterous leafminers, thrips, sawfly larvae, certain psyllids and leaf-feeding beetles and red imported fire ants.

There is potential for residential handler and post-application exposures to both spinosad and spinetoram. Since spinosad and spinetoram control the same pests, EPA concludes that these products will not be used in

combination with each other and combining the residential exposures is unnecessary. Short-term residential inhalation risks were estimated for adult residential handlers, as well as short-term post-application incidental oral risks for toddlers, based on applications to home lawns, home gardens and ornamentals. Dermal exposures were not assessed, since no dermal endpoints of concern were identified in the toxicology studies for spinosad and spinetoram.

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

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to spinosad and any other substances and spinosad does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that spinosad has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of FFDCA provides that EPA shall apply an additional ("10X") tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional FQPA safety factor value based on the use of traditional UFs and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* The following acceptable studies are available for both spinosad and spinoteram: developmental toxicity studies in rats and rabbits and a two–generation reproduction study in rats. There is no evidence of increased susceptibility of rat or rabbit fetuses to *in utero* exposure to spinosad or spinetoram. In the spinosad and spinetoram rat and rabbit developmental toxicity studies, no developmental toxicity was observed at dose levels that induced maternal toxicity. In the spinosad two–generation reproduction study, maternal and offspring toxicity were equally severe, indicating no evidence of increased susceptibility. In the spinetoram 2–generation reproduction study, no adverse effects were observed in the offspring at dose levels that produced parental toxicity. Therefore, there is no evidence of increased susceptibility and there are no concerns or residual uncertainties for pre and/or post-natal toxicity.

3. *Conclusion.* EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X. That decision is based on the following findings:

i. The toxicity database for spinosad is complete. The toxicity database for spinetoram is adequate for this risk assessment despite the lack of a chronic toxicity study in rats. The preliminary review of a mouse carcinogenicity study for spinetoram provides evidence that the chronic toxicity of spinosad and spinetoram are comparable, since spinetoram produced similar toxicity at doses similar to those seen previously with spinosad. Therefore, it is expected that the ongoing spinetoram chronic carcinogenicity study in rats would produce similar chronic toxicity at a similar dose as was seen in the chronic toxicity study in rats with spinosad.

ii. There is no indication that spinosad or spinetoram are neurotoxic chemicals and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that spinosad or spinetoram results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2–generation reproduction studies.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on tolerance-level residues or anticipated residues derived from reliable field trial data. 100 PCT was assumed for all commodities except certain feed crop commodities. The projected PCT estimates used for these commodities are conservative, high-end estimates developed using the market leader approach that are unlikely to be exceeded. Conservative ground and surface water modeling estimates were used. Similarly, conservative Residential SOPs were used to assess incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by spinosad and spinetoram.

E. Aggregate Risks and Determination of Safety

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the aPAD and cPAD. The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* None of the toxicology studies available for spinosad or spinetoram has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure; therefore, spinosad and spinetoram are not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to spinosad and spinetoram from food and water will utilize 81% of the cPAD for children, 1 to 2 years old, the population group with the greatest estimated exposure. Based on the use patterns, chronic residential exposure to residues of spinosad or spinetoram is not expected.

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

Spinosad and spinetoram are currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for spinosad and spinetoram. Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food, water, and residential exposures aggregated result in aggregate MOEs of 650 to 710 for adults and 180 to 300 for infants and children. The aggregate MOEs for adults are based on the residential turf scenario and include combined food, drinking water and handler inhalation exposures

to spinetoram. Inhalation exposures are not expected for residential handlers of spinosad, based on its granular formulation and low vapor pressure. The aggregate MOEs for infants and children include food, drinking water and incidental oral exposures on turf areas previously treated with spinosad or spinetoram. Dermal exposures were not assessed for adults or children, since a dermal endpoint of concern was not identified in the toxicology studies for spinosad or spinetoram.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Spinosad is not registered for use on any sites that would result in intermediate-term (1–6 months) residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which does not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population.* Based on the results of carcinogenicity studies with spinosad in rats and mice and the preliminary results of a carcinogenicity study with spinetoram in mice, spinosad and spinetoram are considered "Not likely to be carcinogenic to humans." Spinosad and spinetoram are not expected to pose a cancer risk.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to spinosad and spinetoram residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

DowElanco Method 97.05, an immunoassay particle-based method, and Dow AgroSciences Method GRM 03.15, a high performance liquid chromatography method with ultraviolet absorption detection (HPLC/UV), have been adequately validated and determined to be acceptable to enforce the tolerance expression in spices and pineapple, respectively. The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov.*

B. International Residue Limits

There are currently no established Codex, Canadian, or Mexican maximum residue levels (MRLs) for spinosad (i.e., the combined residues of spinosyn A and D).

C. Response to Comments

Several comments were received from a private citizen, B. Sachau, objecting to establishing these tolerances for a variety of generalized and unsubstantiated reasons, including the lack of "combinant" testing and long-term testing, pesticide residues and unacceptable risk to Americans. The Agency has received these same or similar comments from this commenter on numerous previous occasions. Refer to **Federal Registers** of June 30, 2005 (70 FR 37683) (FRL–7718–3), January 7, 2005 (70 FR 1349) (FRL–7691–4), and October 29, 2004 (69 FR 63083) (FRL–7681–9) for the Agency's response to these objections. The commenter also objected to issuance of "exemptions" for this pesticide, an irrelevant comment in the context of this tolerance-setting action. Finally, this same commenter raised concerns about risk to insects and other animals from spinosad. EPA considers such environmental risks in deciding whether to register pesticide products under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); however, the safety standard for approving tolerances under section 408 of the FFDCA focuses on potential harms to human health and does not permit consideration of effects on the environment. Therefore, the comment regarding risk to insects and other animals is not relevant to this tolerance action.

V. Conclusion

Therefore, tolerances are established for residues of spinosad, consisting of two related active ingredients: Spinosyn A (Factor A; CAS # 131929–60–7) or 2-[(6-deoxy-2,3,4-tri-*O* -methyl-α-*L*-manno-pyranosyl)oxy]-13-[[5-(dimethylamino)-tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-14-methyl-1H-as-Indaceno[3,2-d]oxacyclododecin-7,15-dione; and Spinosyn D (Factor D; CAS # 131929–63–0) or 2-[(6-deoxy-2,3,4-tri-*O*-methyl-α-*L*-manno-pyranosyl)oxy]-13-[[5-(dimethyl-amino)-tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-4,14-methyl-1H-as-Indaceno[3,2-d]oxacyclododecin-7,15-dione, in or on Spice, subgroup 19B, except black pepper at 1.7 ppm; Pineapple at 0.02 ppm; and Pineapple, process residue at 0.08 ppm.

The table of spinosad tolerances at 40 CFR 180.495(a) currently includes a third column for expiration/revocation dates. Since none of the existing tolerances are time-limited and EPA is not time-limiting the new tolerances for spice and pineapple commodities, there is no need for this column. Therefore, the third column of the table is being deleted.

Time-limited tolerances were established at 40 CFR 180.495(b) for residues of spinosad in or on livestock commodities in connection with FIFRA section 18 emergency exemptions granted by EPA. All of these time-limited tolerances have expired and are no longer necessary, because permanent tolerances have been established on these commodities at higher levels. Therefore, these expired, time-limited tolerances for residues of spinosad (Factor A and Factor D) are revoked.

Finally, EPA is correcting the commodity terminology for "Vegetable, brassica, leafy, group 5" in 40 CFR 180.495(a) to read "Brassica, leafy greens, subgroup 5B" at 10.0 ppm, to undo a transcription error. In 1998, EPA established spinosad tolerances for the two subgroups in Crop Group 5 - Brassica (Cole) Leafy Vegetables (40 CFR 180.41(c)(5). (63 FR 18329, April 15, 1998). The two subgroups in Group 5 are Crop Subgroup 5A - Head and Stem Brassica and Crop Subgroup 5B - Leafy Brassica Greens. Tolerances were established for the subgroups at levels of 2 ppm and 10 ppm respectively. No tolerance applying across the whole brassica crop group was established. Subsequently, in a rulemaking establishing spinosad tolerances for various non-brassica commodities the tolerance for the "greens" subgroup was incorrectly transcribed as a tolerance for the entire brassica group (70 FR 1349, January 7, 2005). This transcription error occurred when the tolerance table, as revised by the addition of the new non-brassica tolerances, was printed in the **Federal Register**. The changing of the subgroup tolerance to a group tolerance was clearly nothing more than a transcription error, because it was not mentioned in the notice of filing for the rulemaking or the preamble to the final rule. Moreover, it is inconsistent with the generic crop group regulation to establish both a crop group and subgroup of that crop group for the same pesticide because the former would displace the latter. This change merely corrects the tolerance regulation to specify the crop subgroup tolerance that was actually promulgated, since this tolerance is intended to cover only those commodities in the "greens" subgroup. A separate, lower tolerance of 2.0 ppm has been established to cover head and stem Brassica in subgroup 5A. The tolerance for the "greens" subgroup was incorrectly modified in connection with the establishment of new spinosad

tolerances in the **Federal Register** of January 7, 2005 (70 FR 1349).

EPA finds there is good cause to make these latter three changes without prior notice and comment because they are technical corrections which either eliminate obsolete or unused portions of the regulation or correct a transcription error. EPA concludes notice and comment are unnecessary on such changes.

VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866, 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) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000) do not apply to this rule. In addition, This rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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 this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: November 27, 2007.

Donald R. Stubbs,

Acting Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. Section 180.495 is revised to read as follows:

§ 180.495 Spinosad; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide spinosad in or on the food commodities in the table to this paragraph. Spinosad is a fermentation product of *Saccharopolyspora spinosa.* The product consists of two related active ingredients: Spinosyn A (Factor A: CAS # 131929–60–7) or 2-[(6-deoxy-2,3,4-tri-*O* -methyl-α-*L*-manno-pyranosyl)oxy]-13-[[5-(dimethylamino)-tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-14-methyl-1H-as-Indaceno[3,2-d]oxacyclododecin-7,15-dione; and Spinosyn D (Factor D; CAS # 131929–63–0) or 2-[(6-deoxy-2,3,4-tri-*O*-methyl-α-*L*-manno-pyranosyl)oxy]-13-[[5-(dimethyl-amino)-tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-4,14-methyl-1H-as-Indaceno[3,2-d]oxacyclododecin-7,15-dione.

Commodity	Parts per million
Acerola	1.5
Alfalfa, seed	0.15
Alfalfa, seed screenings	2.0
Almond, hulls	2.0
Amaranth, grain, grain	1.0
Amaranth, grain, stover	10
Animal feed, nongrass, group, 18	0.02
Animal feed, nongrass, group, 18, forage	35.0
Animal feed, nongrass, group, 18, hay	30.0
Apple pomace	0.5
Artichoke, globe	0.3
Asparagus	0.2
Atemoya	0.3
Avocado	0.3
Banana	0.25
Beet, sugar, molasses	0.75
Biriba	0.3
Brassica, head and stem, subgroup 5A	2.0
Brassica, leafy greens, subgroup 5B	10.0
Bushberry subgroup 13B	0.250
Caneberry subgroup 13A	0.7
Canistel	0.3
Cattle, fat	50
Cattle, liver	10
Cattle, meat	2.0
Cattle, meat byproducts, except liver	5.0
Cherimoya	0.3
Citrus, oil	3.0
Citrus, dried pulp	0.5
Coriander, leaves	8.0
Corn, sweet, kernel plus cob with husks removed	0.02
Cotton, gin byproducts	1.5
Cotton, undelinted seed	0.02
Cranberry	0.01
Custard apple	0.3
Egg	0.30
Feijoa	.05
Fig	0.10
Fish	4.0
Fish-shellfish, crustacean	4.0
Fish-shellfish, mollusc	4.0
Food commodities	0.02
Fruit, citrus, group 10	0.3
Fruit, pome, group 11	0.20

Commodity	Parts per million
Fruit, stone, group 12	0.20
Goat, fat	50
Goat, liver	10
Goat, meat	2.0
Goat, meat byproducts, except liver	5.0
Grain, aspirated fractions	200
Grain, cereal, group 15	1.5
Grain, cereal, group 16, forage, except rice	2.5
Grain, cereal, group 16, hay, except rice	10.0
Grain, cereal, group, 16, stover, except rice	10.0
Grain, cereal, group, 16, straw, except rice	1.0
Grape	0.50
Grape, raisin	0.70
Grass, forage, fodder and hay, group 17, forage	10.0
Grass, forage, fodder and hay, group 17, hay	5.0
Guava	0.3
Herb subgroup 19A, dried	22
Herb subgroup 19A, fresh	3.0
Hog, fat	33
Hog, meat byproducts	8.0
Hog, meat	1.5
Hop, dried cones	22
Horse, fat	50
Horse, liver	10
Horse, meat	2.0
Horse, meat byproducts, except liver	5.0
Ilama	0.3
Jaboticaba	0.3
Juneberry	0.25
Lingonberry	0.250
Longan	0.3
Lychee	0.3
Mango	0.3
Milk	7.0
Milk, fat	85
Nut, tree, group 14	0.02
Okra	0.40
Onion, green	2.0
Papaya	0.3
Passionfruit	0.3
Pea and bean, dried shelled, except soybean, subgroup 6C	0.02
Pea and bean, succulent shelled, subgroup 6B	0.02
Peanut	0.02
Peanut, hay	11.0
Peppermint, tops	3.5
Pineapple	0.02
Pineapple, process residue	0.08
Pistachio	0.020
Poultry, fat	1.3
Poultry, meat	0.10
Poultry, meat byproducts	0.10
Pulasan	0.3
Rambutan	0.3
Rice, hulls	4.0
Salal	0.250
Sapodilla	0.3
Sapote, black	0.3
Sapote, mamey	0.3
Sapote, white	0.3
Sheep, fat	50
Sheep, liver	10
Sheep, meat	2.0
Sheep, meat byproducts, except liver	5.0
Soursop	0.3
Soybean	0.02
Spanish lime	0.3
Spearmint, tops	3.5
Spice, subgroup 19B, except black pepper	1.7
Star apple	0.3
Starfruit	0.3
Strawberry	1.0
Sugar apple	0.3
Ti, leaves	10.0
Vegetable, bulb, group 3, except green onion	0.10
Vegetable, cucurbit, group 9	0.3
Vegetable, foliage of legume, group 7	8.0
Vegetable, fruiting, group 8	0.4
Vegetable, leafy, except brassica, group 4	8.0
Vegetable, leaves of root and tuber, group 2	10.0
Vegetable, legume, edible podded, subgroup 6A	0.30
Vegetable, root and tuber, group 1	0.10
Watercress	8.0
Wax jambu	0.3

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertant residues.* [Reserved]

[FR Doc. E7–23579 Filed 12–4–07; 8:45 am]

BILLING CODE 6560–50–S

Proposed Rules

Federal Register
Vol. 72, No. 233
Wednesday, December 5, 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 AGRICULTURE

Agricultural Marketing Service

7 CFR Part 51

[Docket # AMS–FV–07–0010; FV–06–302]

United States Standards for Grades of Sweet Cherries

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Advanced notice of proposed rulemaking; withdrawal.

SUMMARY: The Agricultural Marketing Service (AMS) is withdrawing the notice soliciting comments on its proposal to amend the voluntary United States Standards for Grades of Sweet Cherries. After reviewing and considering the comments received, the agency has decided not to proceed with this action.

EFFECTIVE DATE: December 5, 2007.

FOR FURTHER INFORMATION CONTACT: Vincent J. Fusaro, Standardization Section, Fresh Products Branch, (202) 720–2185. The United States Standards for Grades of Sweet Cherries are available by accessing the Fresh Products Branch Web site at: *http://www.ams.usda.gov/standards/stanfrfv.htm.*

Background

AMS identified the United States Standards for Grades of Sweet Cherries for possible revisions. The revision would have included adding standardized row sizes into the standard. These standardized row sizes would establish a uniform basis for defining size in the industry. The standards were last revised on May 7, 1971.

On March 30, 2007, AMS published a proposed rule in the **Federal Register** (72 FR 15055) soliciting comments on a possible revision to the United States Standards for Grades of Sweet Cherries. The sixty-day comment period ended May 29, 2007.

Three comments were received. All three comments received, one from a grower, packer, shipper, another from a separate grower, packer, shipper, and one from an association representing independent wholesale receivers, were in opposition to revising the United States Standards for Grades of Sweet Cherries. The first commentor stated that the current standard has not been a problem as it is currently written. The second commenter stated that adding standardized row sizes would limit the ability of farmers to market their sweet cherry crop. This commenter also stated that the market already enforced sizing standards that are firm but flexible, which is necessary because sweet cherries are highly perishable and subject to fluctuations in crop size and market conditions. The third commenter stated that there was concern about the viability of the proposal. This commentor suggested several different solutions, however, those solutions are not within the scope of this proposal and therefore will not be addressed in this action. These comments are available by accessing the *http://www.regulations.gov* Web site.

After reviewing and considering the comments received, AMS has decided not to proceed with the action. Therefore, the proposed rule published March 30, 2007 (72 FR 15055) is withdrawn.

Authority: 7 U.S C. 1621–1627.

Dated: November 29, 2007.

Lloyd C. Day,

Administrator, Agricultural Marketing Service.

[FR Doc. E7–23531 Filed 12–4–07; 8:45 am]

BILLING CODE 3410–02–P

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Parts 4041 and 4042

RIN 1212–AB14

Disclosure of Termination Information

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Proposed rule.

SUMMARY: This is a proposed rule to implement section 506 of the Pension Protection Act of 2006 (Pub. L. 109–280) which amends sections 4041 and 4042 of ERISA. These amendments require that a plan administrator disclose information it has submitted to PBGC in connection with a distress termination filing, and that a plan administrator or plan sponsor disclose information it has submitted to PBGC in connection with a PBGC-initiated termination. The new provisions also require PBGC to disclose the administrative record in a PBGC-initiated termination. The disclosures must be made to an affected party upon request.

DATES: Comments must be submitted on or before February 4, 2008.

ADDRESSES: Comments, identified by Regulatory Information Number (RIN 1212–AB14), may be submitted by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the Web site instructions for submitting comments.
- *E-mail: reg.comments@pbgc.gov.*
- *Fax:* 202–326–4224.
- *Mail or Hand Delivery:* Legislative and Regulatory Department, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005–4026.

Comments received, including personal information provided, will be posted to *http://www.pbgc.gov.* Copies of comments may also be obtained by writing to Disclosure Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005–4026, or calling 202–326–4040 during normal business hours. (TTY and TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4040.)

FOR FURTHER INFORMATION CONTACT: Kenneth Cooper, Attorney, Office of the General Counsel; or Catherine Klion, Manager, Regulatory and Policy Division, Legislative and Regulatory Department, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005–4026; 202–326–4024. (TTY/TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4024.)

SUPPLEMENTARY INFORMATION:

Background

Pension Benefit Guaranty Corporation ("PBGC") administers the pension plan termination insurance program under Title IV of the Employee Retirement Income Security Act of 1974, as amended ("ERISA"), 29 U.S.C. 1301–1461. Sections 4041 and 4042 of ERISA

govern the termination of single-employer defined benefit pension plans that are subject to Title IV. A plan administrator may initiate a distress termination by sending a notice of intent to terminate to all affected parties pursuant to section 4041(a)(2). Under section 4042 of ERISA, PBGC may itself initiate proceedings to terminate a pension plan if it determines that certain conditions are present.

Under section 4041(c), a single-employer plan may terminate in a distress termination if PBGC determines that the requirements of section 4041(c)(2)(B) are met. Before PBGC can make this determination, the plan administrator must provide certain information to PBGC pursuant to section 4041(c)(2)(A). Under section 4041.45(c) of PBGC's regulation on Termination of Single Employer Plans, 29 CFR part 4041, PBGC may also require the submission of additional information.

PBGC determines whether a plan meets the criteria for a distress termination or a PBGC-initiated termination through an informal adjudicatory process. If PBGC staff believe that a plan should be terminated, a written recommendation is prepared. With certain exceptions, the recommendation is then reviewed by the Trusteeship Working Group ("TWG"), an interdepartmental body comprised of representatives from PBGC's financial, actuarial, policy, regulatory, and legal departments. If the TWG agrees with the staff recommendation, it forwards its own recommendation concerning the termination to the Director or other designated official ("Deciding Official"). All determinations are documented in a trusteeship decision record.

As part of the informal adjudicatory process, PBGC staff may present or make available to the TWG information and documents that relate to a termination recommendation and, if the TWG recommends termination, to the Deciding Official. This material may include information that PBGC has obtained from the plan sponsor or plan administrator, as well as other information that PBGC has obtained or generated.

For PBGC-initiated terminations, if the Deciding Official approves the termination, PBGC sends a notice to the plan administrator that the determination has been made ("Notice of Determination"). The plan may then be terminated by agreement or PBGC may apply to the appropriate district court for a decree adjudicating that the plan must be terminated.

PPA 2006 Amendments

On August 17, 2006, the President signed into law the Pension Protection Act of 2006, Pub. L. 109–280 ("PPA 2006"). Section 506 of PPA 2006 adds disclosure provisions to both sections 4041 and 4042 of ERISA. These provisions allow an affected party to request information related to a plan termination from the plan administrator in the case of a distress termination under section 4041, and from the plan administrator, plan sponsor, and PBGC in the case of a termination under section 4042. "Affected party" is defined in section 4001(a)(21) of ERISA to include each participant in the plan, each beneficiary under the plan, each employee organization representing plan participants, and PBGC.

With respect to distress terminations, the new provisions require that a plan administrator that has filed a Notice of Intent to Terminate must provide to an affected party, upon request, information submitted to PBGC in conjunction with the distress termination. This information must be provided not later than 15 days after receipt of the request. One of the new provisions allows a court to limit disclosure of confidential information to an authorized representative of the participants and beneficiaries that agrees to keep the information confidential.

With respect to PBGC-initiated terminations, the new provisions require that, following receipt by the plan administrator of a Notice of Determination, the plan sponsor, plan administrator, and PBGC must provide information related to the termination to an affected party upon request. The plan sponsor or plan administrator must, not later than 15 days after receipt of a request, provide copies of any information it provided to PBGC in connection with the termination. PBGC must, not later than 15 days after receipt of a request, provide a copy of the administrative record, including the trusteeship decision record. As in the distress termination provisions, one of the new provisions allows a court to limit disclosure of confidential information to an authorized representative. The new provisions are applicable to terminations initiated on or after August 17, 2006.

Proposed Regulation

General Provisions

Section 506 of PPA 2006 generally requires that information be provided to an affected party upon request. The proposed regulation requires that all requests to the plan administrator, plan sponsor, or PBGC be made in writing, and contain information relating to the plan, and the requestor's status as an affected party.

Section 506 of PPA 2006 requires that the plan administrator, plan sponsor, or PBGC provide information not later than 15 days after receipt of a request. A plan administrator or plan sponsor must also provide information not later than 15 days after the submission of additional information to PBGC. For this purpose, because a large amount of information may need to be disclosed in a short time, PBGC is interpreting "day" to mean "business day," as defined in § 4000.22 of the PBGC's regulation on Filing, Issuance, Computation of Time, and Record Retention, 29 CFR part 4000.

Sections 4041(c)(2)(D)(iii) and 4042(c)(3)(D) of ERISA, added by PPA 2006, state that PBGC may prescribe the form and manner of the provision of information under the respective provisions. These provisions state that information may be delivered "in written, electronic or other appropriate form to the extent such form is reasonably accessible" to the individual who makes the request. PBGC's issuance rules in part 4000, subpart B, are appropriate for the provision of information under sections 4041(c)(2)(D)(iii) and 4042(c)(3)(D). Accordingly, the provision of information under section 4041(c)(2)(D)(iii) will be governed by § 4041.3 of PBGC's current regulation, which provides that subpart B of part 4000 applies to issuances relating to plan terminations. The date of issuance will be determined in accordance with part 4000, subpart C, as provided in § 4041.3.

With respect to a PBGC-initiated termination, the proposed regulation requires that a plan administrator or plan sponsor respond to a request under section 4042(c)(3)(D) in accordance with part 4000, subpart B. The proposed regulation further provides that the date of issuance is determined in accordance with the rules in part 4000, subpart C.

Sections 4041(c)(2)(D)(iii)(II) and 4042(c)(3)(D)(ii) provide that a plan administrator, in the case of a distress termination, and a plan sponsor, in the case of a PBGC-initiated termination, may charge a reasonable fee for any information provided in other than electronic form. Unlike the "form and manner" provisions, the provisions on fees do not give PBGC authority to prescribe what constitutes a reasonable fee. PBGC does not believe it can prescribe such fees in the absence of specific statutory authorization.

Information To Be Disclosed by Plan Administrator in Distress Terminations

Under section 4041(a)(2) of ERISA, a plan administrator that seeks to terminate a plan in a distress termination must provide a notice of intent to terminate to each affected party. The notice must include information required under PBGC's regulations. Section 4041.43 of PBGC's regulation on Termination of Single Employer Plans specifies the information that must be included in a notice of intent to terminate that is issued to affected parties other than PBGC. The regulation also requires that a separate notice with additional information be filed with PBGC on PBGC Form 600, Distress Termination, Notice of Intent to Terminate. After the notices of intent to terminate have been issued to affected parties other than PBGC and the Form 600 has been filed with PBGC, additional information must be submitted to PBGC at a later date in accordance with section 4041(c)(2) of ERISA and § 4041.45 of the regulation.

Section 4041(c)(2)(D)(i) of ERISA, added by PPA 2006, states in relevant part:

> A plan administrator that has filed a notice of intent to terminate under subsection (a)(2) shall provide to an affected party any information provided to the corporation under subsection (a)(2) not later than 15 days after—
>
> (I) receipt of a request from the affected party for the information; or
>
> (II) the provision of new information to the corporation relating to a previous request.

PBGC is interpreting this provision as requiring disclosure of the Form 600 and any additional information submitted to PBGC under section 4041(c)(2) of ERISA. PBGC recognizes that because the statute references only section 4041(a)(2), which addresses the notice of intent to terminate, it is possible to read section 4041(c)(2)(D)(i) as requiring that a plan administrator disclose only the Form 600. Such a narrow reading, however, would be at odds with Congress's intent to provide greater disclosure of information submitted to PBGC in connection with a distress termination.

The Technical Explanation of PPA 2006 prepared by the staff of the Joint Committee on Taxation states that section 506 requires "a plan administrator to provide an affected party with any information provided to the PBGC in connection with the proposed plan termination." The broad reference to "any information * * * in connection with the proposed plan termination"—without the limitation to section 4041(a)(2)—suggests the required disclosures include information submitted to PBGC under section 4041(c)(2), in addition to the Form 600 filed pursuant to section 4041(a)(2) and the implementing regulation. Further, because a plan administrator files the Form 600 once, requiring disclosure of only the Form 600 would give no effect to the requirement in section 4041(c)(2)(D)(i)(II) that a plan administrator must provide copies of new information it submits to PBGC not later than 15 days after such submission.

In light of these considerations, the proposed regulation provides that, upon written request of an affected party, a plan administrator must provide copies of any information submitted to PBGC pursuant to sections 4041(a)(2) and 4041(c)(2) of ERISA and sections 4041.43 and 4041.45 of the regulation not later than 15 business days after receipt of the request. If PBGC Form 600 has not been filed with PBGC at the time of the request, the proposed regulation requires the plan administrator to provide the information not later than 15 business days after PBGC Form 600 is filed. In addition, the proposed regulation requires that if the plan administrator has provided information in response to a request and later submits additional information to PBGC in connection with the proposed distress termination, the plan administrator must, not later than 15 business days after the submission, provide copies of that information to any affected party that has made a previous request.

If a plan administrator fails to provide information under section 4041(c)(2)(D)(i) of ERISA and the implementing regulation within the specified timeframe, PBGC may assess penalties under section 4071 of ERISA.

Information To Be Disclosed by Plan Administrator and Plan Sponsor in a Termination Initiated by PBGC

Section 4042(c)(3) of ERISA imposes disclosure requirements on the plan administrator, the plan sponsor, and PBGC in connection with a PBGC-initiated termination. With regard to the plan sponsor and plan administrator, the statute provides that, upon request:

> A plan sponsor or plan administrator of a single-employer plan that has received a notice from [PBGC] of a determination that the plan should be terminated under this section shall provide to an affected party any information provided to the corporation in connection with the plan termination. Section 4042(c)(3)(A)(i).

Under this provision, an affected party may request termination information only after the plan administrator has received a Notice of Determination from PBGC that the plan should be terminated. The proposed regulation adopts an assumed receipt date of 3 business days after PBGC issues the Notice of Determination. Thus, a request for information may be made on or after the third business day after the Notice of Determination is issued. Once such a request is received by the plan administrator or plan sponsor, the information must be provided not later than 15 business days after receipt of the request. As in the case of a distress termination, if new information relating to the request is submitted to PBGC, copies must be provided, not later than 15 business days after the submission, to any affected party that has made a previous request.

A plan administrator or plan sponsor that fails to provide information requested under section 4042(c)(3) of ERISA and the implementing regulation within the specified timeframe may be subject to penalties under section 4071 of ERISA.

Disclosure of Administrative Record by PBGC in Terminations Initiated by PBGC

Section 4042(c)(3)(A)(ii) of ERISA states that, upon request of an affected party, PBGC "shall provide a copy of the administrative record, including the trusteeship decision record of a termination of a plan" not later than 15 days after receipt of the request. The right to request a copy of the administrative record arises only after a Notice of Determination that the plan should be terminated is received by the plan administrator. As in the provisions relating to requests for information from the plan administrator or plan sponsor, the proposed regulation adopts an assumed receipt date of 3 business days after PBGC issues the Notice of Determination. Thus, a request for the administrative record may be made on or after the third business day after the Notice of Determination is issued. The proposed regulation further provides that PBGC will send the administrative record to the affected party not later than 15 business days after it receives the request, and will use measures reasonably calculated to ensure actual receipt (including electronic measures). This standard is analogous to the requirements in Part 4000, subpart B, that the plan administrator and plan sponsor must follow.

Disclosure of Confidential Information by Plan Administrator and Plan Sponsor

Sections 4041(c)(2)(D)(ii)(I) and 4042(c)(3)(C)(i) of ERISA prohibit the disclosure by the plan administrator, in connection with a distress termination, and the plan administrator or plan sponsor, in connection with a PBGC-initiated termination, of information "that may directly or indirectly be associated with, or otherwise identify, an individual participant or beneficiary." The proposed regulation incorporates this restriction.

In addition, both sections 4041(c)(2)(D)(ii)(I) and 4042(c)(3)(C)(i) of ERISA provide a means for a plan sponsor or plan administrator to seek to restrict the disclosure of confidential information that would be exempt from disclosure under Freedom of Information Act ("FOIA"). Under section 552(b)(4) of FOIA, an agency has discretion to withhold documents on matters that are "trade secrets and commercial or financial information obtained from a person and privileged or confidential." Sections 4041(c)(2)(D)(ii)(II) and 4042(c)(3)(C)(ii) provide that a court may limit disclosure of confidential information described in section 552(b) of FOIA, 5 U.S.C. 552(b), to "authorized representatives * * * of the participants or beneficiaries that agree to ensure the confidentiality of such information." Section 4041(c)(2)(D)(iv) defines "authorized representative" for purposes of both sections 4041 and 4042 as "any employee organization representing participants in the pension plan." Accordingly, the proposed regulation provides that a plan administrator that has received a request for information in connection with a distress termination, and a plan administrator or plan sponsor that has received a request for information in connection with a PBGC-initiated termination, may seek a court order under which confidential information described in 5 U.S.C. 552(b) will be disclosed only to authorized representatives (within the meaning of section 4041(c)(2)(D)(iv) of ERISA) that agree to ensure the confidentiality of such information, and will not be disclosed to other affected parties.

Typically, the authorized representative will be a labor union in a plan maintained in conjunction with a collective bargaining agreement. However, there may be no authorized representative where the participants are not covered under a collective bargaining agreement. The new PPA 2006 provisions do not address limiting disclosure of confidential information in such cases.

Disclosure of Confidential Information by PBGC

By its terms, section 4042(c)(3)(C)(i) of ERISA, which prohibits disclosure of information that identifies an individual participant or beneficiary, applies to a plan administrator or plan sponsor, but not to PBGC. This may be because PBGC is already prohibited from disclosing such information. Under the Privacy Act, 5 U.S.C. 552a, PBGC is prohibited from disclosing personally identifiable information with regard to a participant or beneficiary, without the individual's written consent. There are narrow exceptions stated in 5 U.S.C. 552a(b), but none apply to disclosure of identifying information that may be part of the administrative record in a PBGC-initiated termination. Accordingly, the proposed regulation states that PBGC shall not disclose any portions of the administrative record that are prohibited from disclosure under 5 U.S.C. 552a.

With respect to disclosure of confidential information, PBGC believes that, under the provisions added by section 506 of PPA 2006, it must disclose any part of the administrative record that contains confidential information, except as limited by a court. Unlike FOIA, which specifies categories of information that are exempt from disclosure, there are no exemptions under section 4042(c)(3) of ERISA. Rather, disclosure may only be limited by a court to the extent provided in section 4042(c)(3)(C)(ii).

In addition, PBGC believes that the Trade Secrets Act, 18 U.S.C. 1805, does not apply to disclosure of the administrative record under section 4042(c)(3) of ERISA. The Trade Secrets Act prohibits disclosure of trade secrets and related information "to any extent not authorized by law." PBGC believes that the disclosure requirements with respect to PBGC, as set forth in section 4042(c)(3), compel PBGC to disclose the administrative record upon request, subject only to limitation by a court as provided in section 4042(c)(3)(C)(ii). As a result, such disclosure is "authorized by law."

Additionally, PBGC does not believe that information it receives under sections 4010 or 4043 of ERISA that becomes part of an administrative record is exempt from disclosure under section 4042(c)(3). Information and documents submitted to PBGC under those sections are "exempt from disclosure under [FOIA], and * * * may not be made public, except as may be relevant to any administrative or judicial action or proceeding." 29 U.S.C. 1310(c), 1343(f). The exemption from disclosure under FOIA does not apply to disclosure of the administrative record because requests for the administrative record are made under section 4042(c)(3), not under FOIA. In addition, since material in the administrative record relates to an administrative action or proceeding, the restriction on making such material public does not apply.

To address the potential disclosure of confidential information that is part of an administrative record, the proposed regulation provides that PBGC will promptly notify the plan administrator and plan sponsor upon receipt of a request for the administrative record from an affected party. PBGC expects that this notification will be made not later than the second business day after receipt of the request. Under the proposed regulation, the plan administrator or plan sponsor may then seek a court order under which disclosure of those portions of the administrative record that contain confidential information described in 5 U.S.C. 552(b) will be made only to authorized representatives (within the meaning of section 4041(c)(2)(D)(iv) of ERISA) that agree to ensure the confidentiality of such information, and will not be disclosed to other affected parties. The proposed regulation further provides that if PBGC receives such a court order prior to the 15th business day after PBGC receives a request for the administrative record, PBGC will disclose confidential information that is part of the administrative record as provided in the order.

Applicability

The amendments in this proposed regulation would be applicable to terminations initiated on or after August 17, 2006, but only to requests for information made on or after the effective date of the final rule.

Compliance With Rulemaking Guidelines

E.O. 12866

The PBGC has determined, in consultation with the Office of Management and Budget, that this rule is a "significant regulatory action" under Executive Order 12866. The Office of Management and Budget has therefore reviewed this notice under E.O. 12866. Pursuant to section 1(b)(1) of E.O. 12866 (as amended by E.O. 13422), PBGC identifies the following specific problems that warrant this agency action:

• The statute does not specify the form and manner in which information requested must be provided to the affected party, but instead states that PBGC may prescribe such requirements. Without rules for how the information is to be provided, plan administrators and plan sponsors will not know whether the method they choose for providing requested information is appropriate.

• There is uncertainty in the statute with respect to the information that a plan administrator that has filed a notice of intent to terminate a plan in a distress termination must provide, upon request, to an affected party. Without rules for what information is to be provided, plan administrators will not know what information they must provide, and affected parties will not know what information they are entitled to receive.

• There is uncertainty in the statute with respect to determining the date as of which an affected party may request information provided to PBGC in connection with a PBGC-initiated termination. Without clarification, affected parties will not know when they can begin to request information, and plan administrators, plan sponsors, and PBGC will not know when their obligation to provide information arises.

• Unlike FOIA, which specifies categories of information that are exempt from disclosure, section 4042(c)(3)(c)(ii) of ERISA provides only that a court may limit disclosure by PBGC of confidential information described in section 552(b) to an authorized representative. The statute does not specify when and by whom court limitation may be sought in cases where PBGC receives a request for the administrative record. Without clarification, plan administrators and plan sponsors will not know how disclosure of confidential information they submitted to PBGC can be limited.

Regulatory Flexibility Act

PBGC certifies under section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) that the amendments in this proposed regulation would not have a significant economic impact on a substantial number of small entities. Accordingly, as provided in section 605 of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), sections 603 and 604 do not apply.

The proposed rule would implement statutory changes made by Congress. It would prescribe the form and manner for providing requested information and clarify the type of information that must be provided and the timeframes for providing such information. It would also provide for notification by PBGC to the plan sponsor and plan administrator of a request for an administrative record so that the plan sponsor or plan administrator can, if it chooses, seek a court order limiting disclosure of confidential information as provided in the statute. These provisions impose no significant burden beyond the burden imposed by statute.

Paperwork Reduction Act

PBGC is submitting the information collection requirements under this proposed regulation to the Office of Management and Budget for review and approval under the Paperwork Reduction Act. Copies of PBGC's request may be obtained free of charge by contacting the Disclosure Division of the Office of the General Counsel of PBGC, 1200 K Street, NW., Washington, DC 20005, 202–326–4040.

This proposed regulation would modify information collection requirements under OMB control number 1212–0036 (expires September 30, 2007). 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.

PBGC needs this information in order to provide sufficient information to affected parties about the termination or possible termination of their pension plans.

Section 506 of PPA 2006 has been in effect for less than a year, and PBGC is not aware of any requests for information that have been made to date under its provisions. PBGC estimates that 100 plans with a total of 100,000 participants will terminate annually, and that 10,000 participants (and other affected parties) will annually make requests for information. PBGC estimates that the total annual burden for the collection of information will be about 30,000 hours and $250,000.

Comments on the paperwork provisions under this proposed regulation should be mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Pension Benefit Guaranty Corporation, Washington, DC 20503. Although comments may be submitted through February 4, 2008, the Office of Management and Budget requests that comments be received on or before January 4, 2008 to ensure their consideration. Comments may address (among other things)—

• Whether the proposed collection of information is needed for the proper performance of PBGC's functions and will have practical utility;

• The accuracy of PBGC's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

• Enhancement of the quality, utility, and clarity of the information to be collected; and

• Minimizing 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.

List of Subjects

29 CFR Part 4041

Disclosure, Pensions, Termination of pension plans.

29 CFR Part 4042

Disclosure, Pensions, Termination of pension plans.

For the reasons given above, PBGC proposes to amend 29 CFR chapter XL as follows:

PART 4041—TERMINATION OF SINGLE-EMPLOYER PLANS

1. The authority citation for part 4041 continues to read as follows:

Authority: 29 U.S.C. 1302(b)(3), 1341, 1344, 1350.

2. New § 4041.51 is added to 29 CFR part 4041 to read as follows:

§ 4041.51 Disclosure of information by plan administrator in distress termination.

(a) *Request for Information.*.

(1) *In general.* If a notice of intent to terminate under § 4041.43 is issued with respect to a plan, an affected party may make a request to the plan administrator for information submitted to PBGC under sections 4041(a)(2) and 4041(c)(2) of ERISA and §§ 4041.43 and 4041.45.

(2) *Requirements.* A request under paragraph (a) of this section must:

(i) Be in writing to the plan administrator;

(ii) State the name of the plan and that the request is for information submitted to PBGC with respect to the application for a distress termination of the plan;

(iii) State the name of the person making the request for information and such person's relationship to the plan (e.g., plan participant), and that such relationship meets the definition of affected party under § 4001.2 of this chapter; and

(iv) Be signed by the person making the request.

(b) *Response by Plan Administrator.*

(1) *Information.* The information that a plan administrator must provide in

response to a request under paragraph (a) of this section includes the PBGC Form 600, and any information submitted to PBGC pursuant to section 4041(c)(2) of ERISA and § 4041.45.

(2) *Timing of response.* A plan administrator that receives a request under paragraph (a) of this section must provide the information requested not later than the 15th business day (as defined in § 4000.22 of this chapter) after receipt of the request.

(3) *Deferral of due date.* If, at the time the plan administrator receives a request under paragraph (a) of this section, the plan administrator has not filed a PBGC Form 600, the plan administrator must provide the information requested under paragraph (a) not later than the 15th business day (as defined in § 4000.22 of this chapter) after a PBGC Form 600 is filed with PBGC.

(4) *Supplemental responses.* If, at any time after the later of the receipt of a request under paragraph (a) of this section, or the filing of PBGC Form 600, the plan administrator submits additional information to PBGC with respect to the plan termination under section 4041(c)(2) of ERISA and § 4041.45, the plan administrator must, not later than the 15th business day (as defined in § 4000.22 of this chapter) after each additional submission, provide the additional information to any affected party that has made a request under paragraph (a) of this section.

(5) *Confidential information.*

(i) In responding to a request under paragraph (a) of this section, the plan administrator shall not provide information that may, directly or indirectly, identify an individual participant or beneficiary of the plan.

(ii) A plan administrator that has received a request under paragraph (a) of this section may seek a court order under which confidential information described in section 552(b) of title 5, United States Code—

(A) Will be disclosed only to authorized representatives (within the meaning of section 4041(c)(2)(D)(iv) of ERISA) that agree to ensure the confidentiality of such information, and,

(B) Will not be disclosed to other affected parties.

3. New part 4042 is added to chapter XL to read as follows:

PART 4042—SINGLE-EMPLOYER PLAN TERMINATION INITIATED BY PBGC

Subpart A—General Provisions

Sec.

Subpart B—Reserved

Subpart C—Disclosure

Authority: 29 U.S.C. 1302(b)(3), 1342.

Subpart A—General Provisions

§ 4042.1 Purpose and scope.

This part sets forth rules and procedures relating to single-employer plan terminations initiated by PBGC under section 4042 of ERISA.

§ 4042.2 Definitions.

The following terms are defined in § 4001.2 of this chapter: affected party, ERISA, PBGC, and plan administrator.

§ 4042.3 Issuance rules.

PBGC applies the rules in subpart B of part 4000 of this chapter to determine permissible methods of issuance under this part. PBGC applies the rules in subpart C of part 4000 of this chapter to determine the date that an issuance under this part was provided.

Subpart B—Reserved

Subpart C—Disclosure

§ 4042.4 Disclosure of information by plan administrator or plan sponsor.

(a) *Request for Information.*

(1) *In general.* Beginning on the third business day (as defined in § 4000.22 of this chapter) after PBGC has issued a notice under section 4042 of ERISA that a plan should be terminated, an affected party may make a request to the plan sponsor or the plan administrator (or both) for any information that such plan administrator or plan sponsor has submitted to PBGC in connection with the plan termination.

(2) *Requirements.* A request under paragraph (a) of this section must:

(i) Be in writing to the plan administrator or plan sponsor;

(ii) State the name of the plan and that the request is for information submitted to PBGC in connection with the plan termination;

(iii) State the name of the person making the request for information and such person's relationship to the plan (e.g., plan participant), and that such relationship meets the definition of affected party under § 4001.2 of this chapter; and

(iv) Be signed by the person making the request.

(b) *Response by Plan Administrator or Plan Sponsor.*

(1) *Timing of response.* A plan administrator or plan sponsor that receives a request under paragraph (a) of this section must provide the information requested not later than the 15th business day (as defined in § 4000.22 of this chapter) after receipt of the request.

(2) *Supplemental responses.* If, at any time after receipt of a request under paragraph (a), the plan administrator or plan sponsor submits additional information to PBGC in connection with the plan termination, the plan administrator or plan sponsor must provide such additional information to any affected party that has made a request under paragraph (a), not later than the 15th business day (as defined in § 4000.22 of this chapter) after the information is submitted to PBGC.

(3) *Confidential information.*

(i) In responding to a request under paragraph (a) of this section, the plan administrator or plan sponsor shall not provide information that may, directly or indirectly, identify an individual participant or beneficiary.

(ii) A plan administrator or plan sponsor that has received a request under paragraph (a) of this section may seek a court order under which confidential information described in section 552(b) of title 5, United States Code—

(A) Will be disclosed only to authorized representatives (within the meaning of section 4041(c)(2)(D)(iv) of ERISA) that agree, to ensure the confidentiality of such information, and

(B) Will not be disclosed to other affected parties.

§ 4042.5 Disclosure of administrative record by PBGC.

(a) *Request for Administrative Record.*

(1) *In general.* Beginning on the third business day (as defined in § 4000.22 of this chapter) after PBGC has issued a notice under section 4042 of ERISA that a plan should be terminated, an affected party with respect to the plan may make a request to PBGC for the administrative record of PBGC's determination that the plan should be terminated.

(2) *Requirements.* A request under paragraph (a) of this section must:

(i) Be in writing;

(ii) State the name of the plan and that the request is for the administrative record with respect to a notice issued by PBGC under section 4042 of ERISA that a plan should be terminated;

(iii) State the name of the person making the request, the person's relationship to the plan (e.g., plan participant), and that such relationship meets the definition of affected party under § 4001.2 of this chapter; and

(iv) Be signed by the person making the request.

(3) A request under paragraph (a) of this section must be sent to PBGC's Disclosure Officer at the address provided on PBGC's Web site. To expedite processing, the request should be prominently identified as an "Administrative Record Request."

(b) *PBGC Response to Request for Administrative Record.*

(1) *Notification of plan administrator and plan sponsor.* Upon receipt of a request under paragraph (a) of this section, PBGC will promptly notify the plan administrator and plan sponsor that it has received a request for the administrative record, and the date by which PBGC will provide the information to the affected party that made the request.

(2) *Confidential information.*

(i) In responding to a request under paragraph (a) of this section, PBGC will not disclose any portions of the administrative record that are prohibited from disclosure under the Privacy Act, 5 U.S.C. 552a.

(ii) A plan administrator or plan sponsor that has received notification pursuant to paragraph (b)(1) of this section may seek a court order under which those portions of the administrative record that contain confidential information described in section 552(b) of title 5, United States Code—

(A) Will be disclosed only to authorized representatives (within the meaning of section 4041(c)(2)(D)(iv)) of ERISA) that agree to ensure the confidentiality of such information, and

(B) Will not be disclosed to other affected parties.

(iii) If, before the 15th business day (as defined in § 4000.22 of this chapter) after PBGC has received a request under paragraph (a), PBGC receives a court order as described in paragraph (b)(2)(ii) of this section, PBGC will disclose those portions of the administrative record that contain confidential information described in section 552(b) of title 5, United States Code, only as provided in the order.

(3) *Timing of response.* PBGC will send the administrative record to the affected party that made the request not later than the 15th business day (as defined in § 4000.22 of this chapter) after it receives the request.

(4) *Form and manner.* PBGC will provide the administrative record using measures (including electronic measures) reasonably calculated to ensure actual receipt of the material by the intended recipient.

Issued in Washington, DC, this 30th day of November, 2007.

Charles E.F. Millard,

Interim Director, Pension Benefit Guaranty Corporation.

[FR Doc. E7–23577 Filed 12–4–07; 8:45 am]

BILLING CODE 7709–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2007–0105]

RIN 1625–AA09

Drawbridge Operation Regulations; Biscayne Bay, Atlantic Intracoastal Waterway, Miami River, and Miami Beach Channel, Miami-Dade County, FL

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to change the regulations governing the operation of the east and west spans of the Venetian Causeway bridges across the Miami Beach Channel on the Atlantic Intracoastal Waterway, the Miami Avenue bridge and the Brickell Avenue bridge across the Miami River, Miami-Dade County. This proposed rule would allow these bridges to remain in the closed position for periods of time during the last Sunday in January during the running of an annual marathon.

DATES: Comments and related material must reach the Coast Guard on or before January 4, 2008.

ADDRESSES: You may submit comments identified by Coast Guard docket number USCG–2007–0105 to the Docket Management Facility at the U.S. Department of Transportation. To avoid duplication, please use only one of the following methods:

(1) *Online: http://www.regulations.gov.*

(2) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.

(3) *Hand delivery:* Room W12–140 on the Ground Floor of the West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

Fax: 202–493–2251.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call Mr. Gwin Tate, Seventh Coast Guard District, Bridge Administration Branch, (305) 415–6747. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted, without change, to *http://www.regulations.gov* and will include any personal information you have provided. We have an agreement with the Department of Transportation (DOT) to use the Docket Management Facility. Please see DOT's "Privacy Act" paragraph below.

Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2007–0105), indicate the specific section of this document to which each comment applies, and give the reason for each comment. We recommend that you include your name and a mailing address, an e-mail address, or a phone number in the body of your document so that we can contact you if we have questions regarding your submission. You may submit your comments and material by electronic means, mail, fax, or delivery to the Docket Management Facility at the address under **ADDRESSES**; but please submit your comments and material by only one means. If you submit them by mail or delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of them.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov* at any time, click on "Search for Dockets," and enter the docket number for this rulemaking (USCG–2007–0105) in the Docket ID box, and click enter. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of

the DOT West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy Act

Anyone can 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 the Department of Transportation's Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477), or you may visit *http://DocketsInfo.dot.gov.*

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one to the Docket Management Facility at the address under **ADDRESSES** explaining why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

As in previous years, the Miami Marathon Director requested that the Coast Guard change the existing regulations governing the operation of the east and west spans of the Venetian Causeway bridges, the Brickell Avenue bridge and the Miami Avenue bridge to allow them to remain in the closed position during periods of time on the last Sunday in January during the running of an annual marathon. Previously, the Coast Guard issued a temporary rule that provided for these bridge closings, which range from 6:00 a.m. through 12:30 p.m. The marathon route will pass over these four bridges and any bridge opening would disrupt the race. Based on the limited amount of time the bridges would be closed, the proposed rule would still provide for the reasonable needs of navigation on the day of the event.

The east and west spans of the Venetian Causeway bridges are located between Miami and Miami Beach. We published the current regulation governing the operation of the east and west spans, mile 1088.6 at Miami, of the Venetian Causeway bridges on April 16, 2007, becoming effective May 16, 2007, which requires the bridges to open on signal, except that from 7 a.m. to 7 p.m., Monday through Friday, except Federal holidays, the drawbridges will open on the hour and half-hour. The regulation governing the Miami Avenue bridge, mile 0.3, at Miami, is published at 33 CFR 117.305(c) and requires that the bridge open on signal; except that, from 7:35 a.m. to 8:59 a.m., 12:05 p.m. to 12:59 p.m. and 4:35 p.m. to 5:59 p.m., Monday through Friday, except Federal holidays, the draw need not open for the passage of vessels.

The regulation governing the Brickell Avenue bridge, mile 0.1, at Miami, is published in 33 CFR 117.305(d) and requires that the bridge open on signal; except that, from 7 a.m. to 7 p.m., Monday through Friday, except Federal holidays, the draw need open only on the hour and half-hour. From 7:35 a.m. to 8:59 a.m., 12:05 p.m. to 12:59 p.m. and 4:35 p.m. to 5:59 p.m., Monday through Friday except Federal holidays, the draw need not open for the passage of vessels.

This proposed rule would not adversely affect the reasonable needs of navigation due to the limited time (six and one-half hours) that the bridges would remain in the closed position.

Discussion of Proposed Rule

The Coast Guard proposes to change the operating regulations of the east and west spans of the Venetian Causeway bridges, the Miami Avenue bridge and the Brickell Avenue bridge annually on the last Sunday in January. This proposed rule would allow, annually on the last Sunday in January, the east span of the Venetian Causeway bridge to remain closed from 6 a.m. to 9 a.m., and the west span of the Venetian Causeway bridge to remain closed from 6:10 a.m. to 9:35 a.m. Annually, on the last Sunday in January, the Miami Avenue bridge would remain closed from 6:25 a.m. to 10:20 a.m., and the Brickell Avenue bridge would remain closed from 7:10 a.m. to 12:30 p.m. Public vessels of the United States and vessels in distress would be allowed to pass at any time, upon signal.

In past years, these schedule changes have been made annually by using a temporary final rule. This NPRM proposes to make the change permanently in the regulation, to prevent the need for annual publications in the **Federal Register**.

Regulatory Evaluation

This proposed rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not "significant" under the regulatory policies and procedures of the Department of Homeland Security.

We expect the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation is unnecessary. The short duration of time during the morning of the last Sunday in January, that the bridges would remain in the closed position to facilitate the running of the marathon would have little, if any, economic impact, as evidenced by the lack of impact in the past years, when the proposed change was implemented on a temporary basis.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities. This proposed rule would affect the following entities, some of which may be small entities: The owners or operators of vessels that would require passage through these bridges during the morning hours annually on the last Sunday in January. These vessels would not be able to pass through these bridges during the effective times of this proposed rule. However, due to the limited effective times of this proposed rule and the nominal amount of marine traffic expected during the early and late morning hours on a Sunday at this time of year, this proposed rule would not have a significant economic impact on a substantial number of small entities.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions

concerning its provisions or options for compliance, please contact the person listed under for **FOR FURTHER INFORMATION CONTACT.** The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520.).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this proposed rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this proposed rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This proposed rule would not affect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would 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.

Energy Effects

We have analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that order because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this proposed rule under Commandant Instruction M16475 which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is not likely to have a significant effect on the human environment because it simply promulgates the operating regulations or procedures for drawbridges. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1(g); Department of Homeland Security Delegation No. 0170.1.

2. In § 117.261, revise paragraph (nn) to read as follows:

§ 117.261 Atlantic Intracoastal Waterway from St. Marys River to Key Largo.

* * * * *

(nn) *The Venetian Causeway Bridge (West), mile 1088.6 at Miami.* The draw shall open on signal; except that, from 7 a.m. to 7 p.m., Monday through Friday, except Federal holidays, the draw need only open on the hour and half-hour; except that on the last Sunday in January, the draw need not open from 6:10 a.m. until 9:35 a.m.

* * * * *

3. Revise § 117.269 to read as follows:

§ 117.269 Biscayne Bay.

The Venetian Causeway Bridge (East), between Miami and Miami Beach, shall open on signal; except that, from 7 a.m. to 7 p.m., Monday through Friday, except Federal holidays, the draw need only open on the hour and half-hour; except that on the last Sunday in January, the draw need not open from 6 a.m. until 9 a.m. Public vessels of the United States and vessels in distress shall be allowed to pass at any time, upon signal.

4. In § 117.305, revise paragraphs (c) and (d) to read as follows:

§ 117.305 Miami River.

* * * * *

(c) The draws of the Miami Avenue Bridge, mile 0.3, and the S.W. Second Avenue Bridge, mile 0.5, at Miami, shall open on signal; except that the draw need not open for the passage of vessels at the following times:

(1) From 7:35 a.m. to 8:59 a.m., Monday through Friday, except Federal holidays,

(2) From 12:05 p.m. to 12:59 p.m., Monday through Friday, except Federal holidays,

(3) From 4:35 p.m. to 5:59 p.m., Monday through Friday, except Federal holidays, and

(4) From 6:25 a.m. to 10:20 a.m., on the last Sunday in January.

(d) The draw of the Brickell Avenue Bridge, mile 0.1, at Miami, shall open on signal; except that, from 7 a.m. to 7 p.m., Monday through Friday except Federal holidays, the draw need open only on the hour and half-hour; except that the draw need not open for the passage of vessels at the following times:

(1) From 7:35 a.m. to 8:59 a.m., Monday through Friday, except Federal holidays,

(2) From 12:05 p.m. to 12:59 p.m., Monday through Friday, except Federal holidays,

(3) From 4:35 p.m. to 5:59 p.m., Monday through Friday, except Federal holidays, and

(4) From 7:10 a.m. to 12:30 p.m., on the last Sunday in January.

Dated: November 21, 2007.

William Lee,

Capt., USCG, Acting District Commander, Seventh Coast Guard District.

[FR Doc, E7–23564 Filed 12–4–07; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2006–1021; FRL–8501–4]

Approval and Promulgation of Air Quality Implementation Plans; Minnesota

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve State Implementation Plan (SIP) revisions to the sulfur dioxide (SO_2) requirements for Northern States Power Company, doing business as Xcel Energy, Inver Hills Generating Plant (Inver Hills), located in Inver Grove Heights, Dakota County, Minnesota. The revisions make the limits of the sulfur content in its fuel and its sulfur dioxide emissions more stringent, and prohibit the burning of residual fuel oil. The revisions allow the facility to use simpler methods to analyze the sulfur content of its fuel. Because the sulfur dioxide emission limits are being reduced, the air quality of Dakota County will be protected.

DATES: Comments must be received on or before January 4, 2008.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2006–1021, by one of the following methods:

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

2. *E-mail: mooney.john@epa.gov.*

3. *Fax:* (312)886–5824.

4. *Mail:* John M. Mooney, Chief, Criteria Pollutant Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

5. *Hand Delivery:* John M. Mooney, Chief, Criteria Pollutant Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m. excluding Federal holidays.

Please see the direct final rule which is located in the Rules section of this **Federal Register** for detailed instructions on how to submit comments.

FOR FURTHER INFORMATION CONTACT: Matt Rau, Environmental Engineer, Criteria Pollutant Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–6524, *rau.matthew@epa.gov.*

SUPPLEMENTARY INFORMATION: In the Final Rules section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this rule, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment. For additional information, see the direct final rule which is located in the Rules section of this **Federal Register**.

Dated: November 20, 2007.

Bharat Mathur,

Acting Regional Administrator, Region 5.

[FR Doc. E7–23497 Filed 12–4–07; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 071029623–7624–01]

RIN 0648–AW21

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Commercial Dolphin/Wahoo Fishery off the Southern Atlantic States; Control Date

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

ACTION: Advanced notice of proposed rulemaking; request for comments.

SUMMARY: NMFS announces that it is considering, and is seeking public comment on proposed rulemaking to control future access to the commercial dolphin/wahoo fishery operating in the exclusive economic zone (EEZ)of the South Atlantic. If changes to the management regime are developed and implemented under the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), a control date could be used to limit the number of participants in the fishery. This announcement is intended, in part, to promote awareness of the potential eligibility criteria for future access so as to discourage speculative entry into the fishery while the South Atlantic Fishery Management Council (Council) and NMFS consider whether and how access to the dolphin/wahoo commercial fishery should be controlled.

DATES: Written comments must be received on or before 5 p.m., local time, January 4, 2008.

ADDRESSES: You may submit comments, identified by 0648–AW03, by any one of the following methods:

- Electronic Submissions: Submit all electronic public comments via the Federal eRulemaking Portal *http://www.regulations.gov.*
- Fax: Attn: Kate Michie 727–824–5308.
- Mail: Kate Michie, NMFS Southeast Regional Office, Sustainable Fisheries Division, 263 13th Avenue South, St. Petersburg, FL 33701.

Instructions: All comments received are a part of the public record and will generally be posted to *http://www.regulations.gov* without change. All Personal Identifying Information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information.

NMFS will accept anonymous comments. Attachments to electronic comments will be accepted in Microsoft Word, Excel, WordPerfect, or Adobe PDF file formats only.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer, South Atlantic Fishery Management Council; toll free 1–866–SAFMC–10 or 843–571–4366; *kim.iverson@safmc.net.*

SUPPLEMENTARY INFORMATION: At the September 2007 Council meeting, the Council recommended a control date of December 5, 2007 for the commercial dolphin/wahoo fishery. The control date would apply to persons who are contemplating entering the commercial dolphin/wahoo fishery in the EEZ of the South Atlantic region. The Council requested that this control date be published in the **Federal Register** to notify fishermen that if they enter such a fishery after December 5, 2007, they may not be assured of future access if the Council and/or NMFS decide to limit entry or impose other measures to manage these fisheries. Establishment of the control date would allow the Council to evaluate the level of participation in the subject fishery and address any level of overcapacity. Control dates are intended to discourage speculative entry into a fishery, as new entrants entering the fishery after the control date are forewarned that they are not guaranteed future participation in the fishery.

Establishment of this control date does not commit the Council or NMFS to any particular management regime or criteria for entry into the commercial dolphin/wahoo fishery. Fishermen are not guaranteed future participation in the fishery regardless of their level of participation before or after the control date. The Council may recommend a different control date or it may recommend a management regime that does not involve a control date. Other criteria, such as documentation of landings or fishing effort, may be used to determine eligibility for participation in a limited access fishery. The Council and/or NMFS also may choose to take no further action to control entry or access to the fisheries, in which case the control date may be rescinded. Any action by the Council will be taken pursuant to the requirements for fishery management plan and amendment development established under the Magnuson-Stevens Act.

This notification also gives the public notice that interested participants should locate and preserve records that substantiate and verify their participation in the commercial dolphin/wahoo fishery in the South Atlantic EEZ.

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

Dated: November 29, 2007.

Samuel D. Rauch III,

Deputy Assistant Administrator For Regulatory Programs, National Marine Fisheries Service.

[FR Doc. E7–23596 Filed 12–4–07; 8:45 am]

BILLING CODE 3510–22–S

Notices

Federal Register
Vol. 72, No. 233
Wednesday, December 5, 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.

AGENCY FOR INTERNATIONAL DEVELOPMENT

Notice of Public Information Collection Requirements Submitted to OMB for Review

SUMMARY: U.S. Agency for International Development (USAID) has submitted the following information collections to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding this information collection are best assured of having their full effect if received within 30 days of this notification. Comments should be sent via e-mail to *David_Rostker@omb.eop.gov* or fax to 202–395–7285. Copies of submission may be obtained by calling (202) 712–1365.

SUPPLEMENTARY INFORMATION:

OMB Number: OMB 0412–NEW.
Form Number: N/A.
Title: Partner Information Form.
Type of Submission: New Information Collection.

Purpose: The United States Agency for International Development (USAID). Office of Security, intends to collect information from approximately 2000 individuals and/or officers of non-governmental organizations (NGOs) who apply for USAID contracts, grants, cooperative agreements, other funding from USAID, or who apply for registration with USAID as Private and Voluntary Organizations (PVO). Collection of personally identifiable information from these individuals is specifically used to conduct screening to ensure that neither USAID funds nor USAID-funded activities inadvertently provide support to entities or individuals associated with terrorism.

Annual Reporting Burden

Respondents: 2000.
Total annual responses: 2000.
Total annual hours requested: 500 hours.

Dated: November 27, 2007.

Joanne Paskar,

Chief, Information and Records Division Office of Administrative Services Bureau for Management.

[FR Doc. 07–5935 Filed 12–4–07; 8:45 am]

BILLING CODE 6116–01–M

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Doc. No. AMS–TM–07–0126; TM–07–13]

Notice of Funds Availability (NOFA) Inviting Applications for the Federal-State Marketing Improvement Program (FSMIP)

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice.

SUMMARY: The Agricultural Marketing Service (AMS) announces the availability of approximately $1.3 million in competitive grant funds for fiscal year 2008 to enable States to explore new market opportunities for U.S. food and agricultural products and to encourage research and innovation aimed at improving the efficiency and performance of the U.S. marketing system. Eligible applicants include State departments of agriculture, State agricultural experiment stations, and other appropriate State Agencies. Applicants are encouraged to involve industry groups, academia, community-based organizations, and other stakeholders in developing proposals and conducting projects. In accordance with the Paperwork Reduction Act of 1995, the information collection requirements have been previously approved by OMB under 0581–0240, Federal-State Marketing Improvement Program (FSMIP).

DATES: Proposals will be accepted through February 11, 2008.

ADDRESSES: Submit proposals and other required documents to: FSMIP Staff Officer, Transportation and Marketing Programs, Agricultural Marketing Service (AMS), U.S. Department of Agriculture, 1400 Independence Avenue, SW., Room 4009 South Building, Washington, DC 20250; telephone (202) 720–8043; e-mail *janise.zygmont@usda.gov.*

FOR FURTHER INFORMATION CONTACT: Janise Zygmont, FSMIP Staff Officer; telephone (202) 720–8043; fax (202) 690–4948; or e-mail *janise.zygmont@usda.gov.*

SUPPLEMENTARY INFORMATION: FSMIP is authorized under Section 204(b) of the Agricultural Marketing Act of 1946 (7 U.S.C. 1621 *et seq.*). FSMIP provides matching grants on a competitive basis to enable States to explore new market opportunities for U.S. food and agricultural products and to encourage research and innovation aimed at improving the efficiency and performance of the U.S. marketing system. Eligible applicants include State departments of agriculture, State agricultural experiment stations, and other appropriate State Agencies. Other organizations interested in participating in this program should contact their State Department of Agriculture's Marketing Division. State agencies specifically named under the authorizing legislation should assume the lead role in FSMIP projects, and use cooperative or contractual linkages with other agencies, universities, institutions, and producer, industry or community-based organizations as appropriate. Multi-State projects are encouraged as long as one State assumes the coordinating role, using appropriate cooperative arrangements with the other States involved. Applicants other than State Departments of Agriculture and State agricultural experiment stations may wish to include with their applications an explanation of how they meet the definition of "other appropriate State agency."

Proposals must be accompanied by completed Standard Forms (SF) 424 and 424A. AMS will not approve the use of FSMIP funds for advertising or, with limited exceptions, for the purchase of equipment. Detailed program guidelines may be obtained from the contact listed above, and are available at the FSMIP Web site: *http://www.ams.usda.gov/tmd/fsmip.htm.*

Background

FSMIP funds a wide range of applied research projects that address barriers, challenges, and opportunities in marketing, transportation, and distribution of U.S. food and agricultural products domestically and internationally.

Eligible agricultural categories include livestock, livestock products, food and feed crops, fish and shellfish,

horticulture, viticulture, apiary, and forest products and processed or manufactured products derived from such commodities. Reflecting the growing diversity of U.S. agriculture, in recent years, FSMIP has funded projects dealing with nutraceuticals, bioenergy, compost, and products made from agricultural residues.

Proposals may deal with barriers, challenges, or opportunities manifesting at any stage of the marketing chain including direct, wholesale, and retail. Proposals may involve small, medium, or large scale agricultural entities but should potentially benefit multiple producers or agribusinesses. Proprietary proposals that benefit one business or individual will not be considered.

Proposals that address issues of importance at the State, regional or national level are appropriate for FSMIP. FSMIP also seeks unique proposals on a smaller scale that may serve as pilot projects or case studies useful as a model for other States. Of particular interest are proposals that reflect a collaborative approach among the States, academia, the farm sector and other appropriate entities and stakeholders. FSMIP's enabling legislation authorizes projects to:

- Determine the best methods for processing, preparing for market, packing, handling, transporting, storing, distributing, and marketing agricultural products.
- Determine the costs of marketing agricultural products in their various forms and through various channels.
- Assist in the development of more efficient marketing methods, practices, and facilities to bring about more efficient and orderly marketing, and reduce the price spread between the producer and the consumer.
- Develop and improve standards of quality, condition, quantity, grade, and packaging in order to encourage uniformity and consistency in commercial practices.
- Eliminate artificial barriers to the free movement of agricultural products in commercial channels.
- Foster new/expanded domestic/foreign markets and new/expanded uses of agricultural products.
- Collect and disseminate marketing information to anticipate and meet consumer requirements, maintain farm income, and balance production and utilization.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995, the FSMIP information collection requirements were previously approved by the Office of Management and Budget (OMB) and were assigned OMB control number 0581–0240.

AMS is committed to compliance with the Government Paperwork Elimination Act (GPEA), which requires Government agencies in general to provide the public with the option of submitted information or transacting business electronically to the maximum extent possible.

How To Submit Proposals and Applications

Applicants have the option of submitting FSMIP applications electronically through the Federal grants Web site, *http://www.grants.gov* instead of mailing hard copy documents. Applicants considering the electronic application option are strongly urged to familiarize themselves with the Federal grants Web site well before the application deadline and to begin the application process before the deadline. Additional details about the FSMIP application process for all applicants are available at the FSMIP Web site: *http://www.ams.usda.gov/tmd/fsmip.htm*.

FSMIP is listed in the "Catalog of Federal Domestic Assistance" under number 10.156 and subject agencies must adhere to Title VI of the Civil Rights Act of 1964, which bars discrimination in all federally assisted programs.

Authority: 7 U.S.C. 1621–1627.

Dated: November 29, 2007.

Lloyd C. Day,

Administrator, Agricultural Marketing Service.

[FR Doc. E7–23528 Filed 12–4–07; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2007–0149]

National Animal Identification System; Updated Program Standards

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability and request for comments.

SUMMARY: We are advising the public that we are making available for review and comment a revised version of the National Animal Identification System (NAIS) Program Standards and Technical Reference document. A previous Program Standards document was originally made available in May 2005. The revised Program Standards and Technical Reference document reflects the continuing evolution of the NAIS, particularly with regard to identification devices available for official use within the system, and provides further guidance to NAIS participants and other interested stakeholders.

ADDRESSES: The revised Program Standards and Technical Reference document is available on the Internet at *http://animalid.aphis.usda.gov/nais/*. The document may also be viewed in our reading room. The reading room is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Adam Grow; Director, Surveillance and Identification Programs, National Center for Animal Health Programs, VS, APHIS, 4700 River Road Unit 200, Riverdale, MD 20737–1231; (301) 734–3752.

SUPPLEMENTARY INFORMATION:

Background

On May 6, 2005, the Animal and Plant Health Inspection Service (APHIS) published in the **Federal Register** (70 FR 23961–23963, Docket No. 05–015–1) a notice advising the public that two documents related to the National Animal Identification System (NAIS), a Draft Strategic Plan and a Draft Program Standards document, were being made available to the public for review and comment. The Draft Program Standards document provided technical data standards to be used for information systems in the NAIS. Subsequently, a Draft User Guide for the NAIS replaced the 2005 Draft Program Standards, as well as other draft NAIS documents. We published a notice of availability of the Draft User Guide in the **Federal Register** (72 FR 4680–4681, Docket No. APHIS–2007–0007) on February 1, 2007. The February 2007 notice also announced the availability of a technical specification document for animal tracking databases and an updated Program Standards and Technical Reference document.

The Program Standards and Technical Reference document supplemented the User Guide and contained an update of the data element standards that were in the 2005 Draft Program Standards. It was targeted to entities that are involved in the administration of the program, including manufacturers of animal identification devices. At that time, only

the Cattle Working Group and the Equine Species Working Group had provided performance standards for APHIS to employ when approving devices for use in the NAIS, so the standards included only the recommendations of those groups. Since then, the Swine Working Group and the Sheep and Goat Working Group have also provided recommendations, and in October 2007, we updated the Program Standards and Technical Reference document to include information specific to those species and made some other changes. We are, therefore, now making available to the public for review and comment this newly updated version of the Program Standards and Technical Reference document. We will continue to solicit public comments and stakeholder feedback on the document through the NAIS Web site.

Updates to the document include the following: (1) Adjustments to performance standards for identification eartags; (2) adjustments to printing standards for individual animal identification eartags; (3) the addition of printing standards for slaughter swine premises identification; and (4) the adjustment of our performance standards for radio frequency identification (RFID) injectable transponders to allow for the potential use of alternate International Organization for Standardization (ISO) or U.S.-based technology standards. These updates are discussed in more detail below.

Performance Standards for Identification Eartags

In the February 2007 Program Standards and Technical Reference document, we included a table outlining performance standards for identification eartags. These standards focused on cattle, since the Cattle Working Group had provided performance standards and since cattle were the primary species using NAIS identification at that time. We have now updated the performance standards for "Readability" and "Tag loss rates" to include information specific to sheep and goats and swine. For readability, we have added a note indicating that, for swine, the premises identification number (PIN) must also be easily and reliably readable. For tag loss rates, we have specified separate performance requirements for cattle (noting that the requirements for cattle should be used for all other species not specified in the table), sheep and goats, and swine. Due to the addition of eartag identification performance standards for species other than cattle, we have also changed the title of the table from "Identification Eartag" to "Performance Standards for Identification Eartags for all Species that use Eartags."

Printing Standards for Eartags

In the February 2007 Program Standards and Technical Reference document, we included a table containing printing standards for identification eartags. As with the performance standards discussed above, the printing standards focused on cattle, since the Cattle Working Group had provided standards and since cattle were the primary species using NAIS identification at that time. We have now updated those standards to address the needs for unique, individual animal identification for sheep and goats and swine. Specifically, we have provided for the following options: (1) The use of smaller print sizes for the U.S. Shield, numbers, and letters, if needed, on tags for sheep and goats; (2) the inclusion of an eight-character series in the National Uniform Eartagging System, in addition to the current nine-character series, to accommodate the need for smaller eartags in smaller species such as swine and sheep; (3) the continuing use of a PIN plus an individual animal number unique to the premises for swine as an alternative to the animal identification number (AIN); and (4) the use of a number issued by the scrapie program consisting of a flock identification number (FIN) plus an individual animal number unique to the flock for sheep and goats as an alternative to the AIN. We have also changed the title of the table from "Printing Standards for Eartags" to "Printing Standards for Individual Animal ID Eartags" to differentiate these standards for "individual animal identification" eartags from the standards for "premises identification" eartags for slaughter swine. Slaughter swine do not require unique, individual animal identification.

Printing Standards for Slaughter Swine Premises Identification

The Swine Working Group recently provided recommendations related to printing standards necessary for official identification for slaughter swine premises identification. This updated October 2007 Program Standards and Technical Reference document now provides a table, directly following the "Printing Standards for Individual Animal ID Eartags" table described above, outlining the printing standards for slaughter swine premises identification eartags. The February 2007 document did not have such a table.

Adjustment to Performance Requirements for RFID Injectable Transponders

The February 2007 Program Standards and Technical Reference document included a table outlining performance requirements for RFID injectable transponders, as recommended by the Equine Species Working Group. Continuing work with this group resulted in an application to be used by manufacturers of such devices to gain approval by APHIS for use in the NAIS. The application indicates that other ISO or U.S.-based technology standards might be approved for use by APHIS, so the "ISO Compliant" standard has been adjusted to read, "All transponders must be certified by ICAR [International Committee for Animal Recording] for conformance with ISO 11784 and 11785, unless other ISO or U.S.-based technology standards are applicable to livestock and approved for use by APHIS."

Comments about the revised Program Standards and Technical Reference document or other aspects of the NAIS may be submitted to USDA through the NAIS Web site e-mail address: *animalidcomments@aphis.usda.gov* or by mail to NAIS Program Staff, VS, APHIS, 4700 River Road, Unit 200, Riverdale, MD 20737.

Done in Washington, DC, this 29th day of November 2007.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E7–23524 Filed 12–4–07; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Grain Inspection, Packers and Stockyards Administration

Opportunity for Designation In Maryland, New Jersey, and New York

AGENCY: Grain Inspection, Packers and Stockyards Administration, USDA.

ACTION: Notice and request for applications.

SUMMARY: The Grain Inspection, Packers and Stockyards Administration (GIPSA) has received inquiries, letters, and requests for official services in the currently unassigned states of Maryland, New Jersey, and New York. GIPSA plans to designate one or more organizations qualified to provide official services in Maryland, New Jersey, and New York. GIPSA is asking persons interested in providing official services in all or part of the unassigned areas of Maryland,

New Jersey, and New York to submit an application for designation.

DATES: Applications must be postmarked or electronically dated on or before January 4, 2008.

ADDRESSES: We invite you to submit applications and comments on this notice. You may submit applications and comments by any of the following methods:

- To apply for designation, go to FGIS online, Web page *https://fgis.gipsa.usda.gov/default_home_FGIS.aspx*. Select *Delegations/Designations and Export Registrations (DDR)*. You need e-authentication and a customer number prior to applying.
- *Hand Delivery or Courier:* Deliver to Karen Guagliardo, Review Branch Chief, Compliance Division, GIPSA, USDA, Room 1647–S, 1400 Independence Avenue, SW., Washington, DC 20250.
- *Fax:* Send by facsimile transmission to (202) 690–2755, attention: Karen Guagliardo.
- *E-mail:* Send via electronic mail to *Karen.W.Guagliardo@usda.gov*.
- *Mail:* Send hardcopy to Karen Guagliardo, Review Branch Chief, Compliance Division, GIPSA, USDA, STOP 3604, 1400 Independence Avenue, SW., Washington, DC 20250–3604.
- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Follow the online instructions for submitting comments and reading any comments posted online.

Read Applications and Comments: All applications and comments will be available for public inspection at the office above during regular business hours (7 CFR 1.27(b)).

FOR FURTHER INFORMATION CONTACT: Karen Guagliardo at 202–720–7312, e-mail *Karen.W.Guagliardo@usda.gov*.

SUPPLEMENTARY INFORMATION: This Action has been reviewed and determined not to be a rule or regulation as defined in Executive Order 12866 and Departmental Regulation 1512–1; therefore, the Executive Order and Departmental Regulation do not apply to this action.

Section 7(f)(1) of the United States Grain Standards Act, as amended (Act), authorizes GIPSA's Administrator to designate a qualified applicant to provide official services in a specified area after determining that the applicant is better able than any other applicant to provide such official services.

Section 7(g)(1) of the Act provides that designations of official agencies shall not end later than triennially and may be renewed according to the criteria and procedures prescribed in section 7(f) of the Act.

GIPSA is asking for applicants to provide official services in Maryland, New Jersey, and New York. The areas being considered for assignment to the applicant or applicants selected for designation, pursuant to section (7)(2) of the Act, are as follows:

The entire state of Maryland, except those export port locations within the State which are served by GIPSA.

The entire state of New Jersey, except those export port locations within the State which are served by GIPSA.

The entire state of New York, except those export port locations within the State which are served by GIPSA.

Opportunity for designation. Interested persons are hereby given the opportunity to apply for designation to provide official services in the geographic areas specified above under the provisions of section 7(f) of the Act and section 800.196(d) of the regulations issued thereunder. Designation in the specified geographic areas is for a period of no more than 3 years. To apply for designation, contact the Compliance Division at the address listed above for forms and information, or obtain applications at the GIPSA Web site, http://www.gipsa.usda.gov. Applications, comments, and other available information will be considered in determining which applicant will be designated.

Authority: 7 U.S.C. 71–87k.

Alan Christian,

Acting Administrator, Grain Inspection, Packers and Stockyards Administration.

[FR Doc. E7–23530 Filed 12–4–07; 8:45 am]

BILLING CODE 3410–KD–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

Information Collection Activity; Comment Request

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended), the Rural Utilities Service (RUS) an agency delivering the U.S. Department of Agriculture (USDA) Rural Development Utilities Programs invites comments on this information collection for which approval from the Office of Management and Budget (OMB) will be requested.

DATES: Comments on this notice must be received by February 4, 2008.

FOR FURTHER INFORMATION CONTACT: Michele L. Brooks, Acting Director, Program Development and Regulatory Analysis, Rural Utilities Service, 1400 Independence Ave., SW., STOP 1522, Room 5159 South Building, Washington, DC 20250–1522. *FAX:* (202) 720–8435.

SUPPLEMENTARY INFORMATION: The Office of Management and Budget's (OMB) regulation (5 CFR part 1320) implementing provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13) requires that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities (see 5 CFR 1320.8(d)). This notice identifies an information collection that RUS is submitting to OMB for extension.

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 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 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 are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be sent to: Michele L. Brooks, Program Development and Regulatory Analysis, Rural Utilities Service, U.S. Department of Agriculture, STOP 1522, 1400 Independence Ave., SW., Washington, DC 20250–1522. *FAX:* (202) 720–8435.

Title: Electric Loan Application and Related Reporting Burdens.

OMB Number: 0572–0032.

Type of Request: Extension of a currently approved information collection.

Abstract: The Rural Electrification Act of 1936 (7 U.S.C. 901 *et seq.*), as amended (RE Act) authorizes and empowers the Administrator of RUS to make and guarantee loans to furnish and improve electric service in rural areas. These loans are amortized over a period of up to 35 years and secured by the borrower's electric assets. In the interest of protecting loan security, monitoring compliance with debt covenants, and ensuring that RUS loan funds are used for purposes authorized by law, RUS requires that borrowers prepare and submit for RUS evaluation, certain

studies and reports. Some of these studies and reports are required only once for each loan application; others must be submitted periodically until the loan is completely repaid.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 14 hours per response.

Respondents: Businesses or other for profits; not-for-profit institutions.

Estimated Number of Respondents: 680.

Estimated Number of Responses per Respondent: 6.

Estimated Total Annual Burden on Respondents: 65,673.

Copies of this information collection, and related form and instructions, can be obtained from Joyce McNeil, Program Development and Regulatory Analysis, at (202) 720–0812. *FAX:* (202) 720–8435.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Dated: November 29, 2007.

James Andrew,

Administrator, Rural Utilities Service.

[FR Doc. E7–23561 Filed 12–4–07; 8:45 am]

BILLING CODE 3410–15–P

COMMISSION ON CIVIL RIGHTS

Information Quality Guidelines

AGENCY: U.S. Commission on Civil Rights.

ACTION: Final Information Quality Guidelines.

SUMMARY: The Office of Management and Budget (OMB) directed Federal agencies to make available on their Web sites guidelines that ensure and maximize the quality, objectivity, utility, and integrity of information (including statistical information) they disseminate. Federal agencies should also make available on their Web sites administrative mechanisms that allow affected persons to seek and obtain correction of information that the agency maintains and disseminated that does not comply with the guidelines. The U.S. Commission on Civil Rights (Commission) now publishes the following guidelines covering pre-dissemination information quality control and an administrative mechanism for requests for correction of information the Commission publicly disseminates. These guidelines were published in the **Federal Register** on July 24, 2006 at 71 FR 41762 and provided that the Commission would receive public comments through August 23, 2006 to be considered in the formulation of these final guidelines. No comments were received. OMB provided the Commission with suggested revisions, which the Commission used in preparing these final guidelines.

FOR FURTHER INFORMATION CONTACT: Contact David P. Blackwood, Esq., General Counsel, United States Commission on Civil Rights, 624 Ninth Street, NW., Suite 620, Washington, DC 20425, (202) 376–8351; *Facsimile:* (202) 376–1163.

SUPPLEMENTARY INFORMATION: In response to the draft guidelines, the Commission received suggested revisions from OMB. The Commission changed the draft guidelines to address these suggestions as follows:

1. Commission-sponsored testimony of Commission officials is now subject to the guidelines if it contains information not previously disseminated by the agency.

2. Statements reasonably expected to become the subject of litigation or other dispute resolution proceedings are now not automatically outside the scope of the guidelines.

3. Petitions for correction of information must now describe the specific corrective action sought.

4. The Commission's corrective actions may now take a number of forms and not simply the issuance of an errata page.

5. Postings of the quality information requests to the Commission's Web site now include: a copy of the requests to seek and obtain correction of information, the Commission's formal response(s), and any communications regarding appeals.

All other OMB suggested changes that were accepted by the Commission were non-substantive (*i.e.*, typographical or grammatical) in nature.

The Commission also substituted the e-mail address provided in Section VII.02(c) of the draft guidelines with *qualityinfo@usccr.gov* and corrected section references to Administrative Instruction 1–6, National Project Development and Implementation.

For the reasons discussed in the summary, the Commission proposes to issue these guidelines pursuant to Section 515 of the Paperwork Reduction Act (44 U.S.C. 3502(1), *et seq.*).

Dated: November 29, 2007.

David P. Blackwood,

General Counsel, United States Commission on Civil Rights.

Section I. The U.S. Commission on Civil Rights' Mission and Mandate

.01 The Commission is an independent, bipartisan, fact-finding Federal agency of the executive branch established under the Civil Rights Act of 1957 to monitor and report on the status of civil rights in the nation. As the nation's conscience on matters of civil rights, the Commission strives to keep the President, Congress, and the public informed about civil rights issues that deserve concerted attention.

.02 The Commission is mandated to:

(a) Investigate complaints alleging that citizens are being deprived of their right to vote by reason of their race, color, religion, sex, age, disability, or national origin, or by reason of fraudulent practices;

(b) Study and collect information relating to discrimination or a denial of equal protection of the laws under the Constitution because of race, color, religion, sex, age, disability, or national origin, or in the administration of justice;

(c) Appraise Federal laws and policies with respect to discrimination or denial of equal protection of the laws because of race, color, religion, sex, age, disability, or national origin, or in the administration of justice;

(d) Serve as a national clearinghouse for information in respect to discrimination or denial of equal protection of the laws because of race, color, religion, sex, age, disability, or national origin;

(e) Submit reports, findings, and recommendations to the President and Congress;

(f) Issue public service announcements to discourage discrimination or denial of equal protection of the laws.

.03 The Commission's National Office is in Washington, DC. Its six Regional Offices are located throughout the nation:

(a) The Eastern Regional Office, Washington, DC;

(b) Southern Regional Office, Atlanta, Georgia;

(c) Midwestern Office, Chicago, Illinois;

(d) Central Regional Office, Kansas City, Kansas;

(e) Rocky Mountain Office, Denver, Colorado; and

(f) Western Regional Office, Los Angeles, California.

.04 State Advisory Committees (SACs) are established in each State and

in Washington, DC. SACs advise the Commission on matters pertaining to discrimination or denials of equal protection of the laws because of race, color, religion, sex, national origin, age, disability, or in the administration of justice. They also assist the Commission in its statutory obligation to serve as a national clearinghouse for information on those subjects. SACs present advice to the Commission in a variety of forms, including formal fact-finding reports and briefing memoranda.

Section II. The Office of Management and Budget Governmentwide Guideline

.01 Section 515 of the Treasury and General Government Appropriation Act for Fiscal Year 2001 (Pub. L. 106–554) directs OMB to issue to Federal agencies subject to the Paper Reduction Act (44 U.S.C. Chapter 3502(1) *et seq.*) governmentwide guidelines that provide policy and procedural guidance for ensuring and maximizing the quality, objectivity, utility, and integrity of the information (including statistical information) that they disseminate. Specifically, the OMB guidelines direct agencies to:

(a) Issue their own guidelines, consistent with governmentwide guidelines, to ensure and maximize the quality, objectivity, utility, and integrity of information (including statistical information) the agency disseminates;

(b) Establish administrative mechanisms allowing affected persons to seek and obtain correction of information the agency maintains and disseminates that does not comply with OMB guidelines; and

(c) Report annually to the OMB Director the number and nature of complaints the agency received regarding compliance with OMB guidelines on quality, objectivity, utility, and integrity of information and how such complaints were resolved.

.02 The OMB guidelines offer three underlying principles. Agencies should ensure that the guidelines:

(a) Are sufficiently flexible to be applied to a wide variety of information activities that range in importance and scope, and to fit all forms of media;

(b) Meet basic information quality standards, although some information may require higher or more specific standards. Agencies should weigh the costs and benefits of higher information quality in the context of their mission, budget constraints, and timeliness in dissemination; and

(c) Are applied in a common-sensical and workable manner. Agencies should incorporate quality information guideline standards and procedures into exisiting processes and procedures. Application of these guidelines should not impose unnecessary administrative burdens.

Section III. The Commission's Existing Policies and Procedures that Ensure and Maximize Information Quality

.01 The Commission disseminates information on civil rights through:

(a) Reports to Congress and the President, including an annual report on civil rights enforcement as required by statute and other reports as considered appropriate;

(b) Program activities, such as hearings, briefings, conferences, and consultations; and

(c) Provision of civil rights information to the public through its clearinghouse function.

.02 In order to ensure the accuracy and the impartiality of the information it provides, the Commission has in place various mechanisms to correct the information it disseminates. OMB's Information Quality Guidelines urge agencies to integrate into existing guidelines for dissemination of information the standards for information quality embodied in the Data Quality Act. The Commission shall improve the quality of the information it disseminates as it seeks to achieve the strategic goals of its mission while adhering to budget and resource priorities.

.03 The mechanisms the Commission uses to ensure information quality are:

(a) Defame and Degrade Review. Commission regulations provide procedural guidelines when statements made at Commission hearings or in reports will defame, degrade or incriminate persons or institutions.

A statement defames and degrades if its probable effect is to damage the person or institution criticized in reputation, business, or otherwise. In determining whether damage is likely to result, it is necessary to consider the substance of the allegations, all the circumstances surrounding it, and the community perception and reaction that is likely to result. All this must all be considered in light of the applicable legal standards governing defamation of public versus private persons and entities.

When in advance of a hearing the Commission determines that certain evidence may tend to defame, degrade, or incriminate any person at any hearing, it shall receive such evidence or testimony, or a summary of such evidence or testimony in executive session. The Commission affords such persons defamed, degraded, or incriminated by such evidence or testimony an opportunity to appear and be heard in executive session with a reasonable number of additional witnesses they request, before deciding to use such evidence or testimony. If the Commission decides to make this information public, it will give the person the opportunity to appear as a voluntary witness or submit a sworn statement. Procedures for addressing evidence presented at a hearing that may tend to defame, degrade, or incriminate any person are specified at 45 CFR 702.11.

If a Commission report tends to defame, degrade, or incriminate any person, the report or relevant portions thereof shall be delivered to such person at least thirty (30) days before the report is published to allow such person the opportunity to make a timely verified answer to the report, or relevant portions thereof. Administrative Instruction 7–1, Procedures for Providing an Opportunity for Response to Persons Criticized by Commission Publications and Audiovisual Products, at section 6 provides that whenever a publication, other than a statutory report, contains material that tends to defame and degrade, such person must be provided a full and fair opportunity to respond to such material. Section 7 of Administrative Instruction 7–1 provides for a defame and degrade review of State Advisory Committee reports. Section 8 of Administrative Instruction 7–1 provides for a defame and degrade review of the *Civil Rights Journal*.

(b) Legal Sufficiency Review.

Administrative Instruction 1–6, National Project Development and Implementation, at section 16 provides for legal sufficiency review by the Office of General Counsel of draft reports and national office publications that are provided to the public. The purpose of the legal sufficiency review is to ensure the adequate interpretation and citation of legal materials and compliance with statutory requirements. SAC reports also will be subject to a legal sufficiency review.

(c) Editorial Policy Review.

Administrative Instruction 1–6, National Project Development and Implementation, at section 15 provides that the Staff Director will appoint members of an editorial policy board to review draft national reports to determine the adequacy and accuracy of the substantive information in the draft document (for example, conceptual soundness, adherence to Commission policy, quality of research, argumentation, and documentation of major points). The project staff revises the draft document in accordance with

the editorial board comments. The appropriate office director apprises the Staff Director by memorandum of areas upon which agreement was not reached and changes were not made. Once the substantive changes are made, the new material must be submitted for an expedited legal sufficiency review.

The Regional Directors are responsible for ensuring that such reports are unbiased, methodologically sound, well written, appropriately organized, and properly formatted. SACs are ultimately responsible for the substance of their reports and memoranda. A report is forwarded to the Staff Director following formal approval from the appropriate State Advisory Committee.

(d) Affected Agency Review.

Administrative Instruction 1–6, National Project Development and Implementation, at section 17 provides that after completing any revisions occasioned by legal and editorial reviews, the director of the appropriate office sends the sections of the draft report that pertain to a government agency to the affected agency for review and comment on the accuracy of the material contained therein. The Commission's draft findings, conclusions, and recommendations are not submitted to the affected agency. Nongovernmental organizations receive pertinent material for review where appropriate. Upon receipt of comments, the project staff prepares the appropriate revisions. SAC reports also are subject to an affected agency review.

.04 Information Technology and Systems Management. Administrative Instruction 4–18, Information Technology and Systems Management, provides guidance for the appropriate management of information technology resources and systems throughout their life cycle, in accordance with federal regulations, policies and guidelines. It also provides for the establishment and maintenance of a strategic information resources management planning process that includes:

(a) An up-to-date five-year plan that has, among others, document linkages between mission needs and information technology capabilities; and

(b) An up-to-date security and disaster preparedness plan for information systems that provides adequate assurances of the availability, confidentiality and integrity of the information systems.

.05 The Staff Director is the Chief Information Officer (CIO) of the agency and has primary responsibility for managing the Commission's information resources. The Deputy CIO will manage the Commission's security systems and procedures, and monitor Commission compliance with appropriate federal policies, principles, standards, guidelines, rules, and administrative instructions.

.06 Data Collection from the Public.

(a) Administrative Instruction 1–6, National Project Development and Implementation, at section 9 provides that the Chief of the Administrative Services and Clearinghouse Division (ASCD) is the Commission's designated paperwork reduction officer, and as such, is responsible for reviewing proposed data collection procedures as required by the Paperwork Reduction Act of 1980. It provides that when collecting information from ten or more persons or organizations, the Commission must receive prior approval from OMB. The appropriate documents are submitted to the ASCD Chief at least fifty (50) days before the anticipated administration of a questionnaire or interview schedule.

(b) The Civil Rights Commission Amendments Act of 1994, Public Law 103–419, 108 Stat. 4338, at 42 U.S.C. 1975a(e) provides that the Commission may issue subpoenas for the attendance of witnesses and the production of written or other matter in a hearing approved by the Commission. In addition, the Commission may use depositions and written interrogatories to obtain information and testimony about matters that are the subject of a Commission hearing or report.

Further, data also are collected at briefings, conferences, hearings, and during consultation and interviews by staff. Staff shall submit the Commission's Privacy Act notice to potential data sources at these prior to collecting the data.

Section IV. Scope and Applicability of the Commission's Quality Information Guidelines

.01 Consistent with OMB guidance, the definitions of information and dissemination set the scope and applicability of the Commission's quality information guidelines. For the purposes of these guidelines, information means any communication or representation of facts or data, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms. This definition includes information that the Commission disseminates from a Web page, but does not include the provision of hyperlinks to information that others disseminate.

.02 This definition of information does not include:

(a) Opinions or policies, where the presentation makes clear that the statements are subjective opinions, rather than facts. Underlying information upon which the opinion or policy is based may be subject to these guidelines only if the Commission publishes that information;

(b) Information originated by and attributed to non-Commission sources, provided the Commission does not expressly rely upon it. Examples include non-U.S. government information reported and duly attributed in materials the Commission prepared and disseminated, hyperlinks on the Commission's Web site to information that others disseminate, and reports of advisory committees published on the Commission's Web site that are not explicitly endorsed by the Commission;

(c) Statements relating solely to the Commission's internal personnel rules and practices and other materials produced for the Commission's employees, contractors, or agents;

(d) Descriptions of the Commission, its responsibilities, and organizational components;

(e) Statements, the modification of which might cause harm to the national security, including harm to the national defense or foreign relations of the United States;

(f) Statements of Commission policy; however, any underlying information the Commission published upon which a statement is based may be subjected to these guidelines;

(g) Testimony or comments of Commission officials before courts, administrative bodies, Congress, or the media, unless such testimony contains new, substantive information not previously disseminated;

(h) Investigatory material compiled pursuant to U.S. law or for law enforcement purposes in the United States; or

.03 Dissemination means Commission initiated or sponsored distribution of information to the public (see 5 CFR 1320.3(d) "Conduct or Sponsor").

.04 This definition of dissemination does not include distributions of information or other materials that are:

(a) Produced in response to requests for Commission records under the Freedom of Information Act, the Privacy Act, the Federal Advisory Committee Act, or similar law; or

(b) Archival records, public filings, responses to subpoena or compulsory document productions, or documents prepared and released in the context of adjudicative processes. These guidelines do not impose any additional requirements on the Commission during adjudicative proceedings and do not

provide parties to such adjudicative proceedings any additional rights of challenge or appeal; and

(c) Limited to Commission employees or Commission contractors or grantees, as well as intra- or inter-agency use or sharing of government information.

.05 Consistent with OMB guidance, the Commission's guidelines apply to any covered information the Commission disseminated on or after October 1, 2002. The Commission's administrative mechanism shall apply to information that it disseminates on or after October 1, 2002, regardless of when it first disseminated the information.

Section V. The Commission's Guidelines for Ensuring and Maximizing Information Quality

.01 In accordance with OMB guidelines, quality encompasses utility, objectivity, and integrity. These four statutory terms sometimes are collectively referred to as quality. The Commission shall adopt a basic standard of quality and take appropriate steps to ensure that all offices in the National Office and each Regional Office incorporate quality criteria into its information dissemination practices.

.02 Utility of Information

(a) Utility means the usefulness of the disseminated information to its intended users, including the public. The Commission is committed to disseminating quality information. Basic to achieving utility is an understanding of what information is needed as the Commission seeks to fulfill its mission and mandate. The Commission shall identify civil rights issues in which there is a critical need for information and shall develop and implement plans to provide such information.

(b) The Commission shall assess the utility of the information it will produce from original research and secondary analysis of existing data. It shall also assess the utility of the information it disseminates that is provided by or obtained from outside sources and which it adopts, endorses, or uses.

(c) When reproducibility and transparency of information are essential for determining information utility, the Commission shall ensure the reproducibility and transparency of the research design and analytic methods. In this context, reproducibility means that the information is capable of being reproduced, subject to an acceptable degree of imprecision. With respect to analytic results, "capable of being substantially reproduced" means that independent analysis of the original or supporting data using identical methods would generate similar analytic results, subject to an acceptable degree of imprecision.

(d) In order to enhance further the utility of information, the Commission shall ensure that the information it will disseminate is clearly written in plain English, grammatically correct, and free of spelling or typographical errors. Where appropriate, the Commission shall include contact information for intended users and the public who may wish to obtain supplementary information, seek further elucidation, or provide comments.

.03 Objectivity of Information

Objectivity concerns substance and presentation of disseminated information. Substance focuses on whether the content of the disseminated information is accurate, reliable, unbiased, and balanced. Presentation concerns whether the disseminated information is presented in an accurate, clear, complete, and unbiased manner. The Commission is committed to disseminating information that reflects these two elements.

(a) In the course of fulfilling its mission and mandate, the Commission conducts social science studies and evaluates federal civil rights enforcement programs, reports on findings and conclusions, and makes recommendations. The Commission strives for a research process that embodies methodological and statistical rigor, intellectual honesty in analysis, and presentation of findings and conclusions in full and proper context in order to achieve accurate, reliable, and unbiased reports. In this respect, the Commission's Administrative Instruction 1–6, National Project Development and Implementation at sections 7 and 8 is instructive. Consistent with it, the Commission shall ensure that the program office primarily responsible for reports:

(1) Develops methodologically strong and practically feasible research designs capable of judging the issues addressed;

(2) Makes explicit the assumptions underlying research efforts;

(3) Conducts thorough review of the literature representing a wide range of perspectives on the subject of study or evaluation;

(4) Uses appropriate and sound research methods to gather information;

(5) Uses appropriate and sound statistical techniques to analyze collected information;

(6) Ensures that the analysis is unbiased;

(7) Presents disseminated information within a full and proper context, including supporting data as appropriate;

(8) Identifies data sources (to the extent possible, consistent with confidentiality protections); and

(9) Specifies limitations of the study or evaluation, including error sources that affect data quality.

The Staff Director is responsible for reviewing national office project designs and proposals to ensure that they reflect objectivity and balance. The Staff Director also reviews State Advisory Committee reports for balance and objectivity.

.04 In conducting social science studies and evaluation of federal civil rights enforcement programs, the Commission may combine original research with secondary analysis of existing data or may rely solely on the latter. The sources of existing data may be other federal government agencies, advisory committees, or other organizations and individuals. The Commission expects that these entities will subject information they submit to adequate quality control measures. Prior to using existing data from outside sources, the responsible program office shall review and verify the data as necessary and appropriate. Data collected at briefings may be verified by requiring the outside sources to submit testimony upon oath or affirmation. Being subject to these guidelines does not necessarily mean that the material the Commission publishes is a policy statement of the United States government.

.05 When the responsible program office determines that the information it will disseminate is influential social science, financial, legal, or statistical information, it shall take extra care to include a high degree of transparency about data and research methods to meet OMB's requirement for the reproducibility of such information. In this context, influential means that such information will have or does have a clear and substantial impact on important public policies pertaining to civil rights issues or important private sector decisions that have civil rights implications. A high degree of transparency for disseminated information here means that the methodology used to derive the results is readily understandable to persons experienced in the appropriate field of study. In determining the appropriate level of transparency, the responsible program office will consider the types of data that can be practically subjected to a reproducibility requirement given ethical, feasibility, confidentiality, and national security constraints. In making this determination, the responsible program office will hold analytical results to an even higher standard than

original data. It is important that analytic results have a high degree of transparency regarding:

(a) The source of the data used;

(b) The various assumptions employed;

(c) The analytic methods applied; and

(d) The statistical procedures employed.

.06 The Commission may contract, from time to time, with organizations or individuals to conduct research and analysis in support of its mission and mandate, but Commission policy does not influence their results. The responsible program office that disseminates contractor-prepared information will maintain records on data sources, data collection methods, and statistical techniques used in analysis, and retain all data and documents employed in preparing contractor reports. The Commission expects that contractors will adhere to research standards set forth in section V.03 and .04 above. When the Lead Office anticipates that the contractor-prepared information it will disseminate is influential social science, financial, or statistical information, it will ensure that the contractor adheres to section V.05 above.

.07 The clearance process contributes in important ways to the objectivity of disseminated information. The Commission's Administrative Instruction 1–6, National Project Development and Implementation, at sections 14, 15, 16, 17 and 18 provides a rigorous, multi-phased quality control clearance. Where appropriate, the Commission will seek substantive input from other government agencies, nongovernment organizations, scholars, and the public. The Commission also will determine if peer review is appropriate and, if necessary, the Lead Office will coordinate such review;

.08 Public dissemination of hard-bound information and all information published in final form on the Commisson's Web site at *http://www.usccr.gov* shall occur only after clearances are obtained from the Office of the Staff Director, and, if appropriate, with the approval of the Commissioners.

.09 These guidelines focus on procedures for the dissemination of information, as those terms are defined herein. Accordingly, procedures specifically applicable to forms of communication outside the scope of these guidelines, such as those for correspondence, press releases, or to other federal employees, among others, are not included.

.10 Integrity of Information

(a) Integrity refers to security, that is, the protection of information from unauthorized access or revision in order to ensure that it is not compromised through corruption or falsification. Information technology is essential to the Commission as it seeks to fulfill its mission and mandate. A critical component of information integrity is protecting information technology systems from unauthorized access that could compromise information stored therein.

.11 Consistent with Administrative Instruction 4–18, Information Technology and Systems Management, the Commission shall ensure that ASCD coordinates and works with all offices in the National Office, the Regional Offices, and SACs to guarantee the integrity of information residing in its technology systems.

.12 To assist in fulfilling its mission, the Commission's Office of Civil Rights Evaluation and Office of General Counsel conduct studies on issues with civil rights implications. They may collect information for analysis and/or obtain existing information from other sources. These program offices shall protect such information from unauthorized, unanticipated, or unintentional modification. They shall use appropriate controls to safeguard draft reports and confidential information, such as interrogatory responses, from improper dissemination.

Section VI. Administrative Procedures for Pre-Dissemination Review

.01 Each Commission's program office in the National Office and each Regional Office shall incorporate OMB and Commission information quality principles into their existing pre-dissemination review procedures as appropriate.

Section VII. Administrative Mechanism for Correction of Information

.01 The Commission shall allow any affected person to request the correction of Commission-disseminated information that does not comply with applicable OMB and Commission information quality guidelines. An affected person is an individual or an entity that may use, benefit from, or be harmed by the disseminated information at issue.

.02 Information Correction Requests

(a) In the Commission's correction request process the burden of proof rests with the requester. An affected person who believes that information the Commission disseminates does not adhere to the information quality guidelines of OMB or the Commission, and who would like to request correction of specific information, needs to submit a Petition for Correction with the following information.

(1) Name, mailing address, e-mail address, telephone number, and organizational affiliation (if any) of the individual or organization submitting a petition;

(2) Detailed description of the information the requester believes does not comply with the Commission's guidelines, including the exact name of the report or publication, the date, and a description of the specific item in question;

(3) Description of the requester's interest in the information and how the requester is affected by the information in question;

(4) Description of reason(s) that the information should be corrected, including the elements of the information quality guidelines that were not followed; and

(5) The specific corrective action sought, including (if applicable) temporary corrective action pending full resolution of the complaint.

(b) The Petition for Correction should be sent to the Deputy Chief Information Officer (DCIO) for Information Management at the following address: Deputy Chief Information Officer, U.S. Commission on Civil Rights, 624 Ninth Street, NW., Washington, DC 20425.

(c) Alternatively, requesters may submit an e-mail request to the following address: *qualityinfo@usccr.gov*. Requesters should indicate that they are submitting an Information Quality Request in the subject line of the e-mail.

.03 The DCIO will review the request and determine whether it contains all the information required for a Petition. If the request is unclear or incomplete, he/she will seek clarification from the requester.

.04 If the request is complete, the DCIO will forward it to the appropriate program office(s) for a response. The responsible office(s) will determine whether a correction is warranted, and if so, what corrective action it will take. The answer will take into consideration the importance of the information involved, the magnitude of the error, and the cost of undertaking the correction.

.05 The Commission is not required to change the content or status of information simply based on the receipt of a Petition for Correction. The Commission may reject a request that appears to be made in bad faith or without justification, and is only required to undertake the degree of correction that is appropriate for the nature and timeliness of the information involved. In addition, the Commission

need not respond to requests involving information not covered by the information quality guidelines.

.06 The Commission will respond to all Petitions for Correction within sixty (60) calendar days of the receipt of the request by the DCIO, unless there is a reasonable basis for an extension. The requester will be told of the right to appeal the decision.

.07 Appeal

(a) If the requester is not satisfied with the Commission's decision on the request, he/she may appeal to the Commission's CIO within thirty (30) calendar days of the receipt of the Commission's decision. This administrative appeal must include a copy of the initial request, a copy of the Commission's decision, and a written narrative explaining why the requester believes the Commission's decision was inadequate, incomplete, or in error.

(b) This appeal will be sent to the Commission's CIO at the following address: The Chief Information Officer, Staff Director's Office, RE: Information Quality Appeal, Room 700, 624 Ninth Street, NW., Washington, DC 20425.

(c) All appeals will be impartially reviewed by parties other than those who prepared the Commission's decision. The Commission will respond to all appeals within sixty (60) calendar days of the CIO's receipt of the appeal.

(d) If the appropriate Commission official, whether at the initial or appeal stage, decides that the requester is correct and the information should be corrected, he/she will notify the Staff Director who will instruct the official to take appropriate corrective actions. Appropriate corrective actions may take a number of forms, including (but not limited to): Errata pages, personal contacts via letter or telephone, form letters, press releases or postings on the Commission's Web site. Corrective measures, where appropriate, should be designed to provide reasonable notice to affected persons of such correction.The Commission will also post information quality correction requests to its Web site. The specific information will include a copy of each correction request, the Commission's formal response(s), and any communications regarding appeals.

[FR Doc. E7–23526 Filed 12–4–07; 8:45 am]
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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–846]

Brake Rotors from the People's Republic of China: Extension of Time Limit for the Final Results of the Expedited Sunset Review of the Antidumping Duty Order

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: December 5, 2007.

FOR FURTHER INFORMATION CONTACT: Frances Veith, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street & Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482–4295.

SUPPLEMENTARY INFORMATION:

Background

On July 2, 2007, the Department of Commerce ("the Department") initiated a sunset review of the antidumping duty order on brake rotors from the People's Republic of China ("PRC") pursuant to section 751(c) of the Tariff Act of 1930, as amended ("the Act"). *See Initiation of Five–Year ("Sunset") Reviews*, 72 FR 35968 (July 2, 2007) ("*Initiation Notice*"). Based on an adequate response from the domestic interested party and an inadequate response from the respondent interested party, the Department is conducting an expedited sunset review to determine whether revocation of the antidumping order would lead to the continuation or recurrence of dumping, pursuant to section 751(c)(3)(B) of the Act and section 351.218(e)(1)(ii)(C)(2) of the Department's regulations. *See* Memorandum to the International Trade Commission regarding, "Expedited Sunset Review of the AD/CVD Order Initiated in July 2007," dated August 21, 2007. On November 5, 2007, the Department published a notice extending the time limit for the completion of the final results of this review by 30 days until November 29, 2007. *See Brake Rotors from the People's Republic of China: Extension of Final Results of the Expedited Sunset Review of Antidumping Duty Order*, 72 FR 62430 (November 5, 2007).

Extension of Time Limits for Final Results

In accordance with section 751(c)(5)(B) of the Act, the Department may extend the 120–day time period for making its determination by not more than 90 days, if it determines that a review is extraordinarily complicated. As set forth in section 751(c)(5)(C)(i) of the Act, the Department may treat a sunset review as extraordinarily complicated if there are a large number of issues, as is the case in this proceeding. In particular, this sunset review involves complicated issues pertaining to adequacy of responses, related party status, and interested party status. Therefore, the Department has determined, pursuant to section 751(c)(5)(C)(i) of the Act, that the second sunset review of brake rotors from the PRC is extraordinarily complicated, as the Department must consider numerous arguments presented in the domestic interested party's and the U.S. importer's August 1, 2007, substantive response and each parties' August 6, 2007, rebuttals to the substantive responses. Based on the timing of the case, the final results of this expedited sunset review cannot be completed within the statutory time limit of 120 days. Accordingly, the Department is extending the time limit for the completion of the final results by an additional 32 days, from the November 29, 2007, extended deadline, to no later than December 31, 2007, in accordance with section 751(c)(5)(B) of the Act.

This notice is published pursuant to sections 751(a)(2)(B)(iv) and 777(i)(1) of the Act.

Dated: November 29, 2007.

Stephen J. Claeys,

Deputy Assistant Secretary for Import Administration.

[FR Doc. E7–23574 Filed 12–4–07; 8:45 am]
BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

A–570–822

Notice of Amended Final Results in Accordance With Court Decision: Helical Spring Lock Washers from the People's Republic of China

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: December 5, 2007.

SUMMARY: On July 16, 2007, the Court of Appeals for the Federal Circuit ("CAFC") affirmed the decision of the U.S. Court of International Trade ("CIT") to sustain the Department of Commerce's ("the Department") remand redetermination in the tenth administrative review of the antidumping duty order on helical spring lock washers from the People's

Republic of China ("PRC"), for the period October 1, 2002, through September 30, 2003. In its redetermination, the Department assigned Hangzhou Spring Washer Co., Ltd. (also known as Zhejiang Wanxin Grp (ZWG)) ("HSW") a dumping margin of 19.48 percent, rather than the 0.00 percent calculated in the final results of the 2002–2003 antidumping duty administrative review of helical spring lock washers from the PRC. As there is now a final and conclusive court decision in this case, the Department is amending the final results of the 2002–2003 antidumping duty administrative review of helical spring lock washers from the PRC. FOR FURTHER INFORMATION CONTACT: Marin Weaver or Charles Riggle, AD/CVD Operations, Office 8, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482–2336 or (202) 482–0650, respectively.

SUPPLEMENTARY INFORMATION:

Background

On May 17, 2005, the Department published its final results of antidumping duty administrative review. *See Certain Helical Spring Lock Washers from the People's Republic of China: Final Results of Antidumping Duty Administrative Review*, 70 FR 28274 (May 17, 2005) ("Final Results"), and accompanying Issues and Decisions Memorandum for the administrative review covering October 1, 2002, through September 30, 2003. In its *Final Results*, the Department calculated an individual rate for the sole respondent, HSW. The petitioner in this case, Shakeproof Assembly Components Division of Illinois Tool Works Inc. ("Shakeproof"), filed a court challenge (Court No. 05–00404) to the Department's *Final Results*. In the CIT proceeding, the Department moved for a voluntary remand, which the court granted. In the remand redetermination, Commerce revisited the methodology employed in the valuation of zinc plating services and determined to rely solely on the value submitted by petitioner, Shakeproof. This resulted in a recalculation of HSW's dumping margin to 19.48 percent. *See Final Results of Redetermination Pursuant to United States Court of International Trade Remand Order Shakeproof Assembly Components Division of Illinois Tool Works, Inc., Plaintiff, v. United States, Defendant, and Hangzhou Spring Washer Co., Ltd., Defendant - Intervenor* (June 2, 2006).

On August 25, 2006, the CIT sustained the final remand redetermination made by the Department. *See Shakeproof Assembly v. United States*, Slip Op. 2006–129, 2006 Ct. Intl. Trade LEXIS 132 (CIT Aug. 25, 2006).

On October 23, 2006, HSW appealed the CIT's decision. Consistent with the Federal Circuit's decision in *Timken Company v. United States*, 893 F.2d 337, 341 (Fed. Cir. 1990), on November 30, 2006, the Department published a "Notice of Court Decision Not in Harmony with *Final Results* of Administrative Review," which continued suspension of liquidation of the subject merchandise until there was a "final and conclusive" decision in this case (71 FR 69204). On July 16, 2007, the CAFC issued a judgment (without an opinion) affirming the CIT's decision upholding Commerce's remand redetermination. The CAFC's final judgment was not in harmony with the Department's Final Results. Appeals of this decision were due by October 15, 2007, and HSW did not file an appeal of the CAFC's decision.

Amended Final Results

As the litigation in this case has concluded, the Department is amending the *Final Results*. The revised dumping margin in the amended final results is as follows:

Exporter	Margin
Hangzhou Spring Washer Co., Ltd. (also known as Zhejiang Wanxin Grp (ZWG))	19.48 percent

The Department intends to issue appropriate assessment instructions to U.S. Customs and Border Protection 15 days after publication of this notice, and cash deposit instructions to revise the cash deposit rate for the company listed above, effective as of the publication date of this notice.

This notice is published in accordance with sections 735(d) and 777(i) of the Tariff Act of 1930, as amended.

Dated: November 23, 2007.

Stephen J. Claeys,

Acting Assistant Secretary for Import Administration.

[FR Doc. E7–23572 Filed 12–4–07; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

[A–428–841, A–570–925]

Sodium Nitrite from the Federal Republic of Germany and the People's Republic of China: Initiation of Antidumping Duty Investigations

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: December 5, 2007.

FOR FURTHER INFORMATION CONTACT: Brian Smith (Federal Republic of Germany) or Magd Zalok (People's Republic of China), AD/CVD Operations, Offices 2 and 4, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482–1766 or (202) 482–4162, respectively.

SUPPLEMENTARY INFORMATION:

The Petitions

On November 8, 2007, the Department of Commerce (the Department) received petitions concerning imports of sodium nitrite from the Federal Republic of Germany (Germany) (German petition) and the People's Republic of China (PRC) (PRC petition) filed in proper form by General Chemical LLC (petitioner). *See* the Petitions on Sodium Nitrite from the Federal Republic of Germany and the People's Republic of China submitted on November 8, 2007. On November 14, 2007, the Department issued a request for additional information and clarification of certain areas of the petitions. Based on the Department's requests, the petitioner filed additional information on November 19, 2007 (three distinct submissions on General, Germany–only and PRC–only material). The period of investigation (POI) for Germany is October 1, 2006, through September 30, 2007. The POI for the PRC is April 1, 2007, through September 30, 2007. *See* 19 CFR 351.204(b)(i).

In accordance with section 732(b) of the Tariff Act of 1930, as amended (the Act), the petitioner alleges that imports of sodium nitrite from Germany and the PRC are being, or are likely to be, sold in the United States at less than fair value, within the meaning of section 731 of the Act, and that such imports are materially injuring, or threatening material injury to, an industry in the United States.

The Department finds that the petitioner filed these petitions on behalf of the domestic industry because the

petitioner is an interested party as defined in section 771(9)(C) of the Act, and has demonstrated sufficient industry support with respect to the antidumping duty investigations that the petitioner is requesting that the Department initiate (*see* "Determination of Industry Support for the Petitions" section below).

Scope of Investigations

The merchandise covered by each of these investigations is sodium nitrite in any form, at any purity level. In addition, the sodium nitrite covered by these investigations may or may not contain an anti–caking agent. Examples of names commonly used to reference sodium nitrite are nitrous acid, sodium salt, anti–rust, diazotizing salts, erinitrit, and filmerine. The chemical composition of sodium nitrite is $NaNO_2$ and it is generally classified under subheading 2834.10.1000 of the Harmonized Tariff Schedule of the United States (HTSUS). The American Chemical Society Chemical Abstract Service (CAS) has assigned the name "sodium nitrite" to sodium nitrite. The CAS registry number is 7632–00–0.

While the HTSUS subheading, CAS registry number, and CAS name are provided for convenience and customs purposes, the written description of the scope of these investigations is dispositive.

Comments on Scope of Investigations

During our review of the petitions, we discussed the scope with the petitioner to ensure that it is an accurate reflection of the products for which the domestic industry is seeking relief. Moreover, as discussed in the preamble to the regulations (*Antidumping Duties; Countervailing Duties; Final Rule*, 62 FR 27296, 27323 (May 19, 1997)), we are setting aside a period for interested parties to raise issues regarding product coverage. The Department encourages all interested parties to submit such comments within 20 calendar days of signature of this notice. Comments should be addressed to Import Administration's Central Records Unit (CRU), Room 1870, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230. The period of scope consultations is intended to provide the Department with ample opportunity to consider all comments and to consult with parties prior to the issuance of the preliminary determinations.

Comments on Product Characteristics for Antidumping Duty Questionnaires

We are requesting comments from interested parties regarding the appropriate physical characteristics of sodium nitrite to be reported in response to the Department's antidumping questionnaires. This information will be used to identify the key physical characteristics of the subject merchandise in order to more accurately report the relevant factors and costs of production, as well as to develop appropriate product comparison criteria.

Interested parties may provide any information or comments that they feel are relevant to the development of an accurate listing of physical characteristics. Specifically, they may provide comments as to which characteristics are appropriate to use as 1) general product characteristics and 2) the product comparison criteria. We note that it is not always appropriate to use all product characteristics as product comparison criteria. We base product comparison criteria on meaningful commercial differences among products. In other words, while there may be some physical product characteristics utilized by manufacturers to describe sodium nitrite, it may be that only a select few product characteristics take into account commercially meaningful physical characteristics. In addition, interested parties may comment on the order in which the physical characteristics should be used in product matching. Generally, the Department attempts to list the most important physical characteristics first and the least important characteristics last.

In order to consider the suggestions of interested parties in developing and issuing the antidumping duty questionnaires, we must receive comments at the above–referenced address by December 18, 2007. Additionally, rebuttal comments must be received by December 28, 2007.

Determination of Industry Support for the Petitions

Section 732(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 732(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (i) at least 25 percent of the total production of the domestic like product; and (ii) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition. Moreover, section 732(c)(4)(D) of the Act provides that, if the petition does not establish support of domestic producers or workers accounting for more than 50 percent of the total production of the domestic like product, the Department shall: (i) poll the industry or rely on other information in order to determine if there is support for the petition, as required by subparagraph (A), or (ii) determine industry support using a statistically valid sampling method.

Section 771(4)(A) of the Act defines the "industry" as the producers as a whole of a domestic like product. Thus, to determine whether a petition has the requisite industry support, the statute directs the Department to look to producers and workers who produce the domestic like product. The International Trade Commission (ITC), which is responsible for determining whether "the domestic industry" has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both the Department and the ITC must apply the same statutory definition regarding the domestic like product (section 771(10) of the Act), they do so for different purposes and pursuant to a separate and distinct authority. In addition, the Department's determination is subject to limitations of time and information. Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to law. *See USEC, Inc. v. United States*, 132 F. Supp. 2d 1, 8 (CIT 2001), citing *Algoma Steel Corp. Ltd. v. United States*, 688 F. Supp. 639, 644 (CIT 1988), *aff'd* 865 F.2d 240 (Fed. Cir. 1989), *cert. denied* 492 U.S. 919 (1989).

Section 771(10) of the Act defines the domestic like product as "a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this subtitle." Thus, the reference point from which the domestic like product analysis begins is "the article subject to an investigation," (*i.e.*, the class or kind of merchandise to be investigated, which normally will be the scope as defined in the petition).

With regard to the domestic like product, the petitioner does not offer a definition of domestic like product distinct from the scope of the investigation. Based on our analysis of the information submitted on the record, we have determined that sodium nitrite constitutes a single domestic like product and we have analyzed industry support in terms of that domestic like product. For a discussion of the domestic like product analysis in this case, *see* the Antidumping Investigation Initiation Checklist: Sodium Nitrite from the Federal Republic of Germany, Industry Support at Attachment II (Germany Initiation Checklist) and the

Antidumping Investigation Initiation Checklist: Sodium Nitrite from the People's Republic of China (PRC), Industry Support at Attachment II (PRC Initiation Checklist) on file in the CRU, Room B–099 of the main Department of Commerce building.

Our review of the data provided in the petitions, supplemental submissions, and other information readily available to the Department indicates that the petitioner has established industry support. To establish industry support, the petitioner demonstrated that it was the sole producer of the domestic like product in 2006. Therefore, the petitions established support from domestic producers (or workers) accounting for more than 50 percent of the total production of the domestic like product and, as such, the Department is not required to take further action in order to evaluate industry support (*e.g.*, polling). *See* Section 732(c)(4)(D) of the Act. In addition, the domestic producers have met the statutory criterion for industry support under section 732(c)(4)(A)(i) of the Act because the domestic producers (or workers) who support the petitions account for at least 25 percent of the total production of the domestic like product. Finally, the domestic producers have met the statutory criterion for industry support under section 732(c)(4)(A)(ii) of the Act because the domestic producers (or workers) who support the petitions account for more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petitions. Accordingly, the Department determines that the petitions were filed on behalf of the domestic industry within the meaning of section 732(b)(1) of the Act. *See* Germany Initiation Checklist at Attachment II (Industry Support) and PRC Initiation Checklist at Attachment II (Industry Support).

The Department finds that the petitioner filed the petitions on behalf of the domestic industry because it is an interested party as defined in section 771(9)(C) of the Act and it has demonstrated sufficient industry support with respect to the antidumping investigations that it is requesting the Department initiate. *See* Germany Initiation Checklist at Attachment II (Industry Support) and PRC Initiation Checklist at Attachment II (Industry Support).

Allegations and Evidence of Material Injury and Causation

The petitioner alleges that the U.S. industry producing the domestic like product is being materially injured, or is threatened with material injury, by reason of the imports of the subject merchandise sold at less than normal value (NV). The petitioner contends that the industry's injured condition is illustrated by reduced market share, lost sales, reduced production, capacity and capacity utilization rate, reduced shipments, underselling and price depressing and suppressing effects, lost revenue, reduced employment, decline in financial performance, and an increase in import penetration. We have assessed the allegations and supporting evidence regarding material injury and causation, and we have determined that these allegations are properly supported by adequate evidence and meet the statutory requirements for initiation. *See* Germany Initiation Checklist at Attachment III (Injury) and PRC Initiation Checklist at Attachment III (Injury).

Allegations of Sales at Less Than Fair Value

The following is a description of the allegations of sales at less than fair value upon which the Department based its decision to initiate these investigations of imports of sodium nitrite from Germany and the PRC. The sources of data for the deductions and adjustments relating to the U.S. price, constructed value (CV) (for Germany), and the factors of production (for the PRC) are also discussed in the country–specific initiation checklists. *See* Germany Initiation Checklist and PRC Initiation Checklist. Should the need arise to use any of this information as facts available under section 776 of the Act in our preliminary or final determinations, we will reexamine the information and revise the margin calculations, if appropriate.

Germany

Constructed Export Price (CEP) and Export Price (EP)

The petitioner calculated three CEPs based on price quotes during the POI obtained from U.S. distributors for German–produced sodium nitrite. The petitioner also calculated an EP using the average unit customs value (AUV) of imports of subject merchandise from Germany during the POI derived from U.S. Census Bureau import statistics. Specifically, for CEPs based on price quotes, the petitioner made adjustments to the starting price, where applicable, for discounts, foreign inland freight, ocean freight, marine insurance, U.S. inland freight and trans–loading fees, U.S. customs and port fees, and warehousing expenses. The petitioner calculated foreign inland freight, ocean freight, marine insurance, U.S. inland freight and trans–loading fees, and warehousing expenses based on price quotes obtained from custom brokers, freight forwarders, and other service providers. U.S. customs and port fees (*i.e.*, U.S. duty, harbor maintenance and processing fees) were based on standard U.S. government percentages, as applied to the petitioner's estimate of entered value. Because the petitioner's calculation of entered value incorrectly excluded foreign inland freight and included U.S. inland freight and trans–loading fees, we have recalculated U.S. customs and port fees based on entered value exclusive of all movement expenses except foreign inland freight. The petitioner also made an adjustment for CEP profit. To calculate CEP profit, the petitioner derived the profit margin from U.S. chemical–industry-wide statistical gross–margin data from the U.S. Census Bureau and applied this profit ratio to gross unit price. However, the petitioner's CEP profit calculation methodology is not in accordance with the Department's practice (*i.e.*, the petitioner applied the profit ratio to gross unit price rather than to CEP selling expenses) (*see, e.g.*, Policy Bulletin 97.1: Calculation of Profit for Constructed Export Price Transactions (September 4, 1997)). The petitioner's methodology overstates the amount of profit included in CEP. The Department requested that the petitioner provide the information necessary to make the proper calculation, but the petitioner stated that this information was not reasonably available to it. Therefore, to be conservative, we have disallowed this adjustment and have recalculated the CEP–to-NV margins exclusive of the CEP profit adjustment for purposes of initiating this investigation. For EP based on AUV, the petitioner made an adjustment only for foreign inland freight, as the AUV is based on FOB foreign port price. *See* Germany Initiation Checklist and "Fair Value Comparisons" section below for the revised CEP–to-NV margins.

NV Based on CV

With respect to NV, the petitioner states that neither home–market prices nor third–country prices of German–produced sodium nitrite were reasonably available. According to the petitioner, it was unsuccessful in obtaining such pricing information, despite its best efforts. *See* German petition at page 10 and the November 19, 2007, supplement to the German petition at pages 4–5. Therefore, the petitioner based NV on CV.

Pursuant to section 773(e) of the Act, CV consists of the cost of manufacture

(COM); selling, general and administrative (SG&A) expenses; packing expenses; and profit. In calculating COM and packing, the petitioner based the quantity of each of the inputs used to manufacture and pack sodium nitrite in Germany on its own production experience during the POI. The petitioner then multiplied the usage quantities by the value of the inputs used to manufacture and pack sodium nitrite in Germany based on publicly available data, data obtained from market research, or its own costs. *See* Volume I of the German petition at pages 10–13.

Raw material (*i.e.*, ammonia and caustic soda) is the most significant input used in the production of sodium nitrite. The petitioner determined the usage of ammonia and caustic soda based on the quantities it used to produce a short ton of sodium nitrite (*i.e.*, technical and food grades). The values of ammonia and caustic soda were based on price data obtained from market research. The price data from market research were contemporaneous with the POI. The values for other raw material inputs and packing material inputs (*e.g.*, silicon dioxide, bags) were based either on a price quote from market research (silicon dioxide) or on the petitioner's own experience (packing materials). *See* Volume I of the German petition at pages 12–13 and 15, and the November 19, 2007, supplement to the German petition at pages 7–9.

The petitioner determined labor costs using the labor inputs derived from its own experience which it valued using an industrial German wage rate obtained from the International Labour Organization's "Laborsta" database at http://laborsta.ilo.org. *See* Volume I of the German petition at page 15.

The petitioner determined energy costs (*i.e.*, electricity, natural gas, steam, cooling water, and city water) using German price data from market research. *See* Volume I of the German petition at pages 13–14.

To calculate factory overhead, the petitioner relied on its own experience (excluding depreciation) and on a German sodium nitrite producer's parent company's consolidated financial data (for depreciation). *See* Volume I of the German petition at pages 15–16.

To calculate SG&A expenses and profit, the petitioner relied on a German sodium nitrite producer's parent company's consolidated financial data, for the fiscal year ending December 31, 2006, the period most contemporaneous with the POI for which the petitioner was able to obtain such information. *See* Volume I of the German petition at pages 16–17.

PRC

EP

The petitioner calculated three EPs from price quotes for sodium nitrite manufactured in the PRC[1] and one EP from the AUVs of imports from the PRC that were classified under HTSUS number 2834.10.1000 for the period April 2007 through September 2007, as reported by the U.S. Census Bureau. Specifically, the petitioner calculated EPs from the price quotes by deducting from the prices, where applicable, the costs associated with exporting and delivering the product, including foreign inland freight, ocean freight and marine insurance, U.S. inland freight, U.S. warehousing expenses, and U.S. duties and port charges. *See* PRC Initiation Checklist. The petitioner calculated foreign inland freight expense using the Indian truck freight rate used by the Department in the investigation of certain lined paper products from the PRC,[2] and information it obtained regarding distances between sodium nitrite producers and the likely port of exportation. *See* Exhibit III–2 of the PRC petition, and Exhibit 2 of the November 19, 2007, supplement to the PRC petition. The petitioner based ocean freight and marine insurance expenses, U.S. warehousing, and rail and truck expenses on price quotes obtained from service providers. *See* Exhibits III–2–5 of the PRC petition. The petitioner based U.S. duties and port charges (*i.e.*, U.S. duty, harbor maintenance and processing fees) on standard charges and duties applicable to sodium nitrite imported under HTSUS number 2834.10.1000. The petitioner calculated an EP from import data by deducting from the AUV of April through September 2007 PRC imports under HTSUS number 2834.10.1000 the expenses for transporting the product from the PRC factory to the port of exportation (the AUV is based on an FOB foreign port price). *See* Exhibit 3 of the November 19, 2007, supplement to the PRC petition. We recalculated the EPs to correct certain errors in the petitioner's calculations. *See* PRC Initiation Checklist.

[1] The prices quotes are for three different types of sodium nitrite falling within the scope of these investigations, for delivery to the U.S. customer within the POI.

[2] *See Preliminary Determination of Sales at Less Than Fair Value, Affirmative Critical Circumstances, In Part, and Postponentent of Final Determination: Certain Lined Paper Products from the People's Republic of China*, 71 FR 19695 (April 17, 2006).

NV

The petitioner stated that the PRC is a non–market economy (NME) country and no determination to the contrary has been made by the Department. Recently, the Department examined the PRC's status and determined that NME status should continue for the PRC. *See* the memorandum to David Spooner, Assistant Secretary for Import Administration, regarding "The People's Republic of China (PRC) Status as a Non–Market Economy (NME)," dated May 15, 2006 (this document is available online at http://ia.ita.doc.gov/download /prc–nme-status/prc–nme-status–memo.pdf). In addition, in two recent antidumping duty investigations, the Department determined that the PRC is an NME country. *See Final Determination of Sales at Less Than Fair Value: Certain Activated Carbon from the People's Republic of China*, 72 FR 9508 (March 2, 2007); *see also Final Determination of Sales at Less Than Fair Value and Partial Affirmative Determination of Critical Circumstances: Certain Polyester Staple Fiber from the People's Republic of China*, 72 FR 19690 (April 19, 2007). In accordance with section 771(18)(C)(i) of the Act, the presumption of NME status remains in effect until revoked by the Department. Because the presumption of NME status for the PRC has not been revoked by the Department, it remains in effect for purposes of this initiation. Accordingly, the NV of the product is appropriately based on factors of production valued in a surrogate market economy country in accordance with section 773(c) of the Act. After initiation, all parties will have the opportunity to provide relevant information regarding the PRC's NME status and whether separate rates should be granted to individual exporters.

The petitioner selected India as the surrogate market economy country. The petitioner claimed, pursuant to section 773(c)(4) of the Act, that India is an appropriate surrogate country because it is at a level of economic development comparable to that of the PRC and is a significant producer of sodium nitrite. *See* Volume I of the PRC petition at pages 21–23. Based on the information provided by the petitioner, we believe that it is appropriate to use India as a surrogate country for initiation purposes. After initiation, we will solicit comments regarding surrogate country selection.

The petitioner calculated NVs for each U.S. price discussed above using the NME methodology required by 19 CFR 351.202(b)(7)(i)(C) and 19 CFR 351.408. Because the quantities of

factors of production consumed by Chinese producers in manufacturing sodium nitrite are not available to the petitioner, the petitioner calculated NVs using its own consumption rates for producing sodium nitrite during the last two completed quarters. *See* the PRC petition at page 23, Exhibit III–9 in Volume I of the PRC petition, and the November 19, 2007, supplement to the PRC petition at Exhibit 9. The petitioner adjusted its NV calculation to account for certain differences between its own manufacturing process and the prilling process used by PRC producers. *See* the PRC petition at page 27, and Exhibit 9 of the November 19, 2007, supplement to the PRC petition. One adjustment involved the number of labor hours required to produce a unit of output. Specifically, the petitioner stated that the production and packing of subject merchandise is more labor intensive in the PRC than in the United States, requiring twice as much labor to produce the same amount of finished product. The petitioner explained that this adjustment is based on its employees' commercial knowledge, observations of production in the PRC, and company resources. *See* Exhibit III–9 of the PRC petition, and the November 19, 2007, supplement to the PRC petition at page 8.

The petitioner based the value of material inputs on official Indian trade statistics from the Indian Department of Commerce's Export–Import Data Bank and prices in the periodical, *ICIS Chemical Bulletin*, dated September 10, 2007. *See* the PRC petition at Exhibits III–12 and III–13. In calculating surrogate values from Indian import data, the petitioner excluded the values of imports from unspecified countries, NME countries, and countries which the Department has found to maintain broadly available, non–industry-specific export subsidies (*i.e.*, Indonesia, the Republic of Korea and Thailand). *See Hand Trucks and Certain Parts Thereof From the People's Republic of China: Final Results of Administrative Review and Final Results of New Shipper Review*, 72 FR 27287 (May 15, 2007), and accompanying Issues and Decision Memorandum at Comment 23. The surrogate values used by the petitioner for material and packing inputs consist of information reasonably available to the petitioner and are, therefore, acceptable for purposes of initiation.

The petitioner was unable to obtain surrogate values that were contemporaneous with the POI for all material inputs and, accordingly, it relied upon the most recently available information. Where a surrogate value was in effect during a period preceding the POI, the petitioner adjusted it using the Indian wholesale price index in the publication, *International Financial Statistics*, which is published by the International Monetary Fund. However, because the petitioner incorrectly calculated these adjustments, the Department has revised them. *See* the PRC Initiation Checklist.

The petitioner based factory overhead expenses, SG&A expenses, and profit on data from an Indian sodium nitrite producer, Deepak Nitrite Limited. The data comes from Deepak Nitrite Limited's most recently available financial statement which covers the period April 1, 2006, through March 31, 2007. *See* the November 19, 2007, supplement to the PRC petition at Exhibit 16. We find the petitioner's use of Deepak Nitrite Limited's data is appropriate for purposes of this initiation. *See* the NV calculation in the November 19, 2007, supplement to the PRC petition at Exhibit 10.

Fair Value Comparisons

Based on the data provided by the petitioner, there is reason to believe that imports of sodium nitrite from Germany and the PRC are being, or are likely to be, sold in the United States at less than fair value. Based on a comparison of CEP and CV, calculated in accordance with section 773(a)(4) of the Act, the revised estimated dumping margins for sodium nitrite from Germany range from 65.58 to 151.98 percent. Based on a comparison of EP and CV, calculated in accordance with section 773(a)(4) of the Act, the estimated dumping margin for sodium nitrite from Germany is 237 percent. *See Germany Initiation Checklist*. Based on comparisons of EP to NV, calculated in accordance with section 773(c) of the Act, the revised estimated dumping margins for sodium nitrite from the PRC range from 131.72 percent to 190.74 percent. *See* PRC Initiation Checklist.

Initiation of Antidumping Investigations

Based upon the examination of the petitions on sodium nitrite from Germany and the PRC, the Department finds that the petitions meet the requirements of section 732 of the Act. Therefore, we are initiating antidumping duty investigations to determine whether imports of sodium nitrite from Germany and the PRC are being, or are likely to be, sold in the United States at less than fair value. In accordance with section 733(b)(1)(A) of the Act, unless postponed, we will make our preliminary determinations no later than 140 days after the date of this initiation.

Separate Rates

In order to obtain separate–rate status in NME investigations, exporters and producers must submit a separate–rate status application. *See* Policy Bulletin 05.1: Separate–Rates Practice and Application of Combination Rates in Antidumping Investigations involving Non–Market Economy Countries (April 5, 2005) (Separate Rates and Combination Rates Bulletin), available on the Department's website at http://ia.ita.doc.gov/policy/bull05–1.pdf. Based on our experience in processing the separate–rate applications in previous antidumping duty investigations, we have modified the application for this investigation to make it more administrable and easier for applicants to complete. *See, e.g., Initiation of Antidumping Duty Investigation: Certain New Pneumatic Off–the-Road Tires From the People's Republic of China*, 72 FR 43591, 43594–95 (August 6, 2007). The specific requirements for submitting the separate–rate application in this investigation are outlined in detail in the application itself, which will be available on the Department's website at http://ia.ita.doc.gov/ia–highlights-and–news.html on the date of publication of this initiation notice in the **Federal Register**. The separate–rate application will be due 60 days after publication of this initiation notice.

Respondent Selection

For these investigations, the Department intends to select respondents based on U.S. Customs and Border Protection (CBP) data for U.S. imports under HTSUS number 2834.10.1000 during the POI. We intend to make our decisions regarding respondent selection within 20 days of publication of this **Federal Register** notice. The Department invites comments regarding the CBP data and respondent selection within seven days of publication of this **Federal Register** notice.

Use of Combination Rates in an NME Investigation

The Department will calculate combination rates for certain respondents that are eligible for a separate rate in this investigation. The Separate Rates and Combination Rates Bulletin, states:

> {w}hile continuing the practice of assigning separate rates only to exporters, all separate rates that the Department will now assign in its NME investigations will be specific to those producers that supplied the exporter during the period of

investigation. Note, however, that one rate is calculated for the exporter and all of the producers which supplied subject merchandise to it during the period of investigation. This practice applies both to mandatory respondents receiving an individually calculated separate rate as well as the pool of non–investigated firms receiving the weighted–average of the individually calculated rates. This practice is referred to as the application of "combination rates" because such rates apply to specific combinations of exporters and one or more producers. The cash–deposit rate assigned to an exporter will apply only to merchandise both exported by the firm in question *and* produced by a firm that supplied the exporter during the period of investigation. (Emphasis added.)

Separate Rates and Combination Rates Bulletin, at page 6.

Distribution of Copies of the Petitions

In accordance with section 732(b)(3)(A) of the Act and 19 CFR 351.202(f), copies of the public versions of the petitions have been provided to the representatives of the Governments of Germany and the PRC. We will attempt to provide a copy of the public version of the petitions to the foreign producers/exporters, consistent with 19 CFR 351.203(c)(2).

International Trade Commission Notification

We have notified the ITC of our initiations, as required by section 732(d) of the Act.

Preliminary Determinations by the International Trade Commission

The ITC will preliminarily determine, no later than December 24, 2007, whether there is a reasonable indication that imports of sodium nitrite from Germany and the PRC are materially injuring, or threatening material injury to, a U.S. industry. A negative ITC determination with respect to either of the investigations will result in that investigation being terminated; otherwise, these investigations will proceed according to statutory and regulatory time limits.

This notice is issued and published pursuant to section 777(i) of the Act.

Dated: November 28, 2007.

David M. Spooner,

Assistant Secretary for Import Administration.

[FR Doc. E7–23489 Filed 12–4–07; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

Battelle Memorial Institute, et al.; Notice of Consolidated Decision on Applications for Duty-Free Entry of Electron Microscopes

This is a decision consolidated pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, as amended by Pub. L. 106–36, 80 Stat. 897; 15 CFR part 301). Related records can be viewed between 8:30 a.m. and 5 p.m. in Room 2104, U.S. Department of Commerce, 14th and Constitution Avenue, NW., Washington, DC.

Docket Number: 07–062. *Applicant:* Battelle Memorial Institute, Richland, WA 99354. *Instrument:* Electron Microscope, Model FIB/SEM. *Manufacturer:* FEI Company, Netherlands. *Intended Use:* See notice at 72 FR 63875, November 13, 2007.

Docket Number: 07–063. *Applicant:* University of California, San Diego, La Jolla, CA 92093–0608. *Instrument:* Electron Microscope, Model Titan 80–300 C-Twin STEM. *Manufacturer:* FEI Company, Netherlands. *Intended Use:* See notice at 72 FR 63875, November 13, 2007.

Docket Number: 07–066. *Applicant:* St. Jude Children's Research Hospital, Memphis, TN 38105. *Instrument:* Electron Microscope, Model Tecnai G2 F20 TWIN. *Manufacturer:* FEI Company, Netherlands. *Intended Use:* See notice at 72 FR 63875, November 13, 2007.

Docket Number: 07–067. *Applicant:* National Institute for Occupational Safety and Health, Cincinnati, OH 45226. *Instrument:* Electron Microscope, Model JEM–2100F. *Manufacturer:* Jeol Ltd., Japan. *Intended Use:* See notice at 72 FR 63875, November 13, 2007.

Comments: None received. *Decision:* Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as these instruments are intended to be used, was being manufactured in the United States at the time the instruments were ordered. *Reasons:* Each foreign instrument is an electron microscope and is intended for research or scientific educational uses requiring an electron microscope. We know of no electron microscope, or any other instrument suited to these purposes, which was being manufactured in the United States at the time of order of each instrument.

Faye Robinson,

Director, Statutory Import Programs Staff, Import Administration.

[FR Doc. E7–23576 Filed 12–4–07; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–926]

Sodium Nitrite from the People's Republic of China: Initiation of Countervailing Duty Investigation

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: (December 5, 2007.

FOR FURTHER INFORMATION CONTACT: Sean Carey or Gene Calvert, AD/CVD Operations, Office 6, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230; telephone: (202) 482–3964 and (202) 482–3586, respectively.

SUPPLEMENTARY INFORMATION:

Initiation of Investigation:

The Petition

On November 8, 2007, the Department of Commerce (the Department) received a petition filed in proper form by General Chemical LLC (petitioner). On November 14 and November 15, 2007, the Department issued requests for additional information and clarification of certain areas of the petition involving general issues and the countervailable subsidy allegations, respectively. Based on the Department's request, petitioner filed additional information concerning the petition on November 19 and November 20, 2007.

In accordance with section 702(b)(1) of the Tariff Act of 1930, as amended (the Act), petitioner alleges that manufacturers, producers, or exporters of sodium nitrite in the People's Republic of China (the PRC) received countervailable subsidies within the meaning of section 701 of the Act, and that such imports are materially injuring or threatening material injury to an industry in the United States.

The Department finds that petitioner filed this petition on behalf of the domestic industry because it is an interested party as defined in section 771(9)(C) of the Act, and petitioner has demonstrated sufficient industry support with respect to the countervailing duty investigation that it

is requesting the Department to initiate (*see, infra*, "Determination of Industry Support for the Petition").

Period of Investigation

The anticipated period of investigation (POI) is calendar year 2006. *See* 19 CFR 351.204(b)(2).

Scope of Investigation

The merchandise covered by this investigation is sodium nitrite in any form, at any purity level. In addition, the sodium nitrite covered by this investigation may or may not contain an anti–caking agent. Examples of names commonly used to reference sodium nitrite are nitrous acid, sodium salt, anti–rust, diazotizing salts, erinitrit, and filmerine. The chemical composition of sodium nitrite is NaNO2 and it is generally classified under subheading 2834.10.1000 of the Harmonized Tariff Schedule of the United States (HTSUS). The American Chemical Society Chemical Abstract Service (CAS) has assigned the name "sodium nitrite" to sodium nitrite. The CAS registry number is 7632–00–0. For purposes of the scope of this investigation, the narrative description is dispositive, not the tariff heading, CAS registry number or CAS name, which are provided for convenience and customs purposes.

Comments on Scope of Investigation

During our review of the petition, we discussed the scope with petitioner to ensure that it is an accurate reflection of the merchandise for which the domestic industry is seeking relief. Moreover, as discussed in the preamble to the regulations (*Antidumping Duties; Countervailing Duties; Final Rule*, 62 FR 27296, 27323 (May 19, 1997)), we are setting aside a period for interested parties to raise issues regarding product coverage. The Department encourages all interested parties to submit such comments within 20 calendar days of the publication of this notice. Comments should be addressed to Import Administration's Central Records Unit (CRU), Room 1870, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230. The period of scope consultations is intended to provide the Department with ample opportunity to consider all comments and to consult with parties prior to the issuance of the preliminary determination.

Consultations

Pursuant to section 702(b)(4)(A)(ii) of the Act, the Department invited representatives of the Government of the People's Republic of China (the GOC) for consultations with respect to the countervailing duty petition. The Department held these consultations in Beijing, China with representatives of the GOC on November 26, 2007. *See* the Memorandum to the File, entitled, "Consultations with Officials from the Government of the People's Republic of China on the Countervailing Duty Petition: *Sodium Nitrite from the People's Republic of China*" (November 26, 2007), a public document on file in the CRU.

Determination of Industry Support for the Petition

Section 702(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 702(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (i) at least 25 percent of the total production of the domestic like product; and (ii) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition. Moreover, section 702(c)(4)(D) of the Act provides that, if the petition does not establish support of domestic producers or workers accounting for more than 50 percent of the total production of the domestic like product, the Department shall: (i) poll the industry or rely on other information in order to determine if there is support for the petition, as required by subparagraph (A), or (ii) determine industry support using a statistically valid sampling method.

Section 771(4)(A) of the Act defines the "industry" as the producers as a whole of a domestic like product. Thus, to determine whether a petition has the requisite industry support, the statute directs the Department to look to producers and workers who produce the domestic like product. The International Trade Commission (ITC), which is responsible for determining whether "the domestic industry" has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both the Department and the ITC must apply the same statutory definition regarding the domestic like product (section 771(10) of the Act), they do so for different purposes and pursuant to a separate and distinct authority. In addition, the Department's determination is subject to limitations of time and information. Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to law. *See USEC, Inc. v. United States*, 132 F. Supp. 2d 1, 8 (CIT 2001), citing *Algoma Steel Corp. Ltd. v. United States*, 688 F. Supp. 639, 644 (1988), *aff'd* 865 F.2d 240 (Fed. Cir. 1989), *cert. denied* 492 U.S. 919 (1989).

Section 771(10) of the Act defines the domestic like product as "a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this subtitle." Thus, the reference point from which the domestic like product analysis begins is "the article subject to an investigation," (*i.e.*, the class or kind of merchandise to be investigated, which normally will be the scope as defined in the petition).

With regard to the domestic like product, petitioner does not offer a definition of domestic like product distinct from the scope of the investigation. Based on our analysis of the information submitted on the record, we have determined that sodium nitrite constitutes a single domestic like product and we have analyzed industry support in terms of that domestic like product. For a discussion of the domestic like product analysis in this case, *see* the *Countervailing Duty Investigation Initiation Checklist: Sodium Nitrite from the People's Republic of China (PRC) (Initiation Checklist)*, Industry Support at Attachment II, on file in the CRU.

Our review of the data provided in the Petition, supplemental submissions, and other information readily available to the Department indicates that the Petitioner has established industry support. To establish industry support, the Petitioner demonstrated that it was the sole producer of the domestic like product in 2006. Therefore, the Petition established support from domestic producers (or workers) accounting for more than 50 percent of the total production of the domestic like product and, as such, the Department is not required to take further action in order to evaluate industry support (e.g., polling). See Section 702(c)(4)(D) of the Act. In addition, the domestic producers have met the statutory criterion for industry support under 702(c)(4)(A)(i) because the domestic producers (or workers) who support the Petition account for at least 25 percent of the total production of the domestic like product. Finally, the domestic producers have met the statutory criterion for industry support under 702(c)(4)(A)(ii) because the domestic producers (or workers) who support the Petition account for more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the

Petition. Accordingly, the Department determines that the petition was filed on behalf of the domestic industry within the meaning of section 702(b)(1) of the Act. *See CVD Initiation Checklist* at Attachment II (Industry Support).

The Department finds petitioner has filed the petition on behalf of the domestic industry because it is an interested party as defined in sections 771(9)(C) of the Act and it has demonstrated sufficient industry support with respect to the countervailing duty investigation that it is requesting the Department to initiate. *See Initiation Checklist* at Attachment II.

Injury Test

Because the PRC is a "Subsidies Agreement Country" within the meaning of section 701(b) of the Act, section 701(a)(2) of the Act applies to this investigation. Accordingly, the ITC must determine whether imports of the subject merchandise from the PRC materially injure, or threaten material injury to, a U.S. industry.

Allegations and Evidence of Material Injury and Causation

The petitioner alleges that the U.S. industry producing the domestic like product is being materially injured, or is threatened with material injury, by reason of the subsidized imports of the subject merchandise. The petitioner contends that the industry's injured condition is illustrated by reduced market share, lost sales, reduced production capacity and capacity utilization rate, reduced shipments, underselling and price depressing and suppressing effects, lost revenue, reduced employment, decline in financial performance, and an increase in import penetration. We have assessed the allegations and supporting evidence regarding material injury and causation, and we have determined that these allegations are properly supported by adequate evidence and meet the statutory requirements for initiation. *See Initiation Checklist* at Attachment III (Injury).

Subsidy Allegations

Section 702(b) of the Act requires the Department to initiate a countervailing duty proceeding whenever an interested party files a petition on behalf of an industry that (1) alleges the elements necessary for an imposition of a duty under section 701(a) of the Act and (2) is accompanied by information reasonably available to the petitioner supporting the allegations. The Department has examined the countervailing duty petition on sodium nitrite from the PRC and found that it complies with the requirements of section 702(b) of the Act. Therefore, in accordance with section 702(b) of the Act, we are initiating a countervailing duty investigation to determine whether manufacturers, producers, or exporters of sodium nitrite in the PRC receive countervailable subsidies. For a discussion of evidence supporting our initiation determination, *see Initiation Checklist.*

We are including in our investigation the following programs alleged in the petition to have provided countervailable subsidies to producers and exporters of the subject merchandise:

GOC Loan Program

1. Loans and Interest Subsidies Related to the Northeast Revitalization Program

GOC Grant Programs

2. The State Key Technology Renovation Project Fund
3. Grants to Loss–Making State–Owned Enterprises

GOC Provision of Goods or Services for Less than Adequate Remuneration

4. Provision of Electricity to State–Owned Enterprises (SOEs) for Less than Adequate Remuneration
5. Provision of Land to SOEs for Less than Adequate Remuneration

GOC Income Tax Programs

6. Income Tax Exemption for Export–Oriented FIEs
7. Preferential Tax Policies for Foreign Invested Enterprises (FIEs) (Two Free, Three Half Program)
8. Reduced Income Tax Rates for FIEs Based on Location
9. Corporate Income Tax Refund Program for Reinvestment of FIE Profits in Export–Oriented Enterprises
10. Reduced Income Tax Rate for New or High Technology Enterprises
11. Preferential Tax Policies for Research and Development by FIEs
12. Income Tax Credits on Purchases of Domestically Produced Equipment by Domestically Owned Companies
13. Income Tax Credits on Purchases of Domestically Produced Equipment by FIEs
14. Reduced Income Tax Rate for FIEs Under the West Revitalization Program
15. Income Tax Reduction or Exemption for Export–Oriented or High Technology Enterprises under the West Revitalization Program
16. Preferential Tax Policies Under the West Revitalization Program

GOC Indirect Tax Programs and Import Tariff Programs

17. VAT Rebate for FIE Purchases of Domestically Produced Equipment
18. VAT and Tariff Exemptions for FIEs and Certain Domestic Enterprises Using Imported Equipment in Encouraged Industries

Provincial Loan Program

19. Reduced Interest Rate Loans Provided by Liaoning Province

Provincial Grant Programs

20. Provincial Export Interest Subsidies (Guangdong and Zhejiang Provinces)
21. Guangdong Province Funds for Outward Expansion of Industries

Provincial and Local Provision of Goods for Less than Adequate Remuneration

22. Provision of Land for Less than Adequate Remuneration (Jiangsu and Zhejiang Provinces, and Chongqing Municipality)
23. Provision of Electricity for Less than Adequate Remuneration (Jiangsu and Zhejiang Provinces)
24. Provision of Water for Less than Adequate Remuneration (Zhejiang Province)

Provincial and Local Income Tax Programs

25. Income Tax Exemption and Reduction Programs (Provinces of Jiangsu, Zhejiang, Guangdong, and Shandong; Municipalities of Beijing, Tianjin, Shanghai, and Chongqing)For further information explaining why the Department is investigating these programs, see the Initiation Checklist.

We are not including in our investigation the following programs alleged to benefit producers and exporters of the subject merchandise in the PRC:

GOC Loan Program

1. Government Policy Lending Program

Petitioner alleges that under the GOC's National Tenth Five-year Plan as well as the Tenth and Eleventh Five-year plans of the Chemical Industry, sodium nitrite producers may benefit from the provision of loans by state–owned commercial banks as part of the GOC's policy to encourage and to advance the chemical industry. In support of its allegation, Petitioner provided translated copies of the "Tenth Five-year Plan for National Economic and Social Development," and the "Tenth Five-year Plan of the Chemical Industry and Its Development," and a short, translated excerpt of the "Eleventh Five-year Plan of the Chemical Industry and Its Development." Our review of these documents did not indicate that financing or loans were available pursuant to the GOC's Chemical Policy.

Accordingly, we find that petitioner has not provided sufficient information to warrant initiation of an investigation of this program.

GOC Provision of Goods for Less than Adequate Remuneration

2. Provision of Natural Gas and Water to State–Owned Enterprises (SOEs) for Less than Adequate Remuneration

Petitioner alleges that the GOC provides natural gas and water to SOEs and special industrial sectors at subsidized prices. Petitioner further alleges that end–user prices for natural gas and for water are set by the National Development and Reform Commission, and rarely reflect the true market price of these commodities. For purposes of this initiation, we find that petitioner has not sufficiently alleged the elements necessary for a less than adequate remuneration subsidy, as identified in 19 CFR 351.511. Petitioner has not provided sufficient information demonstrating that the GOC has provided natural gas and water for less than adequate remuneration and that this program is specific. Accordingly, we find that petitioner has not provided sufficient information to warrant initiation of an investigation of these programs.

GOC Indirect Tax Program and Import Tariff Program

3. VAT Exemptions on Exports

Petitioner alleges that the GOC enterprises are exempted from paying import tariffs and VAT payments on imported equipment provided that these goods are not for resale. Petitioner notes that in certain cases, a full 17–percent VAT exemption will apply upon export. Petitioner states that the program, by definition, is conditioned upon export performance, and therefore, is an export subsidy. Petitioner further alleges that this is a prohibited export subsidy if the exemption or reduction of indirect taxes on the exported product exceeds the indirect taxes levied on the inputs into the exported product. We find that Petitioner has not sufficiently alleged the elements necessary for the imposition of a countervailing duty and did not support the allegation with reasonably available information. Therefore, we are not initiating an investigation of this program.

Application of the Countervailing Duty Law to the PRC

The Department has treated the PRC as a non–market economy (NME) country in all past antidumping investigations and administrative reviews. In accordance with section 771(18)(C)(i) of the Act, any determination that a country is an NME country shall remain in effect until revoked by the administering authority. *See e.g., Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, (TRBs) From the People's Republic of China: Preliminary Results of 2001–2002 Administrative Review and Partial Rescission of Review*, 68 FR 7500, 7500–1 (February 14, 2003), unchanged in *TRBs from the People's Republic of China: Final Results of 2001–2001 Administrative Review*, 68 FR 70488, 70488–89 (December 18, 2003).

In the final affirmative countervailing duty determination on coated free sheet paper from the PRC, the Department determined that the current nature of the PRC economy does not create obstacles to applying the necessary criteria in the countervailing duty law. *See Coated Free Sheet Paper from the People's Republic of China: Final Affirmative Countervailing Duty Determination*, 72 FR 60645 (October 25, 2007), and the accompanying *Issues and Decision Memorandum*, at Comment 1. Therefore, because petitioner has provided sufficient allegations and support of its allegations to meet the statutory criteria for initiating a countervailing duty investigation of sodium nitrite from the PRC, initiation of a countervailing duty investigation is warranted in this case.

Respondent Selection

For this investigation, the Department expects to select respondents based on U.S. Customs and Border Protection (CBP) data for U.S. imports during the POI. We intend to make our decision regarding respondent selection within 20 days of publication of this **Federal Register** notice. The Department invites comments regarding the CBP data and respondent selection within seven calendar days of publication of this **Federal Register** notice.

Distribution of Copies of the Petition

In accordance with section 702(b)(4)(A)(i) of the Act, a copy of the public version of the petition has been provided to the GOC. To the extent practicable, we will attempt to provide a copy of the public version of the petition to each exporter named in the petition, as provided under 19 CFR 351.203(c)(2).

ITC Notification

We have notified the ITC of our initiation, as required by section 702(d) of the Act.

Preliminary Determination by the ITC

The ITC will preliminarily determine, within 25 days after the date on which it receives notice of this initiation, whether there is a reasonable indication that imports of subsidized sodium nitrite from the PRC are materially injuring, or threatening material injury to, a U.S. industry. *See* section 703(a)(2) of the Act. A negative ITC determination will result in the investigation being terminated; otherwise, the investigation will proceed according to statutory and regulatory time limits.

This notice is issued and published pursuant to section 777(i) of the Act.

Dated: November 28, 2007.

David M. Spooner,

Assistant Secretary for Import Administration.

[FR Doc. E7–23573 Filed 12–4–07; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE01

U.S. Climate Change Science Program Synthesis and Assessment Product Draft Report 3.2 "Climate projections for research and assessment based on emissions scenarios developed through the CCTP"

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Department of Commerce.

ACTION: Notice of availability and request for public comments.

SUMMARY: The National Oceanic and Atmospheric Administration publishes this notice to announce a 45-day public comment period for the draft report titled, U.S. Climate Change Science Program Synthesis and Assessment Product 3.2: "Climate projections for research and assessment based on emissions scenarios developed through the CCTP".

This draft document is being released solely for the purpose of pre-dissemination peer review under applicable information quality guidelines. This document has not been formally disseminated by NOAA. It does not represent and should not be construed to represent any Agency policy or determination. After consideration of comments received on the draft report, a revised version along with the comments received will be published on the CCSP web site.

DATES: Comments must be received by January 22, 2008.

ADDRESSES: The draft Synthesis and Assessment Product 3.2: "Climate projections for research and assessment

based on emissions scenarios developed through the CCTP." is posted on the CCSP Web site at:
www.climatescience.gov/Library/sap/sap3-2/public-review-draft/default.htm

Detailed instructions for making comments on this draft report are provided on the link above. Comments must be prepared in accordance to these instructions and must be submitted to: *3.2-climateprojections@usgcrp.gov*

FOR FURTHER INFORMATION CONTACT: Dr. Fabien Laurier, Climate Change Science Program Office, 1717 Pennsylvania Avenue NW, Suite 250, Washington, DC 20006, Telephone: (202) 419-3481.

SUPPLEMENTARY INFORMATION: The CCSP was established by the President in 2002 to coordinate and integrate scientific research on global change and climate change sponsored by 13 participating departments and agencies of the U.S. Government. The CCSP is charged with preparing information resources that promote climate-related discussions and decisions, including scientific synthesis and assessment analyses that support evaluation of important policy issues.

Dated: November 27, 2007.

William J. Brennan,

Deputy Assistant Secretary of Commerce for International Affairs, and Acting Director, Climate Change Science Program.

[FR Doc. E7-23595 Filed 12-4-07; 8:45 am]

BILLING CODE 3510-12-S

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

SUMMARY: The IC Clearance Official, Regulatory Information Management Services, Office of Management, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before February 4, 2008.

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.

The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: November 29, 2007.

Angela C. Arrington,

IC Clearance Official, Regulatory Information Management Services, Office of Management.

Office of Special Education and Rehabilitative Services

Type of Review: Extension.
Title: Protection and Advocacy for Assistive Technology (PAAT).
Frequency: Annually.
Affected Public:
Not-for-profit institutions; State, Local, or Tribal Gov't, SEAs or LEAs.
Reporting and Recordkeeping Hour Burden:
Responses: 57. *Burden Hours:* 912.
Abstract: The Annual PAAT Program Performance Report will be used to analyze and evaluate the PAAT Program administered by eligible systems in states. These systems provide services to eligible individuals with disabilities to assist in the acquisition, utilization, or maintenance of assistive technology devices or assistive technology services. The Rehabilitation Services Administration (RSA) uses the form to meet specific data collection requirements of Section 5 of the Assistive Technology Act of 1998, as amended (AT Act). PAAT programs must report annually using the form, which is due on or before December 30 of each year. The Annual PAAT Performance Report has enabled RSA to furnish the President and Congress with data on the provision of protection and advocacy services and has helped to establish a sound basis for future funding requests. Data from the form have been used to evaluate the effectiveness of eligible systems within individual states in meeting annual priorities and objectives. These data also have been used to indicate trends in the provision of services from year to year.

Requests for copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov*, by selecting the "Browse Pending Collections" link and by clicking on link number 3535. 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. E7-23563 Filed 12-4-07; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF EDUCATION

Privacy Act of 1974; System of Records—Migrant Student Information Exchange

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Notice of a new system of records.

SUMMARY: In accordance with the Privacy Act of 1974, as amended (Privacy Act), the Department of Education (Department) publishes this notice of a new system of records entitled "Migrant Student Information Exchange" (MSIX) (18-14-04).

MSIX will contain information on migrant students who participate in the Migrant Education Program (MEP) authorized under Title I, Part C of the Elementary and Secondary Education Act of 1965 (ESEA), as amended by the No Child Left Behind Act of 2001 (Pub. L. 107-110). Section 1308(b)(2) of ESEA (20 U.S.C. 6398(b)(2)) specifically

authorizes the implementation of MSIX and its associated minimum data elements (MDEs). This statutory provision requires the Secretary to ensure the linkage of migrant student record systems for the purpose of electronically exchanging, among the States, health and educational information regarding all migratory students.

DATES: The Department seeks comment on the new system of records described in this notice, in accordance with the requirements of the Privacy Act. We must receive your comments on the proposed routine uses for the system of records described in this notice on or before January 4, 2008.

The Department filed a report describing the new system of records covered by this notice with the Chair of the Senate Committee on Homeland Security and Governmental Affairs, the Chair of the House Committee on Oversight and Government Reform, and the Administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on November 30, 2007. This system of records will become effective at the later date of—(1) the expiration of the 40-day period for OMB review on January 9, 2008 or (2) January 4, 2008, unless the system of records needs to be changed as a result of public comment or OMB review.

ADDRESSES: Address all comments about the proposed routine uses to Jennifer Dozier, Office of Elementary and Secondary Education, U.S. Department of Education, 400 Maryland Avenue, SW., room 3E327, Washington, DC 20202. Telephone: (202) 205–4421. If you prefer to send comments through the Internet, use the following address: *comments@ed.gov.*

You must include the term "Migrant Student Information Exchange" in the subject line of the electronic message.

During and after the comment period, you may inspect comments about this notice in room 2W224, 400 Maryland Avenue, SW., Washington, DC, between the hours of 8 a.m. and 4:30 p.m., Eastern time, Monday through Friday of each week except Federal holidays.

Assistance to Individuals With Disabilities in Reviewing the Rulemaking Record

On request, we will supply an appropriate aid, such as a reader or print magnifier, to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this notice. If you want to schedule an appointment for this type of aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

FOR FURTHER INFORMATION CONTACT: Jennifer Dozier. Telephone: (202) 205–4421. If you use a telecommunications device for the deaf (TDD), call the Federal Relay Service (FRS) at 1–800–877–8339.

Individuals with disabilities can obtain this document in an alternative format (e.g., Braille, large print, audiotape, or computer diskette) on request to the contact person listed under this section.

SUPPLEMENTARY INFORMATION:

Introduction

MSIX will provide the technology that will allow all States, in accordance with applicable law, to share educational and health information on migrant children who travel from State to State due to their migratory lifestyle and who, as a result, have student records in the migrant student databases of multiple States. Authorized representatives of State and local agencies will use MSIX to assist with school enrollment, grade placement, and accrual of course credits for migrant children nationwide. In doing so, MSIX will work in concert with the existing migrant student information systems that States currently use to manage their migrant student data. Authorized representatives of State educational agencies (SEAs), local educational agencies (LEAs), and other MEP local operating agencies will use MSIX to retrieve educational and health information on migrant students who move from State to State due to their migrant lifestyle.

The Privacy Act (5 U.S.C. 552a(e)(4)) requires the Department to publish in the **Federal Register** this notice of a new system of records maintained by the Department. The Department's regulations implementing the Privacy Act are contained in the Code of Federal Regulations (CFR) in 34 CFR part 5b.

The Privacy Act applies to information about individuals that contains individually identifying information that is retrieved by a unique identifier associated with each individual, such as a name or social security number. The information about each individual is called a "record," and the system, whether manual or computer-based, is called a "system of records." The Privacy Act requires each agency to publish notices of new or altered systems of records in the **Federal Register** and to submit reports to the Administrator of the Office of Information and Regulatory Affairs, OMB, the Chair of the Senate Committee on Homeland Security and Governmental Affairs, and the Chair of the House Committee on Oversight and Government Reform, whenever the agency publishes a new or altered system of records.

Electronic Access to This Document

You may 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: *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 CFR is available on GPO Access at: *www.gpoaccess.gov/nara/index.html.*

Dated: November 30, 2007.

Kerri L. Briggs,

Assistant Secretary for Elementary and Secondary Education.

For the reasons discussed in the preamble, the Assistant Secretary for Elementary and Secondary Education publishes a notice of a new system of records to read as follows:

18–14–04

SYSTEM NAME:

Migrant Student Information Exchange (MSIX).

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

(1) U.S. Department of Education, Office of Elementary and Secondary Education, Office of Migrant Education, 400 Maryland Avenue, SW., room 3E344, Washington, DC 20202–4614.

(2a) Deloitte LLC, 4301 North Fairfax Drive, Suite 210, Arlington, VA 22203–1633 (software development and programming).

(2b) Deloitte LLC, 110 West 7th Street, Suite 1100, Tulsa, OK 74119–1107 (help desk for MSIX).

(3a) EDS Data Center, 6031 South Rio Grande Avenue, Orlando, FL 32809–4613 (MSIX Production Servers).

(3b) EDS, 12000 Research Parkway, Orlando, FL 32826–2943 (back-up tapes).

(4) Navasite Data Center, 8619 Westwood Center Drive, Vienna, VA 22182–2220 (disaster recovery site).

(5) Access to MSIX is available through the Internet from other locations.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

This system contains records on all children whom States have determined to be eligible to participate in the MEP, authorized in Title I, Part C of the Elementary and Secondary Education Act of 1965 (ESEA), as amended by the No Child Left Behind Act of 2001 (Pub. L. 107–110).

CATEGORIES OF RECORDS IN THE SYSTEM:

The categories of records in the system include the migrant child's: Name, date of birth, personal identification numbers assigned by the States and the Department, parent's or parents' name or names, school enrollment data, school contact data, assessment data, and other educational and health data necessary for accurate and timely school enrollment, grade and course placement, and accrual of course credits. The final request for public comment on the minimum data elements (MDEs) to be included in MSIX was published, pursuant to the Paperwork Reduction Act of 1995 clearance process, in the **Federal Register** on August 3, 2007 (72 FR 43253–34). More information on the 66 MDEs is available in the Department's Information Collection Notice at: *http://edicsweb.ed.gov/browse/downldatt.cfm?pkg_serial_num=2841.*

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

MSIX is authorized under section 1308(b)(2) of the ESEA, as amended by the No Child Left Behind Act of 2001 (20 U.S.C. Section 6398(b)(2)).

PURPOSE(S):

The purpose of MSIX is to enhance the continuity of educational and health services for migrant children by providing a mechanism for all States to exchange educational and health related information on migrant children who move from State to State due to their migratory lifestyle. It is anticipated that the existence and use of MSIX will help to improve the timeliness of school enrollments, improve the appropriateness of grade and course placements, and reduce incidences of unnecessary immunizations of migrant children. Further, MSIX will facilitate the accrual of course credits for migrant children in secondary school by providing accurate academic information on the student's course history and academic progress.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

The Department of Education (Department) may disclose information contained in a record in this system of records, under the routine uses listed in this system of records, without the consent of the individual if the disclosure is compatible with the purposes for which the record was collected. The Department may make these disclosures on a case-by-case basis or, if the Department has complied with the computer matching requirements of the Privacy Act, as amended, under a computer matching agreement.

(1) *MEP Services, School Enrollment, Grade or Course Placement, Accrual of High School Credits, Student Record Match Resolution.* The Department may disclose a record in this system of records to authorized representatives of State education agencies (SEAs), local education agencies (LEAs), and other MEP local operating agencies (LOAs) to facilitate one or more of the following for a student: (a) Participation in the MEP, (b) enrollment in school, (c) grade or course placement, (d) credit accrual, and (e) unique student match resolution.

(2) *Contract Disclosure.* If the Department contracts with an entity for the purposes of performing any function that requires disclosure of records in this system to employees of the contractor, the Department may disclose the records to those employees who have received the appropriate level security clearance from the Department. Before entering into such a contract, the Department will require the contractor to maintain Privacy Act safeguards, as required under 5 U.S.C. 552a(m), with respect to the records in the system.

(3) *Research Disclosure.* The Department may disclose records from this system to a researcher if an appropriate official of the Department determines that the individual or organization to which the disclosure would be made is qualified to carry out specific research related to functions or purposes of this system of records. The official may disclose information from this system of records to that researcher solely for the purpose of carrying out that research related to the functions or purposes of this system of records. The researcher will be required to maintain Privacy Act safeguards with respect to the disclosed records.

(4) *Freedom of Information Act (FOIA) and Privacy Act Advice Disclosure.* The Department may disclose records to the U.S. Department of Justice (DOJ) or OMB if the Department concludes that disclosure is desirable or necessary to determine whether particular records are required to be disclosed under FOIA or the Privacy Act.

(5) *Disclosure in the Course of Responding to Breach of Data.* The Department may disclose records to appropriate agencies, entities, and persons when (a) it is suspected or confirmed that the security or confidentiality of information in MSIX has been compromised; (b) 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 MSIX or other systems or programs (whether maintained by the Department or by another agency or entity) that rely upon the compromised information; and, (c) the disclosure is made to such agencies, entities, and persons who are reasonably necessary to assist the Department in responding to the suspected or confirmed compromise and in helping the Department prevent, minimize, or remedy such harm.

(6) *Litigation or Alternative Dispute Resolution (ADR) Disclosure.*

(a) *Introduction.* In the event that one of the following parties is involved in litigation or ADR, or has an interest in litigation or ADR, the Department may disclose certain records to the parties described in paragraphs b, c, and d of this routine use under the conditions specified in those paragraphs:

(i) The Department or any of its components.

(ii) Any Department employee in his or her official capacity.

(iii) Any employee of the Department in his or her individual capacity where DOJ has agreed to or has been requested to provide or arrange for representation of the employee.

(iv) Any employee of the Department in his or her individual capacity where the Department has agreed to represent the employee.

(v) The United States where the Department determines that the litigation is likely to affect the Department or any of its components.

(b) *Disclosure to DOJ.* If the Department determines that disclosure of certain records to DOJ, or attorneys engaged by DOJ, is relevant and necessary to litigation or ADR, and is compatible with the purpose for which the records were collected, the Department may disclose those records as a routine use to DOJ.

(c) *Adjudicative Disclosure.* If the Department determines that disclosure of certain records to an adjudicative body before which the Department is authorized to appear, individual, or

entity designated by the Department or otherwise empowered to resolve or mediate disputes is relevant and necessary to litigation or ADR, and is compatible with the purpose for which the records were collected, the Department may disclose those records as a routine use to the adjudicative body, individual, or entity.

(d) *Disclosure to Parties, Counsel, Representatives, and Witnesses.* If the Department determines that disclosure of certain records to a party, counsel, representative, or witness is relevant and necessary to litigation or ADR, and is compatible with the purpose for which the records were collected, the Department may disclose those records as a routine use to a party, counsel, representative, or witness.

(7) *Congressional Member Disclosure.* The Department may disclose information from a record of an individual to a member of Congress and his or her staff in response to an inquiry from the member made at the written request of that individual. The member's right to the information is no greater than the right of the individual who requested it.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

Not applicable to this system notice.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

The Data Center of the Department's contractor, EDS, stores computerized student records on server hardware and MSIX backup tapes, including MSIX Help Desk tapes, in locked file cabinets.

RETRIEVABILITY:

Records in this system are indexed by a unique number, assigned to each individual, that is cross-referenced by the individual's name.

SAFEGUARDS:

(1) *Introduction*

Security personnel control and monitor all physical access to the site of the Department's contractor and subcontractors, where this system of records is maintained. The computer system employed by the Department offers a high degree of resistance to tampering and circumvention. This computer system limits data access to Department and contract staff on a "need to know" basis, and controls individual users' ability to access and alter records within the system by granting user names and passwords, and assigning user roles to individuals that restrict access based on user category (e.g., district administrator, counselor, state administrator).

The contractor has established a set of procedures to ensure confidentiality of data, and will maintain the security of the complete set of all master data files and documentation. The contractor and subcontractor employees who collect, maintain, use, or disseminate data in this system, must comply with the requirements of the Privacy Act.

(2) *Physical Security of Electronic Data*

Physical security of electronic data will be maintained. The MSIX infrastructure is housed in a secured data center, access to which is controlled by multiple access controls. These access controls include a combination of personal photo identification/card scans, biometric hand scanning, and personal access codes. These access controls also include man-traps and physical barricades that limit access to the data center floor and machine rooms. Further, all entrances, exits, and key points throughout the facility are monitored in real-time via closed circuit television (CCTV) 24 hours per day. All CCTV is recorded and stored on tape for audit purposes. These access control mechanisms are centrally managed by resources within the data center, which is staffed 24 hours per day.

Security personnel are required to inspect picture identification and have visitors sign in before granting access to the facility. Visitors are pre-authorized and registered in a database at least 24 hours prior to their arrival, and are required to provide picture identification that matches the name given previously to the data center. All personnel are required to display an identification badge or an authorized visitor badge at all times while on the premises; and all packages brought into the data center are subject to inspection.

Backup tapes are employed, and numerous mechanisms protect the physical security of these backup tapes. First, in the event of a disaster recovery situation, MSIX backup tapes will be transferred in locking containers. Contractor and subcontractor employees holding Department of Defense (DoD) Secret or Interim Secret clearances will ship the tapes from the EDS Data Center to the Navasite Data Center, the disaster recovery site. Thus, the MSIX system can be restored in the event of a disaster at the Navasite Data Center. Second, the backup tapes are stored in a tape library within the EDS Data Center and are only available to authorized personnel. Access to the backup tapes is limited through the use of biometric access control mechanisms. Third, the backup tapes are stored in fireproof safes.

(c) *User Access to Electronic Data*

MSIX incorporates a series of security controls mandated by the Federal Information Security Management Act of 2002 (FISMA) and the Department. MSIX leverages role-based accounts and security controls to limit access to the application, its servers, and its infrastructure to authorized users. All MSIX users must follow a registration process that involves identity validation and verification prior to gaining access to MSIX. Once validated and approved, MSIX User Administrators will grant access to authorized users by creating their MSIX accounts and assigning the appropriate MSIX roles. MSIX requires users to use strong passwords, comprised of alphanumeric and special characters, and uses Oracle's Internet Directory (OID) application to manage its user accounts. OID stores the name of each MSIX user, each MSIX user's associated roles and access privileges, and each MSIX user's passwords using an encrypted format. The MSIX application is only available to authorized users via a Uniform Resource Locator (URL) that runs under the Hypertext Transfer Protocol over Secure Socket Layer (HTTPS). No user may alter records in this system of records except to identify and assign a student a unique student identifier through the record matching process. Further, MSIX limits data submissions from State systems to specific Internet Protocol addresses and requires the use of Secure File Transfer Protocol.

(d) *Additional Security Measures*

The MSIX infrastructure also leverages a series of firewalls to limit internal access to specific protocols and ports, as well as intrusion detection systems to help identify unauthorized access to MSIX. MSIX logs and tracks login attempts, data modifications, and other key application and system events. The MSIX operations and maintenance team monitors these logs on a regular basis. Further, the MSIX operations and maintenance team performs vulnerability scans on a routine basis, monitors the U.S. Computer Emergency Response Team (CERT) bulletins (see *http://www.us-cert.gov/* for more details), and applies routine operating system and vendor patches as appropriate.

RETENTION AND DISPOSAL:

Records are maintained and disposed of in accordance with the Department's Records Disposition Schedules as listed under ED 231—Public and Restricted Use Data Files—Studies.

SYSTEM MANAGER AND ADDRESS:

Director, Office of Migrant Education, U.S. Department of Education, 400 Maryland Avenue, SW., room 3E317, Washington, DC 20202–0001.

NOTIFICATION PROCEDURE:

If you wish to determine whether a record exists regarding you in the system of records, contact the system manager at the address listed under, **SYSTEM MANAGER AND ADDRESS.** Your request must meet the requirements of regulations in 34 CFR 5b.5, including proof of identity.

RECORD ACCESS PROCEDURE:

If you wish to gain access to your record in the system of records, contact the system manager at the address listed under **SYSTEM MANAGER AND ADDRESS.** Your request must meet the requirements of regulations in 34 CFR 5b.5, including proof of identity.

CONTESTING RECORD PROCEDURE:

If you wish to contest the content of a record regarding you in the system of records, contact the system manager at the address listed under, **SYSTEM MANAGER AND ADDRESS.** Your request must meet the requirements of regulations in 34 CFR 5b.7, including proof of identity.

RECORD SOURCE CATEGORIES:

The system will contain records that are obtained from SEAs and LEAs.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. E7–23541 Filed 12–4–07; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings # 1

November 19, 2007.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER02–1656–034; EL01–68–031.

Applicants: California Independent System Operator Corporation.

Description: Sempra Energy Trading LLC submits a report to state that it does not seek any payment in excess of the negative $30/MWh Cap.

Filed Date: 11/07/2007.

Accession Number: 20071114–0090.

Comment Date: 5 p.m. Eastern Time on Wednesday, November 28, 2007.

Docket Numbers: ER03–428–005.

Applicants: ConocoPhillips Company.

Description: ConocoPhillips Company submits Substitute Third Revised Sheet 1 to its revised FERC Electric Tariff 1, to become effective 9/18/07.

Filed Date: 11/13/2007.

Accession Number: 20071114–0205.

Comment Date: 5 p.m. Eastern Time on Monday, November 26, 2007.

Docket Numbers: ER04–708–004.

Applicants: Horsehead Corp.

Description: Notice of non-material change in status re Horsehead Corp.

Filed Date: 11/09/2007.

Accession Number: 20071114–0077.

Comment Date: 5 p.m. Eastern Time on Friday, November 30, 2007.

Docket Numbers: ER06–758–002; ER06–635–001; ER02–237–009; ER95–1007–020; ER01–2741–005; ER07–34–002; ER03–1151–005; ER00–2235–002; ER99–3320–005; ER06–759–001; ER03–922–006; ER06–634–001.

Applicants: Chambers Cogeneration LP; Edgecombe Genco, LLC; J. Aron & Company; Logan Generating Company, LP; Plains End, LLC; Plains End II, LLC; Power Receivable Finance, LLC; Ouachita Power, LLC; Rathdrum Power, LLC; Selkirk Cogen Partners, L.P.; Southaven Power, LLC; Spruance Genco, LLC.

Description: Chambers Cogeneration, Limited Partnership *et al.* submit a notice of non-material change in status in compliance with FERC's Order 652.

Filed Date: 11/09/2007.

Accession Number: 20071114–0078.

Comment Date: 5 p.m. Eastern Time on Friday, November 30, 2007.

Docket Numbers: ER07–970–002.

Applicants: Midwest Independent Transmission System Operator, Inc.

Description: Midwest Independent Transmission System Operator, Inc. submits a compliance filing of a Large Generator Interconnection Agreement.

Filed Date: 11/13/2007.

Accession Number: 20071115–0057.

Comment Date: 5 p.m. Eastern Time on Tuesday, December 4, 2007.

Docket Numbers: ER07–1203–001.

Applicants: Duke Energy Carolinas, LLC.

Description: Duke Energy Carolinas, LLC submits additional information to support their filing and request to waive the Commission's regulations in order to make the filing effective 1/1/08.

Filed Date: 11/08/2007.

Accession Number: 20071113–0006.

Comment Date: 5 p.m. Eastern Time on Thursday, November 29, 2007.

Docket Numbers: ER07–1250–002.

Applicants: PowerGrid Systems, Inc.

Description: PowerGrid Systems, Inc. submits a Substitute Original Sheet 1 and Original Sheet 2 to its FERC Electric Tariff, Original Volume 1.

Filed Date: 11/15/2007.

Accession Number: 20071119–0019.

Comment Date: 5 p.m. Eastern Time on Thursday, December 6, 2007.

Docket Numbers: ER07–1268–002.

Applicants: PacifiCorp.

Description: Compliance Filing of PacifiCorp.

Filed Date: 11/15/2007.

Accession Number: 20071115–5002.

Comment Date: 5 p.m. Eastern Time on Thursday, December 6, 2007.

Docket Numbers: ER07–1367–001.

Applicants: American Electric Power Service Corporation.

Description: AEP Operating Companies submits their Third Revised Interconnection and Local Delivery Service Agreement with Elk Power Co.

Filed Date: 11/15/2007.

Accession Number: 20071119–0015.

Comment Date: 5 p.m. Eastern Time on Thursday, December 6, 2007.

Docket Numbers: ER07–1402–001.

Applicants: Allegheny Generating Company.

Description: Supplemental Submission of Allegheny Generating Company.

Filed Date: 10/26/2007.

Accession Number: 20071026–5037.

Comment Date: 5 p.m. Eastern Time on Thursday, November 29, 2007.

Docket Numbers: ER08–193–000.

Applicants: Pacific Gas and Electric Company.

Description: Pacific Gas and Electric Co. submits the Midway Interconnection Agreement with Southern California Edison Co.

Filed Date: 11/07/2007.

Accession Number: 20071116–0320.

Comment Date: 5 p.m. Eastern Time on Wednesday, November 28, 2007.

Docket Numbers: ER08–205–000.

Applicants: PJM Interconnection, L.L.C.

Description: PJM Interconnection LLC submits its revisions to Schedule 2 of the PJM Open Access Transmission Tariff.

Filed Date: 11/13/2007.

Accession Number: 20071114–0076.

Comment Date: 5 p.m. Eastern Time on Tuesday, December 4, 2007.

Docket Numbers: ER08–213–000.

Applicants: Round Rock Energy, LP.

Description: Round Rock Energy, LP requests that FERC accept its FERC Electric Tariff, Original Volume 1 etc.

Filed Date: 11/14/2007.

Accession Number: 20071116–0042.

Comment Date: 5 p.m. Eastern Time on Wednesday, December 5, 2007.

Docket Numbers: ER08–214–000.

Applicants: Deephaven RV Sub Fund Ltd.

Description: Deephaven RV Sub Fund Ltd submits a Notice of Cancellation, a Second Revised Sheet 1 to its market-based rate tariff and a Notice of Filing requesting that FERC accept the cancellation documents.

Filed Date: 11/15/2007.

Accession Number: 20071119–0001.

Comment Date: 5 p.m. Eastern Time on Thursday, December 6, 2007.

Docket Numbers: ER08–215–000.

Applicants: Indiana Michigan Power Company.

Description: Indiana Michigan Power Company submits First Revised Sheet 15 *et al.* to FERC Electric Rate Schedule 109.

Filed Date: 11/15/2007.

Accession Number: 20071119–0002.

Comment Date: 5 p.m. Eastern Time on Thursday, December 6, 2007.

Docket Numbers: ER08–216–000.

Applicants: Indiana Michigan Power Company.

Description: Indiana Michigan Power Company submits First Revised Sheet 15 *et al.* to its FERC Rate Schedule 105.

Filed Date: 11/15/2007.

Accession Number: 20071119–0003.

Comment Date: 5 p.m. Eastern Time on Thursday, December 6, 2007.

Docket Numbers: ER08–217–000.

Applicants: Indiana Michigan Power Company.

Description: Indiana Michigan Power Company submits First Revised Sheet 15 *et al.* to its FERC Rate Schedule 104.

Filed Date: 11/15/2007.

Accession Number: 20071119–0005.

Comment Date: 5 p.m. Eastern Time on Thursday, December 6, 2007.

Docket Numbers: ER08–218–000.

Applicants: Indiana Michigan Power Company.

Description: Indiana Michigan Power Company submits First Revised Sheet 16 *et al.* to its FERC Rate Schedule 101.

Filed Date: 11/15/2007.

Accession Number: 20071119–0004.

Comment Date: 5 p.m. Eastern Time on Thursday, December 6, 2007.

Docket Numbers: ER08–219–000.

Applicants: Indiana Michigan Power Company.

Description: Indiana Michigan Power Company submits First Revised Sheet 15 *et al.* to its FERC Rate Schedule 102.

Filed Date: 11/15/2007.

Accession Number: 20071119–0006.

Comment Date: 5 p.m. Eastern Time on Thursday, December 6, 2007.

Docket Numbers: ER08–220–000.

Applicants: New York Independent System Operator, Inc.

Description: New York Independent System Operator Inc. submits First Revised Sheet 710 *et al.* for Attachment V of its Open Access Transmission Tariff to revise its Working Capital Fund provisions.

Filed Date: 11/15/2007.

Accession Number: 20071119–0007.

Comment Date: 5 p.m. Eastern Time on Thursday, December 6, 2007.

Docket Numbers: ER08–221–000.

Applicants: PJM Interconnection, L.L.C.

Description: PJM Interconnection LLC submits an executed interconnection service agreement with Ameresco Stafford LLC *et al.* and a notice of cancellation of an ISA being superseded.

Filed Date: 11/15/2007.

Accession Number: 20071119–0008.

Comment Date: 5 p.m. Eastern Time on Thursday, December 6, 2007.

Docket Numbers: ER08–222–000.

Applicants: Southern California Edison Company.

Description: Southern California Edison Co. submits a Notice of Cancellation of the Amended and Restated Firm Transmission Service Agreement with Arizona Public Service Co.

Filed Date: 11/15/2007.

Accession Number: 20071119–0009.

Comment Date: 5 p.m. Eastern Time on Thursday, December 6, 2007.

Docket Numbers: ER08–223–000.

Applicants: Florida Power Corporation.

Description: Florida Power Corp dba Progress Energy Florida, Inc submits a cost-based power sales agreement with Seminole Electric Coop, Inc.

Filed Date: 11/15/2007.

Accession Number: 20071119–0010.

Comment Date: 5 p.m. Eastern Time on Thursday, December 6, 2007.

Docket Numbers: ER08–224–000

Applicants: Xcel Energy Operating Companies.

Description: Public Service Co of Colorado submits their Second Revised Sheet 328 *et al.* to their Joint Open Access Service Tariff.

Filed Date: 11/15/2007.

Accession Number: 20071119–0011.

Comment Date: 5 p.m. Eastern Time on Thursday, December 6, 2007.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov*. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed dockets(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. E7–23523 Filed 12–4–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

November 29, 2007.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER07–1174–002; OA07–74–002.

Applicants: MATL LLP.

Description: MATL, LLP submits revised tariff sheets to its open access transmission tariff, Open Access

Transmission Tariff, FERC Electric Tariff, Second Revised Volume 1.

Filed Date: 11/26/2007.

Accession Number: 20071128–0045.

Comment Date: 5 p.m. Eastern Time on Monday, December 17, 2007.

Docket Numbers: ER07–1377–001.

Applicants: Central Vermont Public Service Corp.

Description: Central Vermont Public Service Corporation Compliance Refund Report.

Filed Date: 11/21/2007.

Accession Number: 20071121–5023.

Comment Date: 5 p.m. Eastern Time on Wednesday, December 12, 2007.

Docket Numbers: ER08–235–000.

Applicants: The Connecticut Light and Power Company.

Description: The Connecticut Light and Power Co. submits its Notice of Cancellation of FERC Electric Rate Schedule 535 and related supplements.

Filed Date: 11/20/2007.

Accession Number: 20071121–0045.

Comment Date: 5 p.m. Eastern Time on Tuesday, December 11, 2007.

Docket Numbers: ER08–236–000.

Applicants: Northern Maine Independent System Administrator, Inc.

Description: Northern Maine Independent System Administrator, Inc submits a Coordination Agreement with New Brunswick System Operator.

Filed Date: 11/20/2007.

Accession Number: 20071121–0046.

Comment Date: 5 p.m. Eastern Time on Tuesday, December 11, 2007.

Docket Numbers: ER08–237–000.

Applicants: Forward Energy LLC.

Description: Forward Energy, LLC submits their FERC Electric Tariff 1.

Filed Date: 11/20/2007.

Accession Number: 20071121–0047.

Comment Date: 5 p.m. Eastern Time on Tuesday, December 11, 2007.

Docket Numbers: ER08–238–000.

Applicants: PJM Interconnection, L.L.C.

Description: PJM Interconnection LLC submits the signature page to the PJM Consolidated Transmission Owners Agreement.

Filed Date: 11/20/2007.

Accession Number: 20071121–0048.

Comment Date: 5 p.m. Eastern Time on Tuesday, December 11, 2007.

Docket Numbers: ER08–239–000.

Applicants: Indiana Michigan Power Company.

Description: Indiana Michigan Power Co. submits First Revised Sheet 15 et al. to FERC Rate Schedule 107.

Filed Date: 11/20/2007.

Accession Number: 20071121–0049.

Comment Date: 5 p.m. Eastern Time on Tuesday, December 11, 2007.

Docket Numbers: ER08–240–000.

Applicants: Indiana Michigan Power Company.

Description: Indiana Michigan Power Co. submits First Revised Sheet 15 et al. to FERC Rate Schedule 106.

Filed Date: 11/20/2007.

Accession Number: 20071121–0050.

Comment Date: 5 p.m. Eastern Time on Tuesday, December 11, 2007.

Docket Numbers: ER08–241–000.

Applicants: Consolidated Water Power Company.

Description: Consolidated Water Power Co. submits an executed "Service Agreement for Wholesale Distribution Service" with the City of Wisconsin Rapids, Wisconsin.

Filed Date: 11/20/2007.

Accession Number: 20071121–0041.

Comment Date: 5 p.m. Eastern Time on Tuesday, December 11, 2007.

Docket Numbers: ER08–253–000.

Applicants: LSF Limited.

Description: LSF Limited submits a Notice of Cancellation of Market Base Rate Authority.

Filed Date: 11/26/2007.

Accession Number: 20071128–0044.

Comment Date: 5 p.m. Eastern Time on Monday, December 17, 2007.

Docket Numbers: ER08–254–000.

Applicants: Westar Energy, Inc.

Description: Westar Energy, Inc submits a Notice of Termination of a Non-Firm Point-to-Point Transmission Service Agreement with Avista Energy, Inc.

Filed Date: 11/27/2007.

Accession Number: 20071128–0046.

Comment Date: 5 p.m. Eastern Time on Tuesday, December 18, 2007.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov*. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

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Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. E7–23553 Filed 12–4–07; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PL07–2–000]

Composition of Proxy Groups for Determining Gas and Oil Pipeline Return on Equity; Notice of Technical Conference and Request for Additional Comments

Issued November 15, 2007.

Before Commissioners: Joseph T. Kelliher, Chairman; Suedeen G. Kelly, Marc Spitzer, Philip D. Moeller, and Jon Wellinghoff.

1. On July 19, 2007, the Commission issued a proposed policy statement, concerning the composition of the proxy groups used to determine gas and oil pipelines' return on equity (ROE) under the Discounted Cash Flow (DCF) method.[1] Initial and reply comments were due on August 30 and September 19, 2007 respectively. In this notice, the Commission is requesting additional

[1] *Composition of Proxy Groups for Determining Gas and Oil Pipeline Return on Equity*, 120 FERC ¶ 61,068 (2007).

comments on or before December 14, 2007, solely on the issue of master limited partnership growth rates. The Commission is also establishing a technical conference for further consideration of that one issue. The technical conference will be held on January 8, 2008. The technical conference will be organized around panels whose members will be selected from among the parties who file comments. However, all parties and the public are invited to attend. Additional comments on the growth rate issue discussed at the technical conference will be due on January 25, 2008.

I. Background

2. The Commission uses a DCF financial model to develop a range of returns earned on investments in companies with corresponding risks for determining the ROE for natural gas and oil pipelines. In the proposed policy statement, the Commission proposed to modify its current policy regarding the composition of the proxy group used in its DCF analysis to allow master limited partnerships (MLPs) to be included in the proxy group. The proposed policy statement found that cost of service ratemaking requires that firms in the proxy group be of comparable risk to the firm whose ROE is being determined in a particular rate proceeding. The proposed policy statement found that expanding the proxy group to include MLPs whose business is more narrowly focused on pipeline activities would help provide a more representative proxy group. The Commission proposed to cap the cash distribution used to determine an MLP's return under the DCF method at the MLP's reported earnings. The Commission found that this was necessary to exclude that portion of an MLP's distributions constituting return of equity. The Commission also proposed to require a showing that the MLP has had stable earnings over a multi-year period, so as to justify a finding that it will be able to maintain the current level of cash distributions in future years. The proposed policy statement found that these requirements should render the MLP's cash distribution comparable to a corporation's dividend for purposes of the DCF analysis. Under the proposed policy, the Commission would leave to individual cases the determination of which specific MLPs and corporations should be included in the proxy group.

3. Interested parties filed some twenty-two initial comments and fourteen reply comments, which focused on three issues: (1) Whether MLPs should be included in the gas pipeline proxy group at all; (2) whether the proposed cap on the MLP cash distributions used in the DCF analysis is necessary or adequate; and (3) whether the short and long term growth component of the DCF model should be modified given the financial practices of MLPs. Other points include the potential distorting effects of MLP tax treatment, the payouts by MLPs, the general partner's incentive distributions, and the relative returns to the limited and general partners. One party requested a technical conference to discuss the issues.

4. Based on its review of the comments to date, the Commission believes that there is adequate material in the record to address most issues without additional comments or addressing them at the technical conference. These include: (1) Whether the Commission should permit MLPs to be included in the proxy group for both gas and oil pipelines; (2) the proposed earnings cap on the MLPs' distributions; and (3) whether the Commission should explore other means of determining the equity cost of capital at this time.

5. However, the Commission concludes that the current record is inadequate for deciding how an MLP's growth should be projected for purposes of the DCF analysis. Currently, the Commission projects growth in dividends based on an average of short- and long-term growth projections, with two-thirds weight given to the short-term growth forecast and one-third weight given to the long-term growth forecast. The Commission uses the five-year growth forecasts published by the Institutional Brokers Estimate System (IBES) for the short-term growth forecast; long-term growth is based on forecasts of the growth of the economy as a whole, as reflected in Gross Domestic Product (GDP). The commenters generally agree that MLPs will have lower growth potential than corporations, because of their distributions in excess of earnings. However, the existing record is insufficient for the Commission to determine (1) whether its current method of projecting growth adequately reflects the lower growth potential of MLPs, particularly over the long term,[2] and (2) if not, what alternative method should be used to project the growth of MLPs.

6. Therefore, the Commission has determined that the current record must be supplemented before the Commission can resolve the issue of how to project MLP growth rates, if the Commission ultimately decides to permit the use of MLPs in the proxy group. In addition, the Commission recognizes that the various components of the DCF model interact with one another, with the result that the appropriate growth projection for MLPs necessarily depends to some extent on whether the Commission caps the distributions used to determine an MLP's dividend yield. Parties should focus their comments and discussion at the technical conference on the issue of the appropriate MLP growth projection and, in particular, the appropriate growth projection if the Commission, as recommended by certain parties, does not cap the distributions used to determine dividend yield. In order to adequately consider the issue of whether to cap such distributions, the Commission needs a more complete record on the issue of growth projections.

II. Request for Comments and Notice of Technical Conference

7. The Commission requests that the parties submit additional comments on the issue of the appropriate growth component to be used in the Commission's DCF model in the context discussed above, when determining the equity cost of capital for an MLP. The comments must be filed on or before December 14, 2007.

8. The Commission is also establishing a staff led technical conference to discuss the MLP growth issue to be held on Tuesday, January 8, 2008. This conference is intended to be a working session focused solely on the appropriate growth component to be used in the Commission's DCF model when determining the equity cost of capital for an MLP. It is, therefore, not appropriate to discuss at this technical conference how the other components of the DCF model should be applied in determining the equity cost of capital of an MLP. The conference will be organized into a limited number of panel discussions.

9. Parties interested in serving on a panel should so indicate in their comments. To ensure that all points of view are represented and to help the conference move expeditiously, the Commission encourages parties sharing the same position to coordinate their efforts and designate one speaker to represent their shared position.

[2] *See MLPs: Safe to Come Back into the Water*, Wachovia Capital Markets, LLC, Equity Research Department, at 9–10 (August 20, 2007), attached to the initial comments of Enbridge Energy Partners, L.P. and cited to in the reply comments of NYPSC at 5, using a projected MLP long term annual growth rate of 2.5 percent. Currently, GDP is projected to grow at a rate of approximately 4.5 percent.

10. The Commission emphasizes that industry growth rates are a highly technical, if critical issue. For this reason the Commission strongly urges any party filing comments, or participating in a panel, to provide technical analyses and utilize a speaker at the conference who can respond to technical questions from the staff. The list of prospective panel members will be announced in a later notice.

11. All parties, whether or not selected to participate in a panel, may file post-conference comments on or before January 25, 2008. The post-conference comments should address only the MLP growth projection issue discussed at the conference. For more information about the conference or participation in panels, please contact John Robinson by e-mail at *john.robinson@ferc.gov* or by phone at 202–502–6808.

III. Procedure for Comments

12. The comments requested by this notice must refer to Docket No. PL07–2–000, and must include the commentor's name, the organization it represents, if applicable, and its address. To facilitate the Commission's review of the comments, commentors are requested to provide an executive summary of their position. Additional issues the commentors wish to raise should be identified separately. The commentors should double space their comments.

13. Comments may be filed on paper or electronically via the eFiling link on the Commission's Web site at *http://www.ferc.gov*. The Commission accepts most standard word processing formats and commentors may attach additional files with supporting information in certain other file formats. Commentors filing electronically do not need to make a paper filing. Commentors that are not able to file comments electronically must send an original and 14 copies of their comments to: Federal Energy Regulatory Commission, Office of the Secretary, 888 First Street, NE., Washington, DC 20426.

14. All comments will be placed in the Commission's public files and may be viewed, printed, or downloaded remotely as described in the Document Availability section below. Commentors are not required to serve copies of their comments on other commentors.

IV. Document Availability

15. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through the Commission's Home Page (*http://www.ferc.gov*) and in the Commission's Public Reference Room during normal business hours (8:30 a.m. to 5 p.m. Eastern time) at 888 First Street, NE., Room 2A, Washington DC 20426.

16. From the Commission's Home Page on the Internet, this information is available in the Commission's document management system, eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number (excluding the last three digits) in the docket number field.

17. User assistance is available for eLibrary and the Commission's Web site during normal business hours. For assistance, please contact the Commission's Online Support at 1–866–208–3676 (toll free) or 202–502–6652 (e-mail at *FERCOnlineSupport@ferc.gov* or the Public Reference Room at 202–502–8371, TTY 202–502–8659 (e-mail at *public.referenceroom@ferc.gov*).

By the Commission.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. E7–23552 Filed 12–4–07; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2004–0043; FRL–8155–5]

Chlorpyrifos-methyl; Product Cancellation Order

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's order for the cancellations, voluntarily requested by the registrants and accepted by the Agency, of products containing the pesticide chlorpyrifos-methyl, pursuant to section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended. This cancellation order follows the July 7, 2004 **Federal Register** Notice of Receipt of Requests from the chlorpyrifos-methyl registrants to voluntarily cancel their Gustafson Reldan 4E Insecticide and Reldan 4E product registrations. These are not the last chlorpyrifos-methyl products registered for use in the United States. In the July 7, 2004 notice, EPA indicated that it would issue an order implementing the cancellations, unless the Agency received substantive comments within the 30 day comment period that would merit its further review of these requests, or unless the registrants withdrew their requests within this period. The Agency received comments on the notice that merited its further review of the requests. The Agency granted an extension of the existing registration of Gustafson Reldan 4E Insecticide and Reldan 4E until the availability of an equally effective stored grain product was registered. Storicide II, for broad-spectrum control of stored grain insects, was conditionally registered on October 27, 2004. EPA hereby issues in this notice a cancellation order granting the requested cancellations. Any distribution, sale, or use of the chlorpyrifos-methyl products subject to this cancellation order is permitted only in accordance with the terms of this order, including any existing stocks provisions.

DATES: The cancellations are effective December 5, 2007.

FOR FURTHER INFORMATION CONTACT: Dana L. Friedman, Special Review and Reregistration Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 347–8827; fax number: (703) 305–5290; e-mail address: *friedman.dana @epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2004–0043. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S.

Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the **Federal Register** listings at *http://www.epa.gov/fedrgstr.*

II. What Action is the Agency Taking?

This notice announces the cancellation, as requested by registrants, of certain chlorpyrifos-methyl products registered under section 3 of FIFRA. These registrations are listed in sequence by registration number in Table 1 of this unit.

TABLE 1.—CHLORPYRIFOS-METHYL PRODUCT CANCELLATIONS

EPA Registration Number	Product Name
264-934	Gustafson Reldan 4E Insecticide
62719-43	Reldan 4E

Table 2 of this unit includes the names and addresses of record for all registrants of the products in Table 1 of this unit, in sequence by EPA company number. Please note, Gustafson Reldan 4E Insecticide (7501-41) was transferred to Bayer Cropscience LLP (264-934) in May 2005.

TABLE 2.—REGISTRANTS OF CANCELLED AND/OR AMENDED CHLORPYRIFOS-METHYL PRODUCTS

EPA Company Number	Company Name and Address
264	Bayer Cropscience LP 2 T.W. Alexander Drive Research Triangle Park, NC 27709
62719	Dow Agrosciences LLC 9330 Zionsville Rd, 308/2E Indianapolis, Indiana 46268

III. Summary of Public Comments Received and Agency Response to Comments

The Agency received comments on the notice that merited its further review of the requests. The Agency granted an extension of the existing registration of Gustafson Reldan 4E Insecticide and Reldan 4E until an equally effective stored grain product was registered. Storicide II, for broad-spectrum control of stored grain insects, was conditionally registered on October 27, 2004.

IV. Cancellation Order

Pursuant to FIFRA section 6(f), EPA hereby approves the requested cancellations of chlorpyrifos-methyl registrations identified in Table 1 of Unit II. Accordingly, the Agency orders that the chlorpyrifos-methyl product registrations identified in Table 1 of Unit II. are hereby canceled. Any distribution, sale, or use of existing stocks of the products identified in Table 1 of Unit II. in a manner inconsistent with any of the Provisions for Disposition of Existing Stocks set forth in Unit VI will be considered a violation of FIFRA.

V. What is the Agency's Authority for Taking this Action?

Section 6(f)(1) of FIFRA provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled or amended to terminate one or more uses. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Thereafter, following the public comment period, the Administrator may approve such a request.

VI. Provisions for Disposition of Existing Stocks

For the purposes of this Order, the term "existing stocks" is defined as those stocks of registered pesticide products which are currently in the United States and which were packaged, labeled, and released for shipment prior to the effective date of the cancellation action. The cancellation order issued in this notice includes the following existing stocks provisions.

A. Distribution or Sale

The distribution or sale of existing stocks will not be lawful under FIFRA with the date of this cancellation order except for the purposes of returns and relabeling, shipping such stocks for export consistent with the requirements of section 17 of FIFRA, or for proper disposal.

B. Use of Existing Stocks

Use of existing stocks will not be lawful after December 7, 2009 in the **Federal Register** provided such use is in accordance with the provisions of the existing labeling of the product.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: November 20, 2007.

Steven Bradbury,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. E7–23300 Filed 12–4–07; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2002–0302; FRL–8341–2]

Dichlorvos Petition Response; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of EPA's response to the petition dated June 2, 2006 submitted by the Natural Resources Defense Council (NRDC) insofar as the petition seeks to have EPA cancel all registrations for dichlorvos (DDVP). EPA's response is available in the DDVP docket (EPA–HQ–OPP–2002–0302) at www.regulations.gov. Elsewhere in today's **Federal Register**, EPA is making available its response to the June 2, 2006 petition insofar as it seeks to have EPA revoke all tolerances for DDVP. Taken together, these documents form EPA's response to the petition.

FOR FURTHER INFORMATION CONTACT: Susan Bartow, Special Review and Reregistration Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 603–0065; fax number: (703) 308–8005; e-mail address: *bartow.susan@epa.gov.*

SUPPLEMENTARY INFORMATION:

General Information

How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2002–0302. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal

holidays. The Docket Facility telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at *http://www.epa.gov/fedrgstr.*

List of Subjects

Environmental protection, Pesticides, Pests.

Dated: November 28, 2007.

Steven Bradbury,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. E7–23566 Filed 12–4–07; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP-2006-0507; FRL–8154–6]

Naphthalene Acetic Acid, its Salts, Ester, and Acetamide; Reregistration Eligibility Decision and Amendment for Low-Risk Pesticide; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of EPA's Reregistration Eligibility Decision (RED) and Amendment for the pesticide naphthalene acetic acid, its salts, ester, and acetamide, and opens a public comment period on these documents, related risk assessments, and other support documents. EPA has reviewed the low-risk pesticide naphthalene acetic acid, its salts, ester, and acetamide (also referred to as naphthalene acetates or NAA) through a modified, streamlined version of the public participation process that the Agency uses to involve the public in developing pesticide reregistration and tolerance reassessment decisions. Through these programs, EPA is ensuring that all pesticides meet current health and safety standards.

DATES: Comments must be received on or before January 4, 2008.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2006-0507, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

Instructions: Direct your comments to docket ID number EPA–HQ–OPP–2006-0507. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line 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 regulations.gov or e-mail. The regulations.gov website 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 regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the 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.

Docket: All documents in the docket are listed in the docket index available in regulations.gov. To access the electronic docket, go to *http://www.regulations.gov*, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. 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, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Mark T. Howard, Special Review and Reregistration Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8172; fax number: (703) 308–8005; e-mail address: *howard.markt @epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through 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:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. 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.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

A. What Action is the Agency Taking?

Under section 4 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is reevaluating existing pesticides to ensure that they meet current scientific and regulatory standards. Using a modified, streamlined version of its public participation process, EPA has completed a RED and an Amendment for the low-risk naphthalene acetate pesticides under section 4(g)(2)(A) of FIFRA. The naphthalene acetates are plant growth regulators that mimic the function of the naturally occurring plant growth hormone, auxin. They are mainly used on apple and pear trees but also have minor uses on crops such as olives and cherries. They are also used on a wide variety of ornamental plants, trees, and shrubs. In its various forms, NAA can stimulate root growth, thin excess fruit, and prevent premature fruit drop. EPA has determined that the database to support reregistration is substantially complete and that products containing naphthalene acetic acid, its salts, ester, and acetamide will be eligible for reregistration provided the risks are mitigated either in the manner described in the RED Amendment or by another means that achieves equivalent risk reduction. Upon submission of any required product specific data under section 4(g)(2)(B) of FIFRA and any necessary changes to the registration and labeling (either to address any concerns identified in the RED Amendment or as a result of product specific data), EPA will make a final reregistration decision under section 4(g)(2)(C) of FIFRA for products containing naphthalene acetates.

With the May 26, 2004 RED signature, EPA concluded that the use of the naphthalene acetates would have no effect on any endangered or threatened species or their critical habitat from the uses currently registered based on its screening-level assessment. However, the Agency was informed that one very minor use, on olive trees as a chemical thinning agent, has an approved application rate higher than assessed in the RED. Based on screening-level ecological and occupational assessments of the higher use rate, calculated risk quotients (RQs) for NAA use on olive trees then exceeded the level of concern for endangered species and one worker exposure scenario exceeds the occupational level of concern. The Agency performed a refined risk assessment with additional data, which allowed EPA to characterize the risks and determine that risks were at an acceptable level. The Agency is issuing an Amended RED for NAA, which reflects the refined occupational and ecological assessments.

In addition, certain components of the document, which did not affect the final regulatory decision, were undergoing final editing at the time of the RED's signature. These components, including the list of additional generic data requirements, summary of labeling changes, appendices, and other relevant information, have been added to the naphthalene acetic acid, its salts, ester, and acetamide RED Amendment document. Subsequent to signature, EPA identified some minor errors and ambiguities in the original RED. Therefore, for the sake of accuracy, the Agency also has included the appropriate error corrections and clarifications to the RED Amendment. None of these additions or changes impacts the decisions described in the NAA RED or its Amendment. These changes are described in the preamble to the naphthalene acetic acid, its salts, ester, and acetamide RED Amendment.

EPA is applying the principles of public participation to all pesticides undergoing reregistration and tolerance reassessment. The Agency's Pesticide Tolerance Reassessment and Reregistration; Public Participation Process, published in the **Federal Register** on May 14, 2004, (69 FR 26819) (FRL–7357–9) explains that in conducting these programs, the Agency is tailoring its public participation process to be commensurate with the level of risk, extent of use, complexity of issues, and degree of public concern associated with each pesticide. EPA can expeditiously reach decisions for pesticides like the naphthalene acetates, which pose few risk concerns, and require little risk mitigation. Once EPA assesses uses and risks for such low risk pesticides, the Agency may go directly to a decision and prepare a document summarizing its findings, such as the naphthalene acetic acid, its salts, ester, and acetamide RED and its Amendment.

The reregistration program is being conducted under congressionally mandated timeframes, and EPA recognizes the need both to make timely decisions and to involve the public in finding ways to effectively mitigate pesticide risks. NAA, however, poses few risks that require mitigation. The Agency therefore is issuing the naphthalene acetic acid, its salts, ester, and acetamide RED and Amendment, its risk assessments, and related support materials simultaneously for public comment. The comment period is intended to provide an opportunity for public input and a mechanism for initiating any additional amendments to the RED. All comments should be submitted using the methods in **ADDRESSES**, and must be received by EPA on or before the closing date. These comments will become part of the Agency Docket for naphthalene acetic acid, its salts, ester, and acetamide. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments.

EPA will carefully consider all comments received by the closing date and will provide a Response to Comments Memorandum in the Docket and regulations.gov. If any comment significantly affects the document, EPA also will publish an amendment to the RED in the **Federal Register**. In the absence of substantive comments requiring changes, the naphthalene acetic acid, its salts, ester, and acetamide RED as amended will be implemented as it is now presented.

B. What is the Agency's Authority for Taking this Action?

Section 4(g)(2) of FIFRA, as amended, directs that, after submission of all data concerning a pesticide active ingredient, "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration," before calling in product specific data on individual end-use products and either reregistering

products or taking other "appropriate regulatory action."

List of Subjects

Environmental protection, Pesticides and pests, Naphthalene acetic acid, Naphthalene acetates, NAA.

Dated: November 21, 2007.

Steven Bradbury,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. E7–23306 Filed 12–4–07; 8:45 am]
BILLING CODE 6560–50–S

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments on agreements to the Secretary, Federal Maritime Commission, Washington, DC 20573, within ten days of the date this notice appears in the **Federal Register**. Copies of agreements are available through the Commission's Office of Agreements (202–523–5793 or *tradeanalysis@fmc.gov*).

Agreement No.: 011223–041.

Title: Transpacific Stabilization Agreement.

Parties: American President Lines, Ltd.; APL Co. PTE Ltd.; CMA–CGM S.A.; COSCO Container Lines Co., Ltd.; Evergreen Line Joint Service Agreement; Hanjin Shipping Co., Ltd.; Hapag-Lloyd AG; Hyundai Merchant Marine Co., Ltd.; Kawasaki Kisen Kaisha, Ltd.; Mediterranean Shipping Co.; Mitsui O.S.K. Lines, Ltd.; Nippon Yusen Kaisha; Orient Overseas Container Line Limited; and Yangming Marine Transport Corp., and Zim Integrated Shipping Services, Ltd.

Filing Party: David F. Smith, Esq.; Sher & Blackwell LLP; 1850 M Street, NW.; Suite 900; Washington, DC 20036.

Synopsis: The amendment would add China Shipping Container Lines (Hong Kong) Co. Ltd., and China Shipping Container Lines Co. Ltd., operating as a single carrier, as a party to the agreement.

Agreement No.: 011284–064.

Title: Ocean Carrier Equipment Management Association Agreement.

Parties: APL Co. Pte. Ltd.; American President Lines, Ltd.; A.P. Moller-Maersk A/S; CMA CGM, S.A.; Atlantic Container Line; Companhia Libra de Navegacao; Compania Libra de Navegacion Uruguay S.A.; Compania Sudamericana de Vapores, S.A.; COSCO Container Lines Company Limited; Crowley Maritime Corporation; Evergreen Line Joint Service Agreement; Hamburg-Süd; Hapag-Lloyd AG; Hapag-Lloyd USA LLC; Hanjin Shipping Co., Ltd.; Hyundai Merchant Marine Co. Ltd.; Kawasaki Kisen Kaisha, Ltd.; Mitsui O.S.K. Lines Ltd.; Nippon Yusen Kaisha Line; Norasia Container Lines Limited; Orient Overseas Container Line Limited; Yang Ming Marine Transport Corp.; and Zim Integrated Shipping Services, Ltd.

Filing Party: Jeffrey F. Lawrence, Esq.; Sher & Blackwell LLP; 1850 M Street, NW.; Suite 900; Washington, DC 20036.

Synopsis: The amendment would authorize the parties to negotiate, agree on, or jointly contract for insurance related to the operation of a chassis pool. The parties request expedited review.

Agreement No.: 011707–006.

Title: Gulf/South America Discussion Agreement.

Parties: Associated Transport Line, LLC; BBC Chartering & Logistic GMBH & Co. KG; Industrial Maritime Carriers (U.S.A.) Inc.; and West Coast Industrial Express, LLC.

Filing Party: Wade S. Hooker, Esq.; 211 Central Park W; New York, NY 10024.

Synopsis: The amendment deletes Brazil from the geographic scope of the agreement.

Agreement No.: 011962–003.

Title: Consolidated Chassis Management Pool Agreement.

Parties: The Ocean Carrier Equipment Management Association and its member lines; the Association's subsidiary Consolidated Chassis Management LLC and its affiliates; China Shipping Container Lines Co., Ltd.; Companhia Libra de Navegacao; Compania Libra de Navegacion Uruguay; Matson Navigation Co.; Mediterranean Shipping Co., S.A. ; Norasia Container Lines Limited; Westwood Shipping Lines; and Zim Integrated Shipping Services Ltd.

Filing Party: Jeffrey F. Lawrence, Esq.; Sher & Blackwell LLP; 1850 M Street, NW.; Suite 900; Washington, DC 20036.

Synopsis: The amendment would authorize the parties to negotiate, agree on, or jointly contract for insurance related to the operation of a chassis pool. The parties request expedited review.

Agreement No.: 012019–000.

Title: APL/CMA CGM Central America/US East Coast Slot Charter Agreement.

Parties: APL Co. Pte Ltd.; American President Lines, Ltd; and CMA CGM S.A.

Filing Party: Eric C. Jeffrey; Goodwin Procter LLP; 901 New York Avenue, N.W.; Washington, DC 20001.

Synopsis: The agreement authorizes APL to charter space to CMA CGM on certain vessels that APL operates in trade between Guatemala, Honduras and East Coast of the United States.

Agreement No.: 012020–000.

Title: CMA CGM/Maruba Central America to Port Everglades Space Charter Agreement.

Parties: CMA CGM, S.A. and Maruba S.A.

Filing Party: Paul M. Keane, Esq.; Cichanowicz, Callan, Keane, Vengrow & Textor, LLP; 61 Broadway Suite 3000; New York, NY 10006.

Synopsis: The agreement authorizes CMA to charter space to Maruba in the trade between U.S. East Cost ports and ports in Central America.

By Order of the Federal Maritime Commission.

Dated: November 30, 2007.

Karen V. Gregory,

Assistant Secretary.

[FR Doc. E7–23583 Filed 12–4–07; 8:45 am]
BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Revocations

The Federal Maritime Commission hereby gives notice that the following Ocean Transportation Intermediary licenses have been revoked pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. Chapter 409) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, 46 CFR part 515, effective on the corresponding date shown below:

License Number: 020018NF.
Name: D & F Holdings Dba Dfhu Worldwide Shipping.
Address: 12511 Crenshaw Blvd., Hawthorne, CA 90250.
Date Revoked: November 15, 2007.
Reason: Failed To Maintain Valid Bonds.

License Number: 001665F.
Name: Debsar Corporation.
Address: 2145 Edge Hill Road, Huntingdon Valley, PA 19006.
Date Revoked: November 14, 2007.
Reason: Failed To Maintain a Valid Bond.

License Number: 003458F.
Name: Dependable International Services & Transport, Inc.
Address: 243 W. Causeway Approach, Mandeville, LA 70448.
Date Revoked: November 14, 2007.

Reason: Surrendered License Voluntarily.

License Number: 017931N.

Name: Houston Syrius USA, Inc. Dba Syrius USA, Inc.

Address: 3027 Marina Drive, Suite 107, League City, TX 77573.

Date Revoked: November 10, 2007.

Reason: Failed To Maintain a Valid Bond.

License Number: 018614F.

Name: Jack Chiang Dba Continental Resource Company.

Address: 2639 East Avenue, Hayward, CA 94541.

Date Revoked: November 14, 2007.

Reason: Failed To Maintain a Valid Bond.

Sandra L. Kusumoto,

Director, Bureau of Certification and Licensing.

[FR Doc. E7–23597 Filed 12–4–07; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission an application for license as a Non-Vessel Operating Common Carrier and Ocean Freight Forwarder—Ocean Transportation Intermediary pursuant to section 19 of the Shipping Act of 1984 as amended (46 U.S.C. Chapter 409 and 46 CFR part 515).

Persons knowing of any reason why the following applicants should not receive a license are requested to contact the Office of Transportation Intermediaries, Federal Maritime Commission, Washington, DC 20573.

Non-Vessel Operating Common Carrier Ocean Transportation Intermediary Applicant

Junkanoo Shipping, Inc., 3300 NW 112 Ave., Miami, FL 33172. *Officers:* Maria A. Urbina, Vice President (Qualifying Individual), Suresh Khilnani, President.

Non-Vessel Operating Common Carrier and Ocean Freight Forwarder Transportation Intermediary Applicant

Denmark Customs Broker, Inc., 2250 NW 114 Ave., Suite 100, Miami, FL 33172. *Officer:* Ramiro Mark Ramirez, Jr., Vice President (Qualifying Individual).

Ocean Freight Forwarder—Ocean Transportation Intermediary Applicants

Around The World Shipping, Inc., 6726 Reseda Blvd., Suite #A–10, Reseda, CA 91335. *Officers:* Oleg Shkoda, Vice President, (Qualifying Individual), Artak Agamalian, President.

Anmi Logistic Group, Inc., 8534 NW 66 St., Miami, FL 33166. *Officers:* Laura B. Bezrutschko, President, (Qualifying Individual), Alejandro M. Arias, Secretary.

America-WestAfrica Trade Link, Inc., 101 Muses Court, Cary, NC 27513. *Officers:* Romanus E. Ndianefo, CEO (Qualifying Individual), Lilian C. Ndianefo, Secretary.

Roger Baum International Exports Inc., 1602 E 4th Ave., Tampa, FL 33605. *Officers:* Sharon P. Rogers, Owner, Kirsten E. Figueredo, Forwarding Agent (Qualifying Individuals).

Dated: November 30, 2007.

Karen V. Gregory,

Assistant Secretary.

[FR Doc. E7–23584 Filed 12–4–07; 8:45 am]

BILLING CODE 6730–01–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 December 31, 2007.

A. Federal Reserve Bank of Richmond (A. Linwood Gill, III, Vice President) 701 East Byrd Street, Richmond, Virginia 23261–4528:

1. Select Bancorp, Inc., Greenville, North Carolina; to become a bank holding company by acquiring 100 percent of the voting shares of Select Bank and Trust Company, Greenville, North Carolina.

Board of Governors of the Federal Reserve System, November 30, 2007.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E7–23548 Filed 12–4–07; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Notice of Proposals to Engage in Permissible Nonbanking Activities or to Acquire Companies that are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y (12 CFR part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act. 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 the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than December 19, 2007.

A. Federal Reserve Bank of New York (Anne MacEwen, Bank Applications Officer) 33 Liberty Street, New York, New York 10045-0001:

1. Canandaigua National Corporation, Canandaigua, New York; to acquire voting shares of Genesee Valley Trust Company, Pittsford, New York, and thereby engage in trust company activities pursuant to section 225.28(b)(5) of Regulation Y.

Board of Governors of the Federal Reserve System, November 30, 2007.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E7–23547 Filed 12–4–07; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Federal Open Market Committee; Domestic Policy Directive of October 30–31, 2007

In accordance with § 271.25 of its rules regarding availability of information (12 CFR part 271), there is set forth below the domestic policy directive issued by the Federal Open Market Committee at its meeting held on October 30–31, 2007.[1]

The Federal Open Market Committee seeks monetary and financial conditions that will foster price stability and promote sustainable growth in output. To further its long–run objectives, the Committee in the immediate future seeks conditions in reserve markets consistent with reducing the federal funds rate at an average of around 4½ percent.

By order of the Federal Open Market Committee, November 26, 2007.

Brian F. Madigan,

Secretary, Federal Open Market Committee.

[FR Doc. E7–23527 Field 12–4–07; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

Employee Thrift Advisory Council

Time and Date: 10 a.m. (Eastern Time), December 19, 2007.

Place: 4th Floor, Conference Room, 1250 H Street, NW., Washington, DC.

Status: Open.

Matters to be Considered:

1. Approval of the minutes of the June 12, 2007 meeting.
2. Report of the Executive Director on Thrift Savings Plan Status.
3. Discussion of frequent trading.
4. Other proposals.
5. New business.

Contact Person for More Information: Thomas K. Emswiler, Committee Management Officer, (202) 942–1660.

Dated: November 30, 2007.

Thomas K. Emswiler,

General Counsel, Federal Retirement Thrift Investment Board.

[FR Doc. 07–5947 Filed 11–30–07; 4:21 pm]

BILLING CODE 6760–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Child Care and Development Fund Annual Financial Report for Tribes (ACF–696T).

OMB No.: 0970–0195.

Description: The Child Care and Development Fund (CCDF) annual financial reporting form (ACF–696T) provides a mechanism for Indian Tribes to report expenditures under the CCDF program. The CCDF program provides funds to Tribes, as well as States and Territories, to assist low-income families in obtaining child care so that they can work or attend training/education, and to improve the quality of care. Information collected via the ACF–696T allows the Administration for Children and Families (ACF) to monitor Tribal expenditures and to estimate outlays, and may be used to prepare ACF budget submissions to Congress. Office of Management and Budget (OMB) approval for the existing form expires on April 30, 2008.

Respondents: Indian Tribes and Tribal Organizations that are CCDF grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–696T CCDF Financial Reporting Form for Tribes	232	1	8	1,856

Estimated Total Annual Burden Hours: 1,856.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 204447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following:

Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–6974, Attn: Desk Officer for the Administration for Children and Families.

November 29, 2007.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 07–5932 Filed 12–4–07; 8:45 am]

BILLING CODE 4184–07–M

[1] Copies of the Minutes of the Federal Open Market Committee meeting on October 30–31, which includes the domestic policy directive issued at the meeting, are available upon request to the Board of Governors of the Federal Reserve System, Washington, D.C. 20551. The minutes are published in the Federal Reserve Bulletin and in the Board's annual report.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Data System for Organ Procurement and Transplantation Network (42 CFR Part 121, OMB No. 0915–0184): Extension

The operation of the Organ Procurement and Transplantation Network (OPTN) necessitates certain recordkeeping and reporting requirements in order to perform the functions related to organ transplantation under contract to HHS. This is a request for an extension of the current recordkeeping and reporting requirements associated with the OPTN. These data will be used by HRSA in monitoring the contracts for the OPTN and the Scientific Registry of Transplant Recipients (SRTR) and in carrying out other statutory responsibilities. Information is needed to monitor compliance of member organizations with OPTN rules and requirements, to ensure that all qualified entities are accepted for membership in the OPTN, and to ensure patient safety.

Estimated Annual Reporting and Recordkeeping Burden

Section and activity	Number of respondents	Responses per respondents	Total responses	Hours per response	Total burden hours
121.3(b)(2): OPTN membership requirements for OPOs, hospitals, and histocompatibility laboratories	40	1	40	45	1, 800
121.3: Application for Non-Institutional Members	20	1	20	10	200
121.3(b)(4): Appeal for OPTN membership	2	1	2	3	6
121.6(c) (Reporting): Submitting criteria for organ acceptance	900	1	900	0.5	450
121.6(c) (Disclosure): Sending criteria to OPOs	900	1	900	0.5	450
121.7(b)(4): Reasons for Refusal	900	38	34,200	0.5	17,100
121.7(e): Transplant to prevent organ wastage	260	1.5	390	0.5	195
121.9(b): Designated Transplant Program Requirements	10	1	10	5.0	50
121.3: Personnel Change Application	324	1	324	10	3,240
121.9(d): Appeal for designation	2	1	2	6	12
Total	974		39,704		23,503

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by e-mail to *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974. Please direct all correspondence to the "attention of the desk officer for HRSA."

Dated: November 29, 2007.

Alexandra Huttinger,

Acting Director, Division of Policy Review and Coordination.

[FR Doc. E7–23538 Filed 12–4–07; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; the Cardiovascular Health Study (CHS)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval the information collection listed below. This proposed information collection was previously published in the **Federal Register** on September 12, 2007, page 52155, and allowed 60 days for public comment. One comment was received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, any information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: The Cardiovascular Health Study. *Type of Information Request:* Reinstatement (OMB No. 0925–0334). *Need and Use of Information Collection:* This study quantifies associations between conventional and hypothetical risk factors and coronary heart disease (CHD) and stroke in people age 65 years and older. The primary objectives include quantifying associations of risk factors with subclinical disease; characterizing the natural history of CHD and stroke; and identifying factors associated with clinical course. The findings provide important information on cardiovascular disease in an older U.S. population and lead to early treatment of risk factors associated with disease and identification of factors that may be important in disease prevention. OBM clearance is being sought for data collection activities at only one of the four CHS field centers (the Pittsburgh field center), which are expected to end on May 31, 2008. Other data collection efforts in the CHS cohort are supported by various non-contract funding sources. *Frequency of response:* Twice a year (participants) or once per cardiovascular disease event (proxies); *Affected public:* Individuals. *Types of Respondents:* Individuals recruited for CHS and their selected proxies. The annual reporting burden is as follows: *Estimated Number of Respondents:* 467; *Estimated Number of Responses per Respondent:* 1.2; *and Estimated Total Annual Burden Hours Requested:* 281. The annualized cost to respondents is estimated at: $5,225.

There are no capital, operating, or maintenance costs to report.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent *	Average burden hours per response	Estimated total annual burden hours requested
Participants	346	1.2	0.5	208
Participant proxies	121	1.2	0.5	73
Total	467	1.2	0.5	281

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Jean Olson, Epidemiology Branch, Division of Prevention and Population Sciences, NHLBI, NIH, II Rockledge Centre, 6701 Rockledge Drive, Suite 10018, MSC # 7936, Bethesda, MD 20892–7936, or call 301–435–0397 (non-toll-free number), or e-mail your request, including your address to: *OlsonJ@nhlbi.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: November 1, 2007.

Mike Lauer,

Director, Division of Prevention and Population Sciences, NHLBI, National Institutes of Health.

Dated: November 20, 2007.

Suzanne Freeman,

OMB Clearance Officer, NHLBI, National Institutes of Health.

[FR Doc. E7–23515 Filed 12–4–07; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

New Epitopes Recognized by Antibodies Against Human and Avian Influenza for Vaccines and Diagnostic Assays

Description of Technology: Available for licensing and commercial development are intellectual properties drawn to peptides and polypeptides that elicit immunogenic responses in a mammal; especially neutralizing antibodies, against human and avian influenza strains H1N1, H3N2, H5N1 and H7N7. Materials in the form of immunogenic compositions including these peptides and polypeptides can also be in-licensed along with the patent rights. Pharmaceutical compositions including these peptides and polypeptides with or without adjuvants are within the scope of the invention. Nucleic acids and expression cassettes encoding these peptides and polypeptides are also within the scope of the invention. Methods of inhibiting infection by influenza, with or without cell entry, are also within the scope of the invention using the aforementioned peptides and polypeptides.

Applications: Vaccines; Therapeutics; Diagnostics; Influenza.

Inventors: Hana Golding and Surender Khurana (FDA).

Patent Status: U.S. Provisional Application No. 60/929,119 filed 13 June 2007 (HHS Reference No. E–236–2007/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Michael A. Shmilovich, Esq.; 301/435–5019; *shmilovm@mail.nih.gov.*

Collaborative Research Opportunity: The FDA/CBER Laboratory of Retrovirus Research is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact Beatrice A. Droke at 301/827–7008 or *bdroke@oc.fda.gov* for more information.

Trifunctional Imaging Agent for Monoclonal Antibody Tumor-Targeted Imaging

Description of Technology: Available for licensing and commercial development is a novel lysine-based trifunctional chelate which bears both a chelating moiety (CHX–A") for sequestering radiometals (^{86}Y or ^{111}In) and a near-infrared dye, e.g., Cy5.5, for dual modality PET (or SPECT) and fluorescence imaging. Successful conjugation of monoclonal antibody trastuzumab (Herceptin) or cetuximab (Erbitux) has also been achieved by efficient thiol-maleimide chemistry,

thereby yielding an immunoconjugate (Signaling agent (Cy5.5–Lys(SMCC)–CHX–A″) conjugated to trastuzumab) or (Signaling agent (Cy7–Lys(SMCC)–CHX–A″) conjugated to cetuximab). Both specifically target antigen expressing cells and internalization of the agent has been imaged over time. Trastuzumab can be radiolabeled with isothiocyanate derivatives of the bifunctional chelating agents 1B4M (2–(4–aminobenzyl)–6–methyldiethylenetriaminepentaacetic acid); and CHX–A″ (N–[(R)–2–amino–3–(p-aminophenyl)propyl]-trans-(S,S)–cyclohexane–1,2–diamine–N,N,N′,N″,N″–pentaacetic acid).

Applications: Imaging; Diagnostics.

Inventors: Martin W. Brechbiel, Heng Xu, Kwamena E. Baidoo (NCI).

Publication: H Xu et al. Design, synthesis, and characterization of a dual modality positron emission tomography and fluorescence imaging agent for monoclonal antibody tumor-targeted imaging. J Med Chem. 2007 Sep 20;50(19):4759–4765.

Patent Status: U.S. Provisional Application No. 60/929,913 filed 17 Jul 2007 (HHS Reference No. E–194–2007/0–US–01).

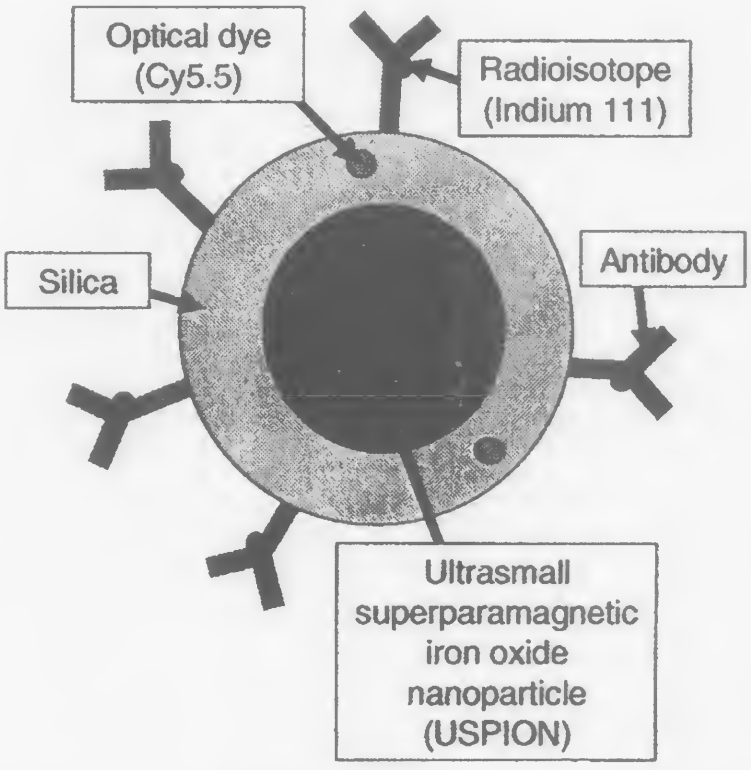
Licensing Status: Available for licensing.

Licensing Contact: Michael A. Shmilovich, Esq.; 301/435–5019; *shmilovm@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute Radiation Oncology Branch is seeking statements of capability or interest from parties interested in collaborative research to further develop, Trifunctional Imaging Agent for Monoclonal Antibody Tumor-Targeted Imaging. Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Nanoparticles for Imaging: Targeted Nanoparticles That Can Be Imaged Through Magnetic Resonance, Optical, and Radioisotope Imaging

Description of Technology: Available for licensing and commercial development are patent rights covering tri-imageable nanoparticles which have great potential for application in the laboratory and clinic for labeling at the cellular level, diagnostics, and drug delivery. The particle includes a silica encased ultrasmall superparamagnetic iron oxide (SPIONs) that can be detected using MRI. A fluorescent probe (e.g., Cy5.5) for optical imaging is embedded in the silica. The resulting particles are about 20–25nm in diameter. Target specific antibodies are attached to the surface of the particles. Chelated to the antibodies is a radioisotope (e.g., Indium–111) useful for particle quantification and can be imaged through techniques such as single photon emission computed tomography (SPECT) or positron emission tomography (PET). A graphical representation of an exemplary nanoparticle according to the invention is shown in the accompanying illustration.



Applications: Imaging; Cancer; Multiple Sclerosis.

Inventors: Martin W. Brechbiel (NCI), Peter L. Choyke (NCI), et al.

Patent Status: U.S. Provisional Application No. 60/907,085 filed 19 Mar 2007 (HHS Reference No. E–157–2007/0–US–01 and HHS Reference No. E–157–2007/1–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Michael A. Shmilovich, Esq.; 301–435–5019; *shmilovm@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute Radiation Oncology Branch is seeking statements

of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize these tri-imageable nanoparticles. Please contact John Hewes, PhD, at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Dated: November 27, 2007.

Steven M. Ferguson,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. E7–23514 Filed 12–4–07; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Alternative Medicine; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Center for Complementary and Alternative Medicine Special Emphasis Panel, December 7, 2007, 8 a.m. to December 7, 2007, 5 p.m., Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD, 20814 which was published in the **Federal Register** on November 13, 2007, 72FR63915.

This meeting is being amended to change the format to a telephone conference and to change the date from December 7, 2007 to December 18, 2007. The meeting is closed to the public.

Dated: November 27, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–5928 Filed 12–04–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Board of Scientific Counselors, National Eye Institute. The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Eye Institute, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Eye Institute.

Date: December 9–11, 2007.

Time: 7 p.m. to 1 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building 31, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Sheldon S. Miller, PhD, Scientific Director, National Institutes of Health, National Eye Institute, Bethesda, MD 20892, (301) 451–6763.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Information is also available on the Institute's/Center's home page: *www.nei.nih.gov*, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: November 28, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–5927 Filed 12–4–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; 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 Child Health and Human Development Special Emphasis Panel; Health and Healthcare Trajectories.

Date: December 11, 2007.

Time: 2 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, 5B01, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Marita R. Hopmann, PhD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health, and Human Development, 6100 Building, Room 5B01, Bethesda, MD 20892, (301) 435–6911, *hopmannm@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: November 27, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–5930 Filed 12–4–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of 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 open to the public as indicated below, 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.

The portions of the meeting devoted to the review and evaluation of journals for potential indexing by the National Library of Medicine will be closed to the public in accordance with the provisions set forth in section 552b(c)(9)(B), Title 5 U.S.C., as amended. Premature disclosure of the titles of the journals as potential titles to be indexed by the National Library of Medicine, the discussions, and the presence of individuals associated with these publications could significantly frustrate the review and evaluation of individual journals.

Name of Committee: Literature Selection Technical Review Committee.

Date: February 28–29, 2008.

Open: February 28, 2008, 9 a.m. to 11 a.m.

Agenda: Administrative reports and program discussion.

Place: National Library of Medicine, Building 38, Board Room, 2nd Floor, 8600 Rockville Pike, Bethesda, MD 20894.

Closed: February 28, 2008, 11 a.m. to 5 p.m.

Agenda: To review and evaluate journals as potential titles to be indexed by the National Library of Medicine.

Place: National Library of Medicine, Building 38, Board Room, 2nd Floor, 8600 Rockville Pike, Bethesda, MD 20894.

Closed: February 29, 2008, 8:30 a.m. to 2 p.m.

Agenda: To review and evaluate journals as potential titles to be indexed by the National Library of Medicine.

Place: National Library of Medicine, Building 38, Board Room, 2nd Floor, 8600 Rockville Pike, Bethesda, MD 20894.

Contact Person: Sheldon Kotzin, MLS, Associate Director, Division of Library Operations, National Library of Medicine, 8600 Rockville Pike, Bldg. 38/Room 2W06, Bethesda, MD 20894, 301–496–6921, *Sheldon_Kotzin@nlm.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 into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign in at the security desk upon entering the building.

(Catalogue of Federal Domestic Assistance Program No. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: November 27, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy, NIH.

[FR Doc. 07–5929 Filed 12–04–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C., Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Kidney Monitoring and Therapeutics Small Business Review.

Date: December 18, 2007.

Time: 2 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Krystyna E. Rys-Sikora, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4016J, MSC 7814, Bethesda, MD 20892, 301–451–1325, *ryssokok@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Hematopoietic Stem Cells.

Date: December 20, 2007.

Time: 11 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Delia Tang, MD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4126, MSC 7802, Bethesda, MD 20892, 301–435–2506, *tangd@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Nanotechnology in Heart, Lung and Blood.

Date: January 16–17, 2008.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Alexandra M. Ainsztein, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5144, MSC 7840, Bethesda, MD 20892, 301–451–3848, *ainsztea@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 28, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–5926 Filed 12–4–07; 8:45 am]

BILLING CODE 4140–01–M

INTERNATIONAL TRADE COMMISSION

[Investigation No. 332–493]

Advice Concerning Possible Modifications to the U.S. Generalized System of Preferences, 2007 Review of Additions and Removals

AGENCY: United States International Trade Commission.

ACTION: Change in scope of investigation.

SUMMARY: Following receipt of a letter on November 26, 2007, from the United States Trade Representative (USTR) advising of the withdrawal of petitions requesting the addition of the following three articles to the list of articles eligible for duty-free treatment under the Generalized System of Preferences (GSP) program, the Commission has terminated its investigation with respect to those three articles and will not provide probable economic effect advice with respect to those articles:

Molybdenum ores and concentrates, roasted (HTS subheading 2613.10.00, USTR accepted case 2007–01);

Molybdenum ores and concentrates, other (HTS subheading 2613.90.00, USTR accepted case 2007–02); and

Other synthetic organic pigments and coloring preparations (HTS subheading 3204.17.90, USTR accepted case 2007–04).

The Commission expects to transmit its report to the USTR providing its advice with respect to the remaining articles that are the subject of the USTR's request for advice by December 19, 2007.

ADDRESSES: All Commission offices, including the Commission's hearing rooms, are located in the United States International Trade Commission Building, 500 E Street, SW., Washington, DC. All written submissions should be addressed to the Secretary, United States International Trade Commission, 500 E Street, SW., Washington, DC 20436. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://www.usitc.gov/secretary/edis.htm.*

FOR FURTHER INFORMATION CONTACT: Information may be obtained from Cynthia B. Foreso, Project Leader, Office

of Industries (202–205–3348 or *cynthia.foreso@usitc.gov*) or Eric Land, Deputy Project Leader, Office of Industries (202–205–3349 or *eric.land@usitc.gov*). For more information on legal aspects of the investigation, contact William Gearhart of the Commission's Office of the General Counsel (202–205–3091 or *william.gearhart@usitc.gov*). The media should contact Margaret O'Laughlin, Office of External Relations (202–205–1819 or *margaret.olaughlin@usitc.gov*). Hearing-impaired individuals may obtain information on this matter by contacting the Commission's TDD terminal at 202–205–1810. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS–ONLINE) at *http://www.usitc.gov/secretary/edis.htm*. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000.

Background: The Commission instituted the investigation on September 12, 2007, following receipt of a letter from the USTR on September 6, 2007. Notice of institution of the investigation and the scheduling of a public hearing (which was held on October 16, 2007) was published in the **Federal Register** of September 19, 2007 (72 F.R. 53604). The notice indicated that the Commission would provide advice with respect to the addition of nine articles and advice with respect to the removal of two articles. The Commission will provide its advice with respect to the addition of the six remaining articles and removal of the two articles by December 19, 2007. The deadline for filing written submissions in this investigation was October 24, 2007.

By order of the Commission.

Issued: November 30, 2007.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. E7–23560 Filed 12–4–07; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree

Notice is hereby given that on November 28, 2007, a proposed Consent Decree was lodged with the United States District Court for the Southern District of Florida in the case *United States* v. *Losada, et al.*, No. 07–10027 (S.D. Fla.)

The United States of America ("United States"), on behalf the National Oceanic and Atmospheric Administration of the Department of Commerce, filed a complaint against defendants Losada and the vessel "Androw" under the National Marine Sanctuaries Act ("NMSA"), 16 U.S.C. 1431, *et seq.*, seeking damages and response costs for Defendants' destruction of natural resources in the Florida Keys National Marine Sanctuary (the "Sanctuary").

Under the proposed Consent Decree, Losada will pay $5,000, and agrees not to operate a vessel or fish within the Sanctuary for a period of five years. The settlement amount is based the defendant's ability to pay. In exchange for the payment, the plaintiff covenants not to sue the defendants for damages and response costs under NMSA with respect to the site of the grounding.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating the proposed Consent Decrees. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and either e-mailed to *pubcomment-ees.enrd@usdoj.gov* or mailed to P.O. Box 7611, U.S. Department of justice, Washington, DC 20044–7611, and should refer to: *United States* v. *Losada, et al.*, No. 07–10027 (S.D. Fla.), referencing DOJ case number 90–5–1–1–09107.

The proposed Consent Decree may be examined at the Office of the United States Attorney for the Southern District of Florida, 99 N.E. 4th Street, Miami, Florida. During the public comment period, the Consent Decree may also be examined on the following Department of Justice Web site, *http://www.usdoj.gov/enrd/Consent_Decrees.html*. A copy of the proposed Consent Decree may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611 or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*), fax no. (202) 514–0097, phone confirmation no. (202) 514–1547. In requesting a copy from the Consent Decree Library, please enclose a check payable to the "U.S. Treasury" or, if by e-mail or fax, forward a check in that amount to the Consent Decree Library at the stated address, in the amount of $2.75 (25 cents per page reproduction cost).

Henry S. Friedman,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 07–5937 Filed 12–4–07; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review: Comment Request

November 29, 2007.

The Department of Labor (DOL) hereby announces the submission 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). A copy 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*.

Interested parties are encouraged to send comments to the Office of Information and Regulatory Affairs, Attn: Brian A. Harris-Kojetin, OMB Desk Officer for the Bureau of Labor Statistics (BLS), Office of Management and Budget, Room 10235, Washington, DC 20503, Telephone: 202–395–7316 / 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: Bureau of Labor Statistics.

Type of Review: Revision of a previously approved collection.

Title: National Longitudinal Survey of Youth 1979.

OMB Control Number: 1220–0109.

Affected Public: Individuals or households.

Estimated Number of Respondents: 15,460.

Estimated Total Annual Burden Hours: 14,741.

Estimated Total Annual Costs Burden: $0.

Description: The information obtained in this survey will be used by the Department of Labor, other government agencies, academic researchers, the news media, and the general public to understand the employment experiences and life-cycle transitions of men and women born in the years 1957 to 1964 and living in the United States when the survey began in 1979. For additional information, please see related notice published at 72 FR 52164 on September 12, 2007.

Darrin A. King,

Acting Departmental Clearance Officer.

[FR Doc. E7–23535 Filed 12–4–07; 8:45 am]

BILLING CODE 4510–24–P

DEPARTMENT OF LABOR

Employee Benefits Security Administration

Agency Information Collection Activities; Announcement of OMB Approvals

AGENCY: Employee Benefits Security Administration, Labor.

ACTION: Notice.

SUMMARY: The Employee Benefits Security Administration (EBSA) announces that the Office of Management and Budget (OMB) has approved certain collections of information, listed in the Supplementary Information below, following EBSA's submission of requests for such approvals under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*). This notice describes the information collections that have been approved or re-approved, their OMB control numbers, and their current expiration dates.

FOR FURTHER INFORMATION CONTACT: G. Christopher Cosby, Office of Policy and Research, Employee Benefits Security Administration, U.S. Department of Labor, 200 Constitution Avenue, NW., Room N–5718, Washington, DC 20210. Telephone: (202) 693–8410; Fax: (202) 219–4745. These are not toll-free numbers.

SUPPLEMENTARY INFORMATION: The PRA and its implementing regulations require Federal agencies to display OMB control numbers and inform respondents of their legal significance after OMB has approved an agency's information collections. In accordance with those requirements, EBSA hereby notifies the public that the following information collections have been re-approved by OMB following EBSA's submission of an information collection request (ICR) for extension of a prior approval:

• OMB Control No. 1210–0101, Notice of Special Enrollment Rights Under Group Health Plans (final regulation). The expiration date for this information collection is December 31, 2009.

• OMB Control No. 1210–0102, Notice of Pre-Existing Condition Exclusion Under Group Health Plans (final regulation). The expiration date for this information collection is December 31, 2009.

• OMB Control No. 1210–0103, Establishing Creditable Coverage under Group Health Plans (final regulation). The expiration date for this information collection is December 31, 2009.

• OMB Control No. 1210–0065, Securities Lending by Employee Benefit Plans (PTE 2006–16). The expiration date for this information collection is December 31, 2009.

• OMB Control No. 1210–0116, Annual Report for Multiemployer Welfare Arrangements (Form M–1). The expiration date for this information collection is February 28, 2010.

• OMB Control No. 1210–0125, ERISA Investment Manager Electronic Registration (final regulation). The expiration date for this information collection is February 28, 2010.

• OMB Control No. 1210–0039, Summary Description Requirements Under ERISA (final regulation). The expiration date for this information collection is March 31, 2010.

• OMB Control No. 1210–0053, Employee Benefit Plan Claims Procedures Under ERISA (final regulation). The expiration date for this information collection is April 30, 2010.

• OMB Control No. 1210–0064, Sale of Securities to Reduce Indebtedness of Party in Interest (PTE 80–63). The expiration date for this information collection is April 30, 2010.

• OMB Control No. 1210–0092, Security Transactions with Broker-Dealers, Reporting Dealers and Banks (PTE 75–1). The expiration date for this information collection is April 30, 2010.

• OMB Control No. 1210–0095, Residential Mortgage Financing Arrangements Involving Employee Benefit Plans (PTE 88–59). The expiration date for this information collection is April 30, 2010.

• OMB Control No. 1210–0119, Petition For Finding Under Section 3(40) of ERISA (final regulation). The expiration date for this information collection is April 30, 2010.

• OMB Control No. 1210–0063, Sale of Individual Life Insurance or Annuity Contracts by a Plan (PTE 92–6). The expiration date for this information collection is August 31, 2010.

• OMB Control No. 1210–0079, Transactions Between Individual Retirement Accounts and Authorized Purchasers of American Eagle Coins (PTE 91–55). The expiration date for this information collection is August 31, 2010.

• OMB Control No. 1210–0094, Prohibited Transaction Class Exemption Permitting Employee Benefit Plans to Invest in Customer Notes of Employers (PTE 85–68). The expiration date for this information collection is August 31, 2010.

• OMB Control No. 1210–0123, Notice Requirements of the Health Care Continuation Provisions (final regulation). The expiration date for this information collection is August 31, 2010.

• OMB Control No. 1210–0110, Annual Information Return/Report (Form 5500). The expiration date for this information collection is September 30, 2010.

EBSA also notifies the public that the following new information collections have been approved by OMB following EBSA's submission of an information collection request (ICR):

• OMB Control No. 1210–0129, HDCI 2 Survey of Group Health Plans (survey). The expiration date for this information collection is April 30, 2010.

• OMB Control No. 1210–0130, Statutory Exemption for Cross-Trading (interim final regulation). The expiration date for this information collection is April 30, 2010.

• OMB Control No. 1210–0132, Default Investment Alternatives under Participant Directed Individual Account Plans (final regulation). The expiration date for this information collection October 31, 2010.

The PRA provides that 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. Publication of this notice satisfies this requirement with respect to the above-listed information collections, as provided in 5 CFR 1320.5(b)(2)(C).

Dated: November 28, 2007.

Joseph S. Piacentini,

Director, Office of Policy and Research, Employee Benefits Security Administration.

[FR Doc. E7–23554 Filed 12–4–07; 8:45 am]

BILLING CODE 4510–29–P

DEPARTMENT OF LABOR

Proposed Information Collection Request for the ETA 586, Interstate Arrangement for Combining Employment and Wages; Comment Request

AGENCY: Employment and Training Administration.

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)2)A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Employment and Training Administration is soliciting comments concerning the proposed extension of the report for the Interstate Arrangement for Combining Employment and Wages, Form ETA 586.

A copy of the proposed information collection request (ICR) can be obtained by contacting the office listed below in the addressee section of this notice or by accessing: *http://www.doleta.gov/OMBCN/OMBControlNumber.cfm.*

DATES: Submit comments on or before February 4, 2008.

ADDRESSES: Send comments to Keith P. Ribnick, Office of Workforce Security, Employment and Training Administration, U.S. Department of Labor, Room S–4516, 200 Constitution Avenue, NW., Washington, DC 20210, telephone number (202) 693–3223 (*this is not a toll-free number*).

FOR FURTHER INFORMATION CONTACT: Keith P. Ribnick, Office of Workforce Security, Employment and Training Administration, U.S. Department of Labor, Room S–4516, 200 Constitution Avenue, NW., Washington, DC 20210, telephone number (202) 693–3223 (*this is not a toll-free number*).

SUPPLEMENTARY INFORMATION:

I. *Background:* Section 3304(a)(9)(B), of the Internal Revenue Code (IRC) of 1986, requires states to participate in an arrangement for combining employment and wages covered under the different state laws for the purpose of determining unemployed workers' entitlement to unemployment compensation. The Interstate Arrangement for Combining Employment and Wages for combined wage claims (CWC), promulgated at 20 CFR 616, requires the prompt transfer of all relevant and available employment and wage data between states upon request. The Benefit Payment Promptness Standard, 20 CFR part 640, requires the prompt payment of unemployment compensation including benefits paid under the CWC arrangement. The ETA 586 report provides the ETA/Office of Workforce Security with information necessary to measure the scope and effect of the CWC program and monitor the performance of each state in responding to wage transfer data requests and the payment of benefits.

II. *Desired Focus of Comments:* Currently, the Department of Labor is soliciting comments concerning the proposed extension of the report for the Interstate Arrangement for Combining Employment and Wages, ETA 586. The Department is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the CWC program, 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 submissions of responses.

A copy of the proposed information collection request (ICR) can be obtained by contacting the office listed above in the addressee section of this notice.

III. *Current Actions:* This information is necessary in order for ETA to analyze program performance, know when corrective action plans are needed and to target technical assistance resources. Without this report, it would be impossible for the ETA to identify claims and benefit activity under the CWC program and carry out the Secretary's responsibility for program oversight.

Type of Review: Extension without change.

Agency: Employment and Training Administration.

Title: Interstate Arrangement for Combining Employment and Wages.

OMB Number: 1205–0029.

Agency Number: ETA 586.

Recordkeeping: 3 years.

Affected Public: State Government.

Cite/Reference/Form: ETA Handbook No. 401, ETA 586.

Total Respondents: 53.

Frequency: Quarterly.

Total Responses: 212.

Average Time per Response: 4 hours.

Estimated Total Burden Hours: 848.

Total Burden Cost (capital/startup): N/A.

Total Burden Cost: $0.

Comments submitted in response to this comment request will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: November 28, 2007.

Cheryl Atkinson,

Administrator, Office of Workforce Security.

[FR Doc. E7–23534 Filed 12–4–07; 8:45 am]

BILLING CODE 4510–FW–P

DEPARTMENT OF LABOR

Employment and Training Administration

Proposed Information Collection Request for the ETA 586, Interstate Arrangement for Combining Employment and Wages; Comment Request

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden

conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506 (c)2)A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Employment and Training Administration is soliciting comments concerning the proposed extension of the report for the Interstate Arrangement for Combining Employment and Wages, Form ETA 586.

A copy of the proposed information collection request (ICR) can be obtained by contacting the office listed below in the addressee section of this notice or by accessing: *http://www.doleta.gov/OMBCN/OMBControlNumber.cfm.*

DATES: Submit comments on or before February 4, 2008.

ADDRESSES: Send comments to Keith P. Ribnick, Office of Workforce Security, Employment and Training Administration, U.S. Department of Labor, Room S–4516, 200 Constitution Avenue, NW., Washington, DC 20210, telephone number (202) 693–3223 (*this is not a toll-free number*).

FOR FURTHER INFORMATION CONTACT: Keith P. Ribnick, Office of Workforce Security, Employment and Training Administration, U.S. Department of Labor, Room S–4516, 200 Constitution Avenue, NW., Washington, DC 20210, telephone number (202) 693–3223 (*this is not a toll-free number*).

SUPPLEMENTARY INFORMATION:

I. Background: Section 3304(a)(9)(B), of the Internal Revenue Code (IRC) of 1986, requires states to participate in an arrangement for combining employment and wages covered under the different state laws for the purpose of determining unemployed workers' entitlement to unemployment compensation. The Interstate Arrangement for Combining Employment and Wages for combined wage claims (CWC), promulgated at 20 CFR part 616, requires the prompt transfer of all relevant and available employment and wage data between states upon request. The Benefit Payment Promptness Standard, 20 CFR part 640, requires the prompt payment of unemployment compensation including benefits paid under the CWC arrangement. The ETA 586 report provides the ETA/Office of Workforce Security with information necessary to measure the scope and effect of the CWC program and monitor the performance of each state in responding to wage transfer data requests and the payment of benefits.

II. Desired Focus of Comments: Currently, the Department of Labor is soliciting comments concerning the proposed extension of the report for the Interstate Arrangement for Combining Employment and Wages, ETA 586. The Department is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the CWC program, 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 submissions of responses.

A copy of the proposed information collection request (ICR) can be obtained by contacting the office listed above in the addressee section of this notice.

III. Current Actions: This information is necessary in order for ETA to analyze program performance, know when corrective action plans are needed and to target technical assistance resources. Without this report, it would be impossible for the ETA to identify claims and benefit activity under the CWC program and carry out the Secretary's responsibility for program oversight.

Type of Review: Extension without change.

Agency: Employment and Training Administration.

Title: Interstate Arrangement for Combining Employment and Wages.

OMB Number: 1205–0029.

Agency Number: ETA 586.

Recordkeeping: 3 years.

Affected Public: State Government.

Cite/Reference/Form: ETA Handbook No. 401, ETA 586.

Total Respondents: 53.

Frequency: Quarterly.

Total Responses: 212.

Average Time per Response: 4 hours.

Estimated Total Burden Hours: 848.

Total Burden Cost (capital/startup): N/A.

Total Burden Cost: $0.

Comments submitted in response to this comment request will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: November 28, 2007.

Cheryl Atkinson,

Administrator, Office of Workforce Security.

[FR Doc. E7–23555 Filed 12–4–07; 8:45 am]

BILLING CODE 4510–FW–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–370]

Duke Power Company LLC; Notice of Consideration of Issuance of Amendment to Facility Operating License and Opportunity for a Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. NPF–17, issued to Duke Power Company LLC (the licensee), for operation of the McGuire Nuclear Station, Unit 2 (McGuire 2), located in Mecklenburg County, North Carolina.

The proposed amendment would allow the McGuire 2 auxiliary feedwater system (AFW) "A" train to be declared inoperable for an additional 72 hours beyond the allowed 72 hours for piping modifications and testing of the Nuclear Service Water System. The evolution is scheduled to be performed within the allowed time (72 hours) for one train of AFW to be inoperable. However, implementation and schedule uncertainty could lead to exceeding the allowed 72 hours for the AFW system Technical Specification (TS). Therefore, in an effort to avoid an unnecessary Unit 2 shutdown or submittal of a request for enforcement discretion, McGuire 2 is requesting a one-time limited duration TS change.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act), and the Commission's regulations.

The filing of requests for hearing and petitions for leave to intervene is discussed below.

Within 60 days after the date of publication of this notice, the person(s) may file a request for a hearing with respect to issuance of the amendment to

the subject facility operating license and any person(s) whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request via electronic submission through the NRC E-filing system for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR part 2. Interested person(s) should consult a current copy of 10 CFR 2.309, which is available at the Commission's PDR, located at One White Flint North, Public File Area O1F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible from the Agencywide Documents Access and Management System's (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/reading-rm/doc-collections/cfr/*. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the Chief Administrative Judge of the Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner/requestor in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements: (1) The name, address and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The petition must also identify the specific contentions which the petitioner/requestor seeks to have litigated at the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner/requestor shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. The petition must include sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner/requestor to relief. A petitioner/requestor who fails to satisfy these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing.

A request for hearing or a petition for leave to intervene must be filed in accordance with the NRC E-Filing rule, which the NRC promulgated on August 28, 2007 (72 FR 49139). The E-Filing process requires participants to submit and serve documents over the internet or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek a waiver in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least five (5) days prior to the filing deadline, the petitioner/requestor must contact the Office of the Secretary by e-mail at *HEARINGDOCKET@NRC.GOV*, or by calling (301) 415–1677, to request (1) a digital ID certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and/or (2) creation of an electronic docket for the proceeding (even in instances in which the petitioner/requestor (or its counsel or representative) already holds an NRC-issued digital ID certificate). Each petitioner/requestor will need to download the Workplace Forms Viewer™ to access the Electronic Information Exchange (EIE), a component of the E-Filing system. The Workplace Forms Viewer™ is free and is available at *http://www.nrc.gov/site-help/e-submittals/install-viewer.html*. Information about applying for a digital ID certificate is available on NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/apply-certificates.html*.

Once a petitioner/requestor has obtained a digital ID certificate, had a docket created, and downloaded the EIE viewer, it can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC public Web site at *http://www.nrc.gov/site-help/e-submittals.html*. A filing is considered complete at the time the filer submits its documents through EIE. To be timely, an electronic filing must be submitted to the EIE system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an e-mail notice confirming receipt of the document. The EIE system also distributes an e-mail notice that provides access to the document to the NRC Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically may seek assistance through the "Contact Us" link located on the NRC Web site at *http://www.nrc.gov/site-help/e-submittals.html* or by calling the NRC technical help line, which is available between 8:30 a.m. and 4:15 p.m., Eastern Time, Monday through Friday. The help line number is (800) 397–4209 or locally, (301) 415–4737. Participants who believe that they have a good cause for not submitting documents electronically must file a motion, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, *Attention:* Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville, Pike, Rockville, Maryland, 20852, *Attention:*

Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service.

Non-timely requests and/or petitions and contentions will not be entertained absent a determination by the Commission, the presiding officer, or the Atomic Safety and Licensing Board that the petition and/or request should be granted and/or the contentions should be admitted, based on a balancing of the factors specified in 10 CFR 2.309(c)(1)(i)–(viii). To be timely, filings must be submitted no later than 11:59 p.m. Eastern Time on the due date.

Documents submitted in adjudicatory proceedings will appear in NRC's electronic hearing docket which is available to the public at *http://ehd.nrc.gov/EHD_Proceeding/home.asp*, unless excluded pursuant to an order of the Commission, an Atomic Safety and Licensing Board, or a Presiding Officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, Participants are requested not to include copyrighted materials in their submissions.

For further details with respect to this license amendment application, see the application for amendment dated November 7, 2007, which is/are available for public inspection at the Commission's PDR, located at One White Flint North, Public File Area O1 F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible electronically from the ADAMS Public Electronic Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/reading-rm/adams.html*. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC PDR Reference staff by telephone at 1–800–397–4209, or 301–415–4737, or by e-mail to *pdr@nrc.gov*.

Dated at Rockville, Maryland, this 29th day of November 2007.

For the Nuclear Regulatory Commission.

John Stang,

Project Manager, Plant Licensing Branch II–1, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. E7–23542 Filed 12–4–07; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 52–012 And 52–013]

South Texas Project Nuclear Operating Company; Acceptance for Docketing of an Application for Combined License for South Texas Project Units 3 and 4

On September 27, 2007, the U.S. Nuclear Regulatory Commission (NRC, the Commission) received a combined license (COL) application from South Texas Project Nuclear Operating Company (STPNOC), dated September 20, 2007, as supplemented by letters dated September 26, 2007, October 15, 2007, October 18, 2007, November 8, 2007, November 12, 2007, November 13, 2007, and November 21, 2007, filed pursuant to Section 103 of the Atomic Energy Act and Subpart C, "Combined Licenses," of Title 10 of the Code of Federal Regulations (10 CFR), Part 52, "License Certifications and Approvals for Nuclear Power Plants." The site location is in Matagorda County, Texas and is identified as the South Texas Project Electrical Generating Station site. A notice of receipt and availability of this application was previously published in the **Federal Register** (72 FR 60394) on October 24, 2007.

The NRC staff has determined that STPNOC has submitted information in accordance with 10 CFR part 2, "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders," and 10 CFR part 52 that is acceptable for docketing. The docket numbers established for Units 3 and 4 are 52–012 and 52–013, respectively.

The NRC staff will perform a detailed technical review of the COL application. Docketing of the COL application does not preclude the NRC from requesting additional information from the applicant as the review proceeds, nor does it predict whether the Commission will grant or deny the application. The Commission will conduct a hearing in accordance with subpart L, "Informal Hearing Procedures for NRC Adjudications," of 10 CFR part 2 and will receive a report on the COL application from the Advisory Committee on Reactor Safeguards in accordance with 10 CFR 52.87, "Referral to the Advisory Committee on Reactor Safeguards (ACRS)." If the Commission finds that the COL application meets the applicable standards of the Atomic Energy Act and the Commission's regulations, and that required notifications to other agencies and bodies have been made, the Commission will issue a COL, in the form and containing conditions and limitations that the Commission finds appropriate and necessary.

In accordance with 10 CFR part 51, the Commission will also prepare an environmental impact statement for the proposed action. Pursuant to 10 CFR 51.26, and as part of the environmental scoping process, the staff intends to hold a public scoping meeting. Detailed information regarding this meeting will be included in a future **Federal Register** notice.

Finally, the Commission will announce in a future **Federal Register** notice, the opportunity to petition for leave to intervene in the hearing required for this application by 10 CFR 52.85.

Documents may be examined, and/or copied for a fee, at the NRC's Public Document Room (PDR), located at One White Flint North, Public File Area O1 F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852, and will be accessible electronically through the Agencywide Documents Access and Management System (ADAMS) Public Electronic Reading Room link at the NRC Web site *http://www.nrc.gov/reading-rm/adams.html*. Persons who do not have access to ADAMS, or who encounter problems in accessing documents located in ADAMS should contact the NRC PDR Reference staff by telephone at 1–800–397–4209, 301–415–4737, or by e-mail to *pdr@nrc.gov*. The application is also available at *http://www.nrc.gov/reactors/new-licensing/col.html*.

Dated at Rockville, Maryland this 29th day of November 2007.

For the Nuclear Regulatory Commission.

Thomas A. Bergman,

Deputy Director, Division of New Reactor Licensing, Office of New Reactors.

[FR Doc. E7–23539 Filed 12–4–07; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–498 and 50–499]

STP Nuclear Operating Company; Notice of Withdrawal of Application for Amendments to Facility Operating Licenses

The U.S. Nuclear Regulatory Commission (the Commission) has granted the request of STP Nuclear Operating Company (the licensee) to withdraw its June 7, 2006, application for proposed amendments to Facility Operating License Nos. NPF–76 and NPF–80, respectively, for the South Texas Project, Units 1 and 2, located in Matagorda County.

The proposed amendments would have revised the facility's Spent Fuel Pool and In-Containment Storage Area Criticality Analysis.

The Commission had previously issued a Notice of Consideration of Issuance of Amendments published in the **Federal Register** on September 12, 2006 (71 FR 53721). However, by letter dated November 28, 2007, the licensee withdrew the proposed request for amendments.

For further details with respect to this action, see the application for amendments dated June 7, 2006, and the licensee's letter dated November 28, 2007, which withdrew the application for license amendments. Documents may be examined, and/or copied for a fee, at the NRC's Public Document Room (PDR), located at One White Flint North, Public File Area O1 F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible electronically from the Agencywide Documents Access and Management Systems (ADAMS) Public Electronic Reading Room on the internet at the NRC Web site, *http://www.nrc.gov/reading-rm.html*. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC PDR Reference staff by telephone at 1–800–397–4209, or 301–415–4737 or by e-mail to *pdr@nrc.gov*.

Dated at Rockville, Maryland, this 28th day of November, 2007.

For the Nuclear Regulatory Commission.

Carl F. Lyon,

Project Manager, Plant Licensing Branch IV, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. E7–23536 Filed 12–4–07; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–387 and 50–388]

PPL Susquehanna, LLC; Susquehanna Steam Electric Station, Units 1 and 2; Draft Environmental Assessment and Finding of No Significant Impact Related to the Proposed License Amendment To Increase the Maximum Reactor Power Level

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Notice of Opportunity for Public Comment.

SUMMARY: The NRC has prepared a Draft Environmental Assessment as its evaluation of a request by PPL Susquehanna, LLC for a license amendment to increase the maximum thermal power at Susquehanna Steam Electric Station, Units 1 and 2 (SSES 1 and 2), from 3,489 megawatts-thermal (MWt) to 3,952 MWt at each unit. This represents a power increase of approximately 13 percent thermal power. As stated in the NRC staff's position paper dated February 8, 1996, on the Boiling-Water Reactor Extended Power Uprate (EPU) Program, the NRC staff (the staff) will prepare an environmental impact statement if it believes a power uprate would have a significant impact on the human environment. The staff did not identify any significant impact from the information provided in the licensee's EPU application for Susquehanna Steam Electric Station, Units 1 and 2, or the staff's independent review; therefore, the staff is documenting its environmental review in an Environmental Assessment. Also, in accordance with the position paper, the Draft Environmental Assessment and Finding of No Significant Impact is being published in the **Federal Register** with a 30-day public comment period.

Environmental Assessment

Plant Site and Environs

SSES is located just west of the Susquehanna River approximately 5 miles northeast of Berwick, in Luzerne County, Pennsylvania. In total, SSES majority owner and licensed operator, PPL Susquehanna, LLC (PPL, the licensee), owns 2,355 acres of land on both sides of the Susquehanna River. Generally, this land is characterized by open deciduous woodlands interspersed with grasslands and orchards. Approximately 487 acres are used for generation facilities and associated maintenance facilities, laydown areas, parking lots, and roads. Approximately 130 acres are leased to local farmers. PPL maintains a 401-acre nature preserve, referred to as the Susquehanna Riverlands, which is located between SSES and the river; U.S. Route 11 separates the Susquehanna Riverlands from the plant site. The land on the west side of the river is about 1,573 acres and Gould Island, a 65-acre island just north of SSES on the Susquehanna River, is currently jointly owned between PPL (90%) and Allegheny Electric Cooperative (10%). Also, PPL currently owns an additional 717 acres of mostly undeveloped land, which includes natural recreational, and wildlife areas on the east side of the river (Reference 10).

SSES is a two-unit plant with General Electric boiling-water reactors and generators. NRC approved the Unit 1 operating license on July 17, 1982, and commercial operation began June 8, 1983. The Unit 2 operating license was issued on March 3, 1984, and commercial operation began February 12, 1985. Units 1 and 2 both currently operate at 3,489 MWt (Reference 8). The units share a common control room, refueling floor, turbine operating deck, radwaste system, and other auxiliary systems (Reference 9).

SSES uses a closed-cycle heat dissipation system (two natural-draft cooling towers) to transfer waste heat from the circulating water system to the atmosphere. The circulating water and the service water systems draw water from, and discharge to, the Susquehanna River. The river intake structure is located on the western bank of the river and consists of two water entrance chambers with 1-inch, on-center vertical trash bars and ⅜-inch-mesh traveling screens. A low-pressure screen-wash system periodically operates to release aquatic organisms and debris impinged on the traveling screens to a pit with debris removal equipment that collects material into a dumpster for offsite disposal. Cooling tower blowdown, spray pond overflow, and other permitted effluents are discharged to the Susquehanna River through a buried pipe leading to a submerged discharge diffuser structure, approximately 600 feet downstream of the river intake structure. The diffuser pipe is 200-feet long, with the last 120 feet containing 72 four-inch portals that direct the discharge at a 45-degree angle upwards and downstream. Warm circulating water from the cooling towers can be diverted to the river intake structure to prevent icing; this usually occurs from November through March on an as-needed basis (Reference 10).

For the specific purpose of connecting SSES to the regional transmission system, there are approximately 150 miles of transmission line corridors that occupy 3,341 acres of land. The corridors pass through land that is primarily agricultural and forested with low population densities. Two 500–kilovolt (kV) lines and one 230–kV line connect SSES to the electric grid, with approximately 2.3 miles of short ties in the immediate plant vicinity to connect SSES to the 230–kV system. The Stanton-Susquehanna #2 230–kV transmission line corridor runs northeast from the plant for approximately 30 miles and ranges from 100–400 feet wide. The Susquehanna-Wescosville-Alburtis 500–kV transmission line corridor ranges from 100 to 350 feet wide and runs generally southeast from the plant for approximately 76 miles; the Sunbury-Susquehanna #2 500–kV transmission line corridor is approximately 325 feet wide and runs 44 miles west-southwest from the plant. The transmission line corridors cross the following Pennsylvania counties: Luzerne (the location of SSES), Carbon, Columbia, Lehigh, Northampton, Northumberland, Montour, and Snyder. These transmission lines are currently owned by PPL Electric Utilities with the exception of 42.3 miles of the 44.2 mile Sunbury-Susquehanna #2 500–kV line which is currently owned by Allegheny Electric Cooperative. All of these lines however, are integral to the larger transmission system, and as such PPL Electric Utilities plans to operate and maintain these lines indefinitely. Except for the short ties on the plant site, the lines would likely remain a permanent part of the transmission system even after SSES is decommissioned (Reference 10).

Identification of the Proposed Action

By letter dated October 11, 2006, PPL proposed amendments to the operating licenses for SSES Units 1 and 2 to increase the maximum thermal power level of both units by approximately 13 percent thermal power, from 3,489 MWt to 3,952 MWt (Reference 8). The change is considered an EPU because it would raise the reactor core power level more than 7 percent above the original licensed maximum power level. This amendment would allow the heat output of the reactor to increase, which would increase the flow of steam to the turbine. This would result in the increase in production of electricity and the amount of waste heat delivered to the condenser, and an increase in the temperature of the water being discharged to the Susquehanna River.

PPL plans to implement the proposed EPU in two phases to obtain optimal fuel utilization and to ensure that manageable core thermal limits are maintained. The core thermal power level of Unit 2 would be increased by approximately 13 percent following the spring 2009 refueling outage. Unit 1's core thermal power level would be increased in two stages of about 7 percent each during the spring 2008 and spring 2010 refueling outages (Reference 8).

The original operating licenses for Units 1 and 2 authorized operation up to a maximum power level of 3,293 MWt per unit. Since the units went online, SSES has implemented two power uprates. Stretch uprates (4.5 percent each) were implemented in 1994 (Unit 2) and 1995 (Unit 1), increasing the licensed thermal power levels of SSES Units 1 and 2 from 3,293 MWt to 3,441 MWt. Two separate NRC environmental assessments each resulted in a finding of no significant impact and determined that these actions "* * * would have no significant impact on the quality of the human environment." These decisions were published in the **Federal Register**, Vol. 59, No. 53, pp. 12990–12992 and Vol. 60, No. 9, pp. 3278–3280 (Reference 12, 13). In 2001, a Measurement Uncertainty Recapture (MUR) uprate of 1.4 percent increased the licensed thermal power levels of SSES Units 1 and 2 to 3,489 MWt. The NRC environmental assessment for this action also resulted in a finding of no significant impact and was published in the **Federal Register**, Vol. 66, No. 122, pp. 33716–33717 (Reference 14).

The Need for the Proposed Action

SSES is within the transmission area controlled by PJM Interconnection, L.L.C. (PJM). PJM operates the largest regional transmission territory in the U.S., currently serving a 164,260-square-mile area in all or parts of 13 states and the District of Columbia, representing approximately 163,806 megawatts electrical (MWe) of generating capacity. PJM has forecasted that the summer unrestricted peak load in the Mid-Atlantic geographic zone where SSES is located would grow at an annual average rate of 1.8 percent for the next 10 years. This represents an increase in peak load of almost 6,000 MWe from 2005 to 2010, when the proposed SSES EPU is scheduled to be completed. The proposed EPU would add an average of 205 MWe of base load generation to the grid from both Units 1 and 2. This added electricity is projected to be enough to meet the power needs of approximately 195,000 homes and is forecasted to be produced for the PJM grid at a cost lower than the projected market price (Reference 9).

PJM uses a queue system to manage requests to add or remove generation from the regional transmission system. SSES submitted an application to PJM for the EPU additional generation on May 19, 2004. The PJM Interconnection Service Agreements and Construction Service Agreements were signed for Unit 2 on July 7, 2005, and for Unit 1 on January 20, 2006 (Reference 9).

Environmental Impacts of the Proposed Action

At the time of issuance of the operating licenses for SSES, the staff noted that any activity authorized by the licenses would be encompassed by the overall action evaluated in the Final Environmental Statement (FES) for the operation of SSES, which was issued by the NRC in June 1981. This Environmental Assessment summarizes the radiological and non-radiological impacts in the environment that may result from the proposed action.

Non-Radiological Impacts

Land Use Impacts

Potential land use impacts due to the proposed EPU include impacts from construction and plant modifications at SSES. While some plant components would be modified, most plant changes related to the proposed EPU would occur within existing structures, buildings, and fenced equipment yards housing major components within the developed part of the site. No new construction would occur outside of existing facilities, and no expansion of buildings, roads, parking lots, equipment storage areas, or transmission facilities would be required to support the proposed EPU with the following exceptions.

The 230–kV switchyard located on PPL property across the river from the station, and the 500–kV switchyard located on the plant site would both be expanded to house additional capacitor banks. The site road adjacent to the 500–kV switchyard would be moved to accommodate this expansion. Both switchyard modifications would require no land disturbance outside the power block area. Relocation of the road adjacent to the 500–kV switchyard would occur in a previously developed area of the plant site, resulting in no or little impact to land use. In addition, the turbine building may be expanded to allow for the installation of condensate filters, and additional aboveground storage tanks may be required to support cooling tower basin acid injection. If

required, storage tank installation and turbine building expansion would be located in the developed part of the site (Reference 8, 9). An above ground shielded storage facility will be constructed onsite within the Protected Area to store the original steam dryers.

Existing parking lots, road access, laydown areas, offices, workshops, warehouses, and restrooms would be used during construction and plant modifications. Therefore, land use conditions would not change at SSES. Also, there would be no land use changes along transmission lines (no new lines would be required for the proposed EPU), transmission corridors, switch yards, or substations. Because land use conditions would not change at SSES and because any disturbance would occur within previously disturbed areas within the plant site, there would be little or no impact to aesthetic resources (except during outside construction) and historic and archeological resources in the vicinity of SSES.

The impacts of continued operation of SSES Units 1 and 2 combined with the proposed EPU would be bounded by the scope of the original FES for operation, "Final Environmental Statement Related to the Operation of Susquehanna Steam Electric Station, Units 1 and 2," dated 1981, and therefore, the staff concludes that there would be no significant impacts to land use, aesthetics, and historic and archaeological resources from the proposed EPU.

Non-Radiological Waste

SSES generates both hazardous and non-hazardous waste. Under the Resource Conservation and Recovery Act (RCRA) Subtitle C, SSES is classified as a Large Quantity Generator of hazardous waste, including spent batteries, solvents, corrosives, and paint thinners. According to the Environmental Protection Agency's *Envirofacts Warehouse* database, there are no RCRA violations listed for SSES related to the management of these hazardous wastes (Reference 11). Non-hazardous waste is managed by SSES's current program and includes municipal waste, maintenance waste, wood, and non-friable asbestos. Plant modifications necessary for the proposed EPU may result in additional hazardous and non-hazardous waste generation; however, all wastes would continue to be managed by the waste management program currently in place at SSES, which is designed to minimize hazardous waste generation and promote recycling of waste whenever possible (Reference 9) and subject to state (commonwealth) and Federal oversight. As such, the staff concludes there would be no impacts from additional non-radiological waste generated as a result of the proposed EPU.

Cooling Tower Impacts

SSES operates two natural draft cooling towers to transfer waste heat from the circulating water system (which cools the main condensers) to the atmosphere. No additional cooling tower capacity is planned to accommodate the proposed EPU. However, additional aboveground storage tanks could be required to support cooling tower basin acid injection. If built, these tanks would be located in the developed part of the plant site (Reference 9).

Aesthetic impacts associated with cooling tower operation following implementation of the proposed action would be similar to those associated with current operating conditions and include noise and visual impacts from the plume such as fogging and icing.

No significant increase in noise is anticipated for cooling tower operation following the proposed EPU. The FES for operation evaluated the potential noise impacts of operation of SSES and determined that pump and motor noise from the cooling water system would not exceed ambient (baseline) levels in offsite areas and that cooling tower noise would be audible for no more than a mile offsite to the west, southwest, and southeast of the station. PPL conducted an initial noise survey in 1985 after commercial operation of both units began, and again in 1995 following the stretch uprate. The 1995 noise measurements were similar to those recorded in 1985, and PPL received no noise complaints following implementation of the stretch uprate. The staff concludes that the proposed EPU, like the stretch uprate, would not produce measurable changes in the character, sources, or intensity of noises generated by the station's cooling water system or cooling towers (Reference 9).

Conclusions reached in NUREG–1437, "Generic Environmental Impact Statement for License Renewal of Nuclear Plants (GEIS)," Volumes 1 and 2, dated 1996, apply to the proposed action regarding cooling tower impacts on crops, ornamental vegetation, and native plants. The GEIS concluded that natural-draft cooling towers release drift and moisture high into the atmosphere where they are dispersed over long distances, and increased fogging, cloud cover, salt drift, and relative humidity have little potential to affect crops, ornamental vegetation, and native plants.

Impacts associated with continued cooling tower operation at SSES following the proposed EPU, including noise, fogging, cloud cover, salt drift, and icing would not change significantly from current impacts. Therefore, the staff concludes there would be no significant impacts associated with cooling tower operation for the proposed action.

Transmission Facility Impacts

The potential impacts associated with transmission facilities for the proposed action include changes in transmission line corridor maintenance and electric shock hazards due to increased current. The proposed EPU would not require any new transmission lines and would not require changes in the maintenance and operation of existing transmission lines or substations. Corridor maintenance practices (including vegetative management) would not be affected by the proposed EPU.

The proposed EPU would require the installation of additional capacitor banks in the 500– and 230–kV switchyards, and PPL plans to conduct a power delivery environmental risk identification evaluation prior to these installations. The capacitor bank installations are the only modification of transmission facilities that would accompany the proposed EPU. The only operational change to transmission lines resulting from the proposed EPU would be increased current; voltage would remain unchanged. As PPL states in its October 11, 2006, application, page 7–2, "increased current may cause transmission lines to sag more, but there would still be adequate clearance between energized conductors and the ground to prevent electrical shock." Additionally, PPL has evaluated all related transmission facilities and found these facilities to be within acceptable design parameters (Reference 9).

The National Electric Safety Code (NESC) provides design criteria that limit hazards from steady-state currents. The NESC limits the short-circuit current to ground to less than 5 milliamps. As stated above, there would be an increase in current passing through the transmission lines associated with the increased power level of the proposed EPU. The higher electrical current passing through the transmission lines would cause an increase in electromagnetic field strength. However, with the proposed increase in power level, the impact of exposure to electromagnetic fields from the offsite transmission lines would not be expected to increase significantly over the current impact. The transmission lines meet the applicable

shock prevention provisions of the NESC. Therefore, even with the small increase in current attributable to the proposed EPU, adequate protection is provided against hazards from electric shock.

The impacts associated with transmission facilities for the proposed action would not change significantly from the impacts associated with current plant operation. There would be no physical modifications to the transmission lines, transmission line corridor maintenance practices would not change, there would be no changes to transmission line corridors or vertical clearances, electric current passing through the transmission lines would increase only slightly, and capacitor bank modifications would occur only within the existing power blocks. Therefore, the staff concludes that there would be no significant impacts associated with transmission facilities for the proposed action.

Water Use Impacts

Potential water use impacts from the proposed action include hydrological alterations to the Susquehanna River and changes to plant water supply. SSES uses cooling water from the Susquehanna River and discharges water back to the river at a point approximately 600 feet downstream of the intake structure. River water enters the plant cooling system via cooling tower basins and provides water to the circulating water and service water systems. SSES uses a closed-cycle, natural-draft cooling tower heat dissipation system to remove waste heat from the main condensers; cooling tower blowdown is discharged back to the Susquehanna River (Reference 9).

No changes to the cooling water intake system are expected during the proposed action. While the volume of intake embayments would not change, the intake flow rate would increase from an average of 58.3 million gallons per day (gpd) to an average of 60.9 million gpd, as the amount of time all four river intake pumps operate would increase. This represents a 4.5-percent increase in intake water withdrawn from the Susquehanna River and is not expected to alter the hydrology of the river significantly (Reference 9). The maximum withdrawal rate possible as a result of the proposed EPU is 65.4 million gpd, which was calculated using worst-case meteorological conditions (NRC 2006). This represents a 12.2-percent increase in intake water withdrawn from the river and is not expected to alter the hydrology of the river significantly.

The amount of consumptive water usage due to evaporation and drift of cooling water through the cooling towers is expected to increase from a monthly average of 38 million gpd to 44 million gpd. This represents a 15.7-percent increase over current usage. Based on the Susquehanna River's average annual flow rate of 9,427 million gpd, the proposed EPU would result in an average annual loss of 0.5 percent of river water at that location. During low-flow conditions, which usually occur in late August, the average evaporative loss at SSES may approach 1 percent of the low-flow river value (Reference 9). The staff concludes that the amount of water consumed by SSES under the proposed EPU conditions would not result in significant alterations to Susquehanna River flow patterns at this location.

Consumptive water usage at SSES is regulated by the Susquehanna River Basin Commission (SRBC), an independent agency that manages water usage along the entire length of the Susquehanna River. The current permit granted for SSES operation by SRBC is for average monthly consumptive water usage up to 40 million gpd (permit #19950301 EPUL–0578). In December 2006, PPL submitted an application to SRBC to eliminate the 40 million gpd average monthly limit and to approve a maximum daily river water withdrawal of 66 million gpd (Reference 15). SRBC is currently reviewing PPL's application and will make a decision independent of the NRC whether to allow the increased consumptive water usage required to implement the proposed EPU. The SRBC permit is required for plant operation, and PPL must adhere to the prescribed water usage limits and any applicable mitigative measures.

No changes to the cooling water intake system and the volume of intake embayment are expected for the proposed EPU, but the average intake flow would increase by 4.5 percent. The staff concludes this increase would not alter significantly the hydrology of the Susquehanna River. The proposed EPU would result in a small increase in the amount of Susquehanna River consumptive water usage due to evaporative losses. However, the increased loss would be insignificant relative to the flow of the Susquehanna River, and SRBC would continue to regulate SSES's consumptive water usage. With respect to the proposed action, the staff concludes there would be no significant impact to the hydrological pattern on the Susquehanna River, and there would be no significant impact to the plant's consumptive water supply.

Discharge Impacts

Potential impacts to the Susquehanna River from the SSES discharge include increased turbidity, scouring, erosion, and sedimentation. These discharge-related impacts apply to the region near the discharge structure due to the large volume of cooling water released to the river. However, since the proposed EPU would result in no significant changes in discharge volume or velocity, there would be no expected changes in turbidity, scouring, erosion or sedimentation related to the proposed EPU.

Surface and wastewater discharges at SSES are regulated through the National Pollutant Discharge Elimination System (NPDES) permit (No. PA0047325), which is issued and enforced by the Pennsylvania Department of Environmental Protection (DEP) Bureau of Water Supply and Wastewater Management. The DEP periodically reviews and renews the NPDES permit; SSES's current NPDES permit was effective beginning September 1, 2005, and is valid through August 31, 2010. The NPDES permit sets water quality standards for all plant discharges to the Susquehanna River, including limits on free available chlorine, total zinc, and total chromium in cooling tower blowdown. According to Pennsylvania's Environmental Facility Application Compliance Tracking System (eFACTS), there are no past or current NPDES violations listed for SSES (Reference 4).

While the proposed EPU would increase the amount of cooling tower blowdown to the Susquehanna River, there is no expected increase in associated biocides, solvents, or dissolved solids entering the river, and SSES would continue to adhere to the water quality standards set within the NPDES permit. The NPDES permit does not contain thermal discharge temperature limits, but SSES must adhere to Susquehanna River temperature limits prescribed by Pennsylvania Code water quality standards (Reference 1). Thermal discharge effects and applicable Pennsylvania Code water quality standards will be discussed further in the Impacts on Aquatic Biota section.

No expected changes in turbidity, scouring, erosion or sedimentation are expected as a result of the proposed EPU. Surface and wastewater discharges to the Susquehanna River would continue to be regulated by the Pennsylvania DEP. Any discharge-related impacts for the proposed action would be similar to current impacts from plant operation, and therefore, the staff concludes the proposed action

would not result in significant impacts on the Susquehanna River from cooling water discharge.

Impacts on Aquatic Biota

The potential impacts to aquatic biota from the proposed EPU include impingement, entrainment, thermal discharge effects, and impacts due to transmission line right-of-way maintenance. The aquatic species evaluated in this draft Environmental Assessment are those in the vicinity of the SSES cooling water intake and discharge structures along the Susquehanna River, and those that occur in water bodies crossed by transmission lines associated with SSES.

The licensee has conducted aquatic biota studies of the Susquehanna River upstream and downstream of SSES since 1971. The studies assessed water quality, algae (periphyton and photoplankton), macroinvertebrates, and fish from 1971 to 1994, with annual fish studies beginning in 1976. The Susquehanna River in the vicinity of SSES has both coolwater and warmwater fishes, primarily consisting of minnows (*Cyprinidae*), suckers (*Catastomidae*), catfish (*Icaluridae*), sunfish (*Centrarchidae*), and darters and perch (*Percidae*). There are also records of smallmouth bass (*Micropterus dolomieu*), walleye (*Sander vitreus*), and channel catfish (*Ictalurus punctatus*) found in proximity to SSES. Monitoring of benthic macroinvertebrates and biofouling mollusks was also included in the studies. No zebra mussels (*Dreissena polymorpha*) have been recorded at SSES or in the vicinity of the North Branch of the Susquehanna River; however, Asiatic clams (*Corbicula fluminea*) have been found in the North Branch of the Susquehanna River for several years and were collected by scuba divers in the SSES engineered safeguard service water spray pond in July 2005.

No sensitive aquatic species are known to occur at or near SSES (Reference 9); however, the 1981 FES for operation indicated that two endangered and two rare fish listed by the Pennsylvania Fish Commission (now the Pennsylvania Fish & Boat Commission) have ranges that fall within SSES transmission line corridors (NRC 1981). PPL has provided the staff with a vegetative management program for its transmission line corridors that states no herbicides shall be applied within 50 feet of any water body, except stump treatments and herbicides approved for watershed/aquatic use. Additionally, the transmission line corridor maintenance activities in the vicinity of stream and river crossings employ procedures to minimize erosion and shoreline disturbance while encouraging vegetative cover (Reference 7).

In addition to setting water quality parameters for surface and wastewater discharges, the SSES NPDES permit (PA–0047325) also regulates entrainment and impingement of aquatic species at SSES. Because SSES uses a closed-cycle, recirculating cooling water system, entrainment and impingement impacts on aquatic biota resulting from the proposed EPU are not expected to be significant.

The proposed EPU would require additional water withdrawal from the Susquehanna River for increased cooling tower evaporative losses and other plant needs. The average increase in daily water withdrawal from the Susquehanna River would be approximately 4.4 percent, from 58.3 million gpd to 60.9 million gpd. PPL also reported a maximum daily water withdrawal estimate of 65.4 million gpd (an 11.2 percent increase), which would only occur during worst-case meteorological conditions (Reference 15). Under the proposed EPU conditions, the average increase in water withdrawal would result in the impingement of approximately one additional fish per day (from 21 to 22) and entrainment of approximately 15,972 additional larvae per day (from 363,000 to 378,000) during spawning season. These small increases in entrainment and impingement related to the proposed EPU would result in no significant impact to the Susquehanna River aquatic community (Reference 9).

Effective July 9, 2007, the EPA suspended the Phase II rule (NRC 2007b). As a result, all permits for Phase II facilities should include conditions under Section 316(b) of the Clean Water Act that are developed on a Best Professional Judgment basis, rather than best technology available. Best Professional Judgment is used by National Pollutant Discharge Elimination System (NPDES) permit writers to develop technology-based permit conditions on a case-by-case basis using all reasonably available and relevant data. Any site-specific mitigation required under the NPDES permitting process would result in a reduction in the impacts of continued plant operations.

The NPDES permit issued by the Pennsylvania DEP does not specify thermal discharge limits; however, the amount and temperature of heated effluent discharged to the Susquehanna River is governed by Section 93.7 of Pennsylvania Code, which places restrictions on waters designated "Warm Water Fisheries." During the July 1–August 31 time frame, the highest river water temperature allowable is 87 degrees Fahrenheit (°F), with lower temperature limits during other parts of the year (Reference 1). In the 1981 FES for operation, the NRC performed an analysis of SSES blowdown plume characteristics. The analysis concluded that blowdown temperatures during all four seasons were lower than the maximum river temperatures set by Section 93.7. The location and design of the SSES cooling water discharge structure and the high flow rate of the Susquehanna River allow for sufficient mixing and cooling of heated effluent. Using conservative assumptions similar to those used in the original FES thermal plume analysis, PPL calculated that after implementation of the proposed EPU, blowdown temperatures would increase by 2 °F. This would result in a 0.6 °F increase in the maximum expected temperature at the edge of the thermal plume mixing zone (maximum temperature 86.5 °F). The staff concludes that the increase in thermal discharge temperature and volume resulting from the proposed EPU would still fall within the guidelines prescribed by the original FES for operation (NRC 1981).

Liquid effluents discharged to the Susquehanna River include cooling tower blowdown, spray pond overflow, liquid rad waste treatment effluents, and surface and wastewater discharges. The Commonwealth of Pennsylvania regulates these discharges through SSES's NPDES permit, which sets water quality standards for all plant discharges to the Susquehanna River. Ecological studies of the Susquehanna River conducted for the licensee indicate that river water quality in the vicinity of SSES continues to improve. From 1973 through 2002, there was a significant decreasing trend in turbidity, sulfate, total iron, and total suspended solids; and a significant increasing trend in river temperature, pH, total alkalinity, and dissolved oxygen. A reduction in acid-mine drainage pollutants and improvements in upstream waste-water treatment have likely contributed to the overall-improved river ecosystem health (Ecology III 2003).

SSES operates a closed-cycle cooling water system, and as such, the staff concludes that impacts to aquatic biota in the Susquehanna River from entrainment, impingement, and thermal discharge resulting from the proposed EPU would not be significant. The Pennsylvania DEP will continue to

regulate the performance of the SSES cooling water system and surface and wastewater discharges through the NPDES permit and Pennsylvania Code designed to protect warm water fisheries. Furthermore, SSES transmission line corridor maintenance practices would not change upon implementation of the proposed EPU; thus, the staff concludes there would be no significant impacts to aquatic species associated with transmission line corridor maintenance.

Impacts on Terrestrial Biota

Potential impacts to terrestrial biota from the proposed EPU include impacts due to transmission line corridor maintenance and any planned new construction. The natural communities at SSES and in the surrounding areas consist of river floodplain forest, upland forest, marshes, and wetlands. The river floodplain forest at SSES is dominated by silver maple (*Acer saccharinum*), river birch (*Betula nigra*), and Northern red oak (*Quercus rubra*). The upland forest is dominated by Virginia pine (*Pinus virginiana*), sweet birch (*Betula lenta*), flowering dogwood (*Cornaceae cornus*), white oak (*Fagaceae quercus*), Northern red oak, black oak (*Q. velutina*), and yellow poplar (*Liriodendron tulipifera*). The marshes are dominated by a variety of emergent vegetation such as sedges (*Cyperaceae*), bulrush and cattail (*Typhaceae*), and cutgrass (*Poaceae*) (Reference 9). Although wetlands do occur at the SSES site, none of the wetlands would be affected by the proposed action.

As stated in the Cooling Tower Impacts section, no significant increase in noise is anticipated for cooling tower operation following the proposed EPU, and as such, biota would not be impacted. The staff agrees with the conclusions reached in the GEIS regarding bird collisions with cooling towers: Avian mortality due to collisions with cooling towers is considered to be of small significance if the losses do not destabilize local populations of any species and there is no noticeable impairment of its function with the local ecosystem (NRC 1996).

The proposed action would not involve new land disturbance outside of the existing power block or developed areas, and as discussed in the Transmission Facilities Impacts section, there would be no changes to transmission line corridor maintenance practices. Thus, the staff concludes that there would be no significant impacts to terrestrial species or their habitat associated with the proposed action, including transmission line right-of-way maintenance.

Impacts on Threatened and Endangered Species

Potential impacts to threatened and endangered species from the proposed action include the impacts assessed in the aquatic and terrestrial biota sections of this Environmental Assessment. These impacts include impingement, entrainment, thermal discharge effects, and impacts from transmission line right-of-way maintenance for aquatic and terrestrial species. A review of databases maintained by the U.S. Fish and Wildlife Service (FWS) and the Pennsylvania Natural Heritage Program indicate that several animal and plant species that are Federally or Commonwealth-listed as threatened or endangered occur in the vicinity of SSES and its associated transmission line corridors. Informal consultation with FWS Pennsylvania Field Office regarding the proposed EPU's potential impact on threatened or endangered species is ongoing.

Four species listed as threatened or endangered under the Endangered Species Act and 24 species that are listed by the Commonwealth of Pennsylvania as threatened or endangered occur within the counties where SSES and its associated transmission line corridors are located. These species are listed below in Table 1.

TABLE 1.—ENDANGERED AND THREATENED SPECIES THAT COULD OCCUR IN THE VICINITY OF SSES OR IN COUNTIES CROSSED BY SSES TRANSMISSION LINES

Scientific name	Common name	Federal status*	State status*
Mammals:			
Neotoma magister	Allegheny woodrat	—	T
Myotis sodalis	Indiana bat	E	E
Myotis leibii	Small-footed myotis	—	T
Sciurus niger	Eastern fox squirrel	—	T
Birds:			
Ardia alba	Great egret	—	E
Asio flammeus	Short-eared owl	—	E
Bartramia longicauda	Upland sandpiper	—	T
Botaurus lentiginosus	American bittern	—	E
Chlidonias niger	Black tern	—	E
Cistothorus platensis	Sedge wren	—	T
Falco peregrinus	Peregrine falcon	—	E
Haliaeetus leucocephalus	Bald eagle	T	E
Ixobrychus exilis	Least bittern	—	E
Pandion haliaetus	Osprey	—	T
Reptiles:			
Clemmys muhlenbergii	Bog Turtle	T	E
Invertebrates:			
Enodia anthedon	Northern peary-eye	—	VS
Euphydryas phaeton	Baltimore checkerspot	—	VS
Poanes massasoit	Mulberry wing	—	V
Polites mystic	Long dash	—	V
Speyeria idalia	Regal fritillary	—	E
Speyeria aphrodite	Aphrodite fritillary	—	VS

*T = Threatened, E = Endangered, V = Vulnerable, VS = Vulnerable to Apparently Secure
— = Not Listed

(*Sources:* References 3, 5, 6, 16).

The proposed EPU would involve no new land disturbance, and any construction necessary would be minimal and would only occur in previously developed areas of SSES. Additionally, no changes would be made to the transmission line corridor maintenance program, including vegetative maintenance. As such, the staff concludes that the proposed action would have no significant impact on Federally or Commonwealth-listed species in the vicinity of SSES and its transmission line corridors.

Social and Economic Impacts

Potential socioeconomic impacts due to the proposed EPU include changes in the payments in lieu of taxes for Luzerne County and changes in the size of the workforce at SSES. Currently SSES employs approximately 1,200 full-time staff, 89 percent of whom live in Luzerne or Columbia Counties, and approximately 260 contract employees. During outages, approximately 1,400 personnel provide additional support (Reference 9).

The proposed EPU is not expected to increase the size of the permanent SSES workforce, since proposed plant modifications would be phased in during planned outages when SSES has the support of 1,400 additional workers. In addition, the proposed EPU would not require an increase in the size of the SSES workforce during future refueling outages. Accordingly, the proposed EPU would not have any measurable effect on annual earnings and income in Luzerne and Columbia Counties or on community services (Reference 9).

According to the 2000 Census, Luzerne and Columbia County populations were about 2.9 and 2.0 percent minority, respectively, which is well below the Commonwealth minority population of 13.2 percent. The poverty rates in 1999 for individuals living in Luzerne and Columbia Counties are 11.1 percent and 13.1 percent, respectively, which are slightly higher than the Commonwealth's average of 11.0 percent. Due to the lack of significant environmental impacts resulting from the proposed action, the proposed EPU would not have any disproportionately high and adverse impacts to minority or low-income populations (Reference 9).

In the past, PPL paid real estate taxes to the Commonwealth of Pennsylvania for power generation, transmission, and distribution facilities. Under authority of the Pennsylvania Utility Realty Tax Act (PURTA), real estate taxes collected from all utilities (water, telephone, electric, and railroads) were redistributed to the taxing jurisdictions within the Commonwealth. In Pennsylvania, these jurisdictions include counties, cities, townships, boroughs, and school districts. The distribution of PURTA funds was determined by formula and was not necessarily based on the individual utility's effect on a particular government entity (Reference 9).

In 1996, Electricity Generation Customer Choice and Competition Act became law, which allows consumers to choose among competitive suppliers of electrical power. As a result of utility restructuring, Act 4 of 1999 revised the tax base assessment methodology for utilities from the depreciated book value to the market value of utility property. Additionally, as of January 1, 2000, PPL was required to begin paying real estate taxes directly to local jurisdictions, ceasing payments to the Commonwealth's PURTA fund. PPL currently pays annual real estate taxes to the Berwick Area School District, Luzerne County, and Salem Township (Reference 9).

The proposed EPU could increase SSES's value, thus resulting in a larger allocation of the payment to the Berwick Area School District, Luzerne County, and Salem Township. Because the proposed EPU would increase the economic viability of SSES, the probability of early plant retirement would be reduced. Early plant retirement would be expected to have negative impacts on the local economy and the community by reducing tax payments and limiting local employment opportunities for the long term (Reference 9).

Since the proposed EPU would not have any measurable effect on the annual earnings and income in Luzerne and Columbia Counties or on community services and due to the lack of significant environmental impacts on minority or low-income populations, there would be no significant socioeconomic or environmental justice impacts associated with the proposed EPU. Conversely, the proposed EPU could have a positive effect on the regional economy because of the potential increase in the tax payments received by the Berwick Area School District, Luzerne County, and Salem Township, due to the potential increase in the book value of SSES, and the increased long-term viability of SSES.

Summary

The proposed EPU would not result in a significant change in non-radiological impacts in the areas of land use, water use, cooling tower operation, terrestrial and aquatic biota, transmission facility operation, or social and economic factors. No other non-radiological impacts were identified or would be expected. Table 2 summarizes the non-radiological environmental impacts of the proposed EPU at SSES.

TABLE 2.—SUMMARY OF NON-RADIOLOGICAL ENVIRONMENTAL IMPACTS

Land Use	No significant land-use modifications.
Non-Radiological Waste	Any additional hazardous and non-hazardous waste as a result of the proposed EPU would continue to be regulated by RCRA and managed by SSES's waste management program.
Cooling Tower	Impacts associated with continued cooling tower operation following the proposed EPU, including noise, fogging, cloud cover, salt drift, and icing would not change significantly from current impacts.
Transmission Facilities	No physical modifications to transmission lines; lines meet electrical shock safety requirements; no changes to transmission line corridor maintenance; small increase in electrical current would cause small increase in electromagnetic field around transmission lines; no changes to voltage.
Water Use	No configuration change to intake structure; increase in cooling water flow rate; increase in consumptive use due to evaporation; SRBC would continue to regulate consumptive water usage at SSES.
Discharge	Small increase in discharge temperature and volume; no increases in other effluents; discharge would remain within Pennsylvania water quality limits, and SSES would continue to operate under NPDES permit regulations.
Aquatic Biota	Small increases in entrainment and impingement are not expected to affect the Susquehanna River aquatic biota; increase in volume and temperature of thermal discharge would remain within original FES guidelines and below Pennsylvania Code Section 93.7 temperature limits; SSES would continue to operate under NPDES permit regulations with regard to entrainment and impingement.
Terrestrial Biota	No land disturbance or changes to transmission line corridor maintenance are expected; therefore, there would be no significant effects on terrestrial species or their habitat.

TABLE 2.—SUMMARY OF NON-RADIOLOGICAL ENVIRONMENTAL IMPACTS—Continued

Threatened and Endangered Species	As evaluated for aquatic and terrestrial biota, no significant impacts are expected on protected species or their habitat.
Social and Economic	No change in size of SSES labor force required for plant operation or for planned outages; proposed EPU could increase payments to Luzerne County and book value of SSES; there would be no disproportionately high and adverse impact on minority and low-income populations.

Radiological Impacts

Radioactive Waste Stream Impacts

SSES uses waste treatment systems designed to collect, process, and dispose of gaseous, liquid, and solid wastes that might contain radioactive material in a safe and controlled manner such that the discharges are in accordance with the requirements of Title 10 of the Code of Federal Regulations (10 CFR) part 20, and the design objectives of Appendix I to 10 CFR part 50 (Reference 9).

Minimal changes will be made to the waste treatment systems to handle the additional waste expected to be generated by the proposed EPU; the installation of an additional condensate filter and demineralizer. The gaseous, liquid, and solid radioactive wastes are discussed individually (Reference 9).

Gaseous Radioactive Waste and Offsite Doses

During normal operation, the gaseous effluent treatment system processes and controls the release of small quantities of radioactive noble gases, halogens, tritium, and particulate materials to the environment. The gaseous waste management system includes the offgas system and various building ventilation systems. The single year highest annual releases of radioactive material, for the time period 2000–2005 were; 2002 for noble gases with 9.68 Curies, 2001 for particulates and iodines with 0.0074 Curies, and 2004 for tritium with 160 Curies (Reference 9).

The licensee has estimated that the amount of radioactive material released in gaseous effluents would increase in proportion to the increase in power level (20 percent) (Reference 9). Based on experience from EPUs at other plants, the staff concludes that this is an acceptable estimate. The offsite dose to a member of the public, including the additional radioactive material that would be released from the proposed EPU, is calculated to still be well within the radiation standards of 10 CFR part 20 and the design objectives of Appendix I to 10 CFR part 50. Therefore, the staff concludes the increase in offsite dose due to gaseous effluent release following implementation of the proposed EPU would not be significant.

Liquid Radioactive Waste and Offsite Doses

During normal operation, the liquid effluent treatment system processes and controls the release of radioactive liquid effluents to the environment, such that the dose to individuals offsite are maintained within the limits of 10 CFR part 20 and the design objectives of Appendix I to 10 CFR part 50. The liquid radioactive waste system is designed to process and purify the waste and then recycle it for use within the plant, or to discharge it to the environment as radioactive liquid waste effluent in accordance with facility procedures which comply with Commonwealth of Pennsylvania and Federal regulations. The single year highest radioactive liquid releases, for the time period 2000–2005 were: 2005 at 1,470,000 gallons, 2003 with 70.25 Curies of tritium, 2000 with 36.95 Curies of fission and activation products, and 2002 with 0.0003 Curies of dissolved and entrained gases (Reference 9).

Even though the EPU would produce a larger amount of radioactive fission and activation products and a larger volume of liquid to be processed, the licensee performed an evaluation which shows that the liquid radwaste treatment system would remove all but a small amount of the increased radioactive material. The licensee estimated that the volume of radioactive liquid effluents released to the environment and the amount of radioactive material in the liquid effluents would increase slightly (less than 1 percent) due to the proposed EPU. Based on experience from EPUs at other plants, the staff concludes that this is an acceptable estimate. The dose to a member of the public from the radioactive releases described above, increased by 1 percent, would still be well within the radiation standards of 10 CFR part 20 and the design objectives of Appendix I to 10 CFR part 50. Therefore, the staff concludes that there would not be a significant environmental impact from the additional amount of radioactive material generated following implementation of the proposed EPU.

Solid Radioactive Wastes

The solid radioactive waste system collects, processes, packages, and temporarily stores radioactive dry and wet solid wastes prior to shipment offsite for permanent disposal. The volume of solid radioactive waste generated varied from about 2500 to almost 8000 cubic feet (ft^3) per year in the time period 2000–2005; the largest volume generated was 7980 ft^3 in 2003. The annual amount of radioactive material in the waste generated varied from 2500 to almost 190,000 Curies during that same period. The largest amount of radioactive material generated in the solid waste was 189,995 Curies in 2000 (Reference 9).

The proposed EPU would produce a larger amount of radioactive fission and activation products which would require more frequent replacement or regeneration of radwaste treatment system filters and demineralizer resins. The licensee has estimated that the volume of solid radioactive waste would increase by approximately 11 percent due to the proposed EPU (Reference 9). Based on experience from EPUs at other plants, the staff concludes that this is an acceptable estimate. The increased volume of the solid waste would still be bounded by the estimate of 10,400 ft^3 in the 1981 FES for operation. Therefore, the staff concludes that the impact from the increased volume of solid radwaste generated due to the proposed EPU would not be significant.

The licensee did not provide an estimate of the increase in the amount of radioactive solid waste in terms of Curies. However, for 4 of the 6 years between 2000 and 2005, the annual amount of radioactive material in the solid waste generated varied from 2500 to 5779 Curies (Reference 9). Based on experience from EPUs at other plants, the staff estimated that the amount of radioactive material in the solid waste would increase by 20 percent, proportional to the proposed EPU power increase. In 2000 and 2003, work was done that generated large amounts of used irradiated components, accounting for 98 percent and 92 percent, respectively, of the radioactive material generated in solid radwaste. Such work and the solid radwaste generated by that work occasionally occurs at SSES, but the range of 2500 to 5779 Curies is more

typical (Reference 9). The annual average of radioactive material generated after the proposed EPU would still be bounded by the estimate of 5500 Curies in the 1981 FES for operation. In addition, the licensee must continue to meet all NRC and Department of Transportation regulations for transportation of solid radioactive waste. Therefore, the staff concludes that the impact from the increased amount of radioactive material in the solid radwaste due to the proposed EPU would not be significant.

The licensee estimates that the EPU would require replacement of 10 percent more fuel assemblies at each refueling. This increase in the amount of spent fuel being generated would require an increase in the number of dry fuel storage casks used to store spent fuel. The current dry fuel storage facility at SSES has been evaluated and can accommodate the increase (Reference 9). Therefore, the staff concludes that there would be no significant environmental impacts resulting from storage of the additional fuel assemblies.

In-Plant Radiation Doses

The proposed EPU would result in the production of more radioactive material and higher radiation dose rates in the restricted areas at SSES. SSES's radiation protection staff will continue monitoring dose rates and would make adjustments in shielding, access requirements, decontamination methods, and procedures as necessary to minimize the dose to workers. In addition, occupational dose to individual workers must be maintained within the limits of 10 CFR part 20 and as low as reasonably achievable (Reference 9).

The licensee has estimated that the work necessary to implement the proposed EPU at the plant would also increase the collective occupational radiation dose at the plant to approximately 230 person-rem per year until the implementation is completed in 2009. After the implementation is completed, the licensee estimates that the annual collective occupational dose would be in the range of 200 person-rem, roughly 12 percent higher than the current dose of 182 person-rem in 2005 and 184 person-rem in 2006 (Reference 9). Based on experience from EPUs at other plants, the staff concludes that these estimates are acceptable. The staff notes that SSES is allowed a maximum of 3,200 person-rem per year as provided in the 1981 Final Environmental Statement—Operating Stage. Therefore, the staff concludes that the increase in occupational exposure would not be significant.

Direct Radiation Doses Offsite

Offsite radiation dose consists of three components: Gaseous, liquid, and direct gamma radiation. As previously discussed under the Gaseous Radiological Waste and Liquid Radiological Waste sections, the estimated doses to a member of the public from radioactive gaseous and liquid effluents after the proposed EPU is implemented, would be well within the dose limits of 10 CFR part 20 and the design objectives of Appendix I to 10 CFR part 50.

The final component of offsite dose is from direct gamma radiation from radioactive waste stored temporarily onsite, including spent fuel in dry cask storage, and radionuclides (mainly nitrogen-16) in the steam from the reactor passing through the turbine system. The high energy radiation from nitrogen-16 is scattered or reflected by the air above the facility and represents an additional public radiation dose pathway known as "skyshine." The licensee estimated that the offsite radiation dose from skyshine would increase linearly with the increase in power level from the proposed EPU (20 percent); more nitrogen-16 is produced at the higher EPU power, and less of the nitrogen-16 decays before it reaches the turbine system because of the higher rate of steam flow due to the EPU. The licensee's radiological environmental monitoring program measures radiation dose at the site boundary and in the area around the facility with an array of thermoluminescent dosimeters. The licensee reported doses ranging from 0.2 to 1.3 mrem per year for the time period 2000–2005. The licensee estimated that the dose would increase approximately in proportion to the EPU power increase (20 percent) (Reference 9). Based on experience from EPUs at other plants, the staff concludes that this is an acceptable estimate. EPA regulation 40 CFR part 190 and NRC regulation 10 CFR part 20 limit the annual dose to any member of the public to 25 mrem to the whole body from the nuclear fuel cycle. The offsite dose from all sources, including radioactive gaseous and liquid effluents and direct radiation, would still be well within this limit after the proposed EPU is implemented. Therefore, the staff concludes that the increase in offsite radiation dose would not be significant.

Postulated Accident Doses

As a result of implementation of the proposed EPU, there would be an increase in the inventory of radionuclides in the reactor core; the core inventory of radionuclides would increase as power level increases. The concentration of radionuclides in the reactor coolant may also increase; however, this concentration is limited by the SSES Technical Specifications. Therefore, the reactor coolant concentration of radionuclides would not be expected to increase significantly. Some of the radioactive waste streams and storage systems may also contain slightly higher quantities of radioactive material. The calculated doses from design basis postulated accidents for SSES are currently well below the criteria of 10 CFR 50.67; this was confirmed by the NRC staff in the Safety Evaluation Report supporting a license amendment for SSES dated January 31, 2007. The licensee has estimated that the radiological consequences of postulated accidents would increase approximately in proportion to the increase in power level from the proposed EPU (20 percent) (Reference 9). Based on experience from EPUs at other plants, the NRC staff concludes that this is an acceptable estimate. The calculated doses from design basis postulated accidents are based on conservative assumption and would still be well within the criteria of 10 CFR 50.67 after the increase due to the implementation of the proposed EPU.

The staff has reviewed the licensee's analyses and performed confirmatory calculations to verify the acceptability of the licensee's calculated doses under accident conditions. The staff's independent review of dose calculations under postulated accident conditions determined that dose would be within regulatory limits. Therefore, the staff concludes that the EPU would not significantly increase the consequences of accidents and would not result in a significant increase in the radiological environmental impact of SSES 1 and 2 from postulated accidents.

Fuel Cycle and Transportation Impacts

Tables S–3 and S–4 in 10 CFR part 51 specify the environmental impacts due to the uranium fuel cycle and transportation of fuel and wastes, respectively. SSES's EPU would increase the power level to 3952 mega-watt thermal (Mwt), which is 3.3 percent above the reference power level for Table S–4. The increased power level of 3952 Mwt corresponds to 1300 mega-watt electric (Mwe), which is 30 percent above the reference power level for Table S–3. Part of the increase is due to a more efficient turbine design; this increase in efficiency does not affect the impacts of the fuel cycle and transportation of wastes. However, more fuel will be used in the reactor (more

fuel assemblies will be replaced at each refueling outage), and that will potentially affect the impacts of the fuel cycle and transportation of wastes. The fuel enrichment and burn-up rate criteria of Tables S–3 and S–4 will still be met because fuel enrichment will be maintained no greater than 5 percent, and the fuel burn-up rate will be maintained within 60 giga-watt-days/metric ton uranium (Gwd/MTU). The staff concludes that after adjusting for the effects of the more efficient turbine, the potential increases in the impact due to the uranium fuel cycle and the transportation of fuel and wastes from the larger amount of fuel used would be small and would not be significant.

Summary

Based on staff review of licensee submissions and the 1981 FES for operation, it is concluded that the proposed EPU would not significantly increase the consequences of accidents, would not result in a significant increase in occupational or public radiation exposure, and would not result in significant additional fuel cycle environmental impacts. Accordingly, the staff concludes that there would be no significant radiological environmental impacts associated with the proposed action. Table 3 summarizes the radiological environmental impacts of the proposed EPU at SSES.

TABLE 3.—SUMMARY OF RADIOLOGICAL ENVIRONMENTAL IMPACTS

Gaseous Radiological Effluents	Increased gaseous effluents (20 percent) would remain within NRC limits and dose design objectives.
Liquid Radiological Effluents	Increased liquid effluents (1 percent) would remain within NRC limits and dose design objectives.
Solid Radioactive Waste	Increased amount of solid radioactive waste generated (11 percent by volume and 20 percent by radioactivity) would remain bounded by evaluation in the FES.
Occupational Radiation Doses	Occupational dose would increase by approximately 20 percent. Doses would be maintained within NRC limits and as low as is reasonably achievable.
Offsite Radiation Doses	Radiation doses to members of the public would continue to be very small, well within NRC and EPA regulations.
Postulated Accident Doses	Calculated doses for postulated design basis accidents would remain within NRC limits.
Fuel Cycle and Transportation Impacts	Fuel enrichment and burn-up rate criteria of Tables S–3 and S–4 are met because fuel enrichment will be maintained no greater than 5 percent, and the fuel burn-up rate will be maintained within 60 Gwd/MTU. After adjusting for the effects of the more efficient turbine, the potential increases in impacts due to the fuel cycle and transportation of fuel and wastes would not be significant.

Alternatives to Proposed Action

As an alternative to the proposed action, the staff considered denial of the proposed EPU (i.e., the □no-action" alternative). Denial of the application would result in no change in the current environmental impacts. However, if the proposed EPU were not approved, other agencies and electric power organizations may be required to pursue alternative means of providing electric generation capacity to offset the increased power demand forecasted for the PJM regional transmission territory.

A reasonable alternative to the proposed EPU would be to purchase power from other generators in the PJM network. In 2003, generating capacity in PJM consisted primarily of fossil fuel-fired generators: coal generated 36.2 percent of PJM capacity, oil 14.3 percent, and natural gas 6.8 percent (Reference 10). This indicates that purchased power in the PJM territory would likely be generated by a fossil-fuel-fired facility. Construction (if new generation is needed) and operation of a fossil fuel plant would create impacts in air quality, land use, and waste management significantly greater than those identified for the proposed EPU at SSES. SSES's nuclear units do not emit sulfur dioxide, nitrogen oxides, carbon dioxide, or other atmospheric pollutants that are commonly associated with fossil fuel plants. Conservation programs such as demand-side management could feasibly replace the proposed EPU's additional power output. However, forecasted future energy demand in the PJM territory may exceed conservation savings and still require additional generating capacity (Reference 9). The proposed EPU does not involve environmental impacts that are significantly different from those originally identified in the 1981 SSES FES for operation.

Alternative Use of Resources

This action does not involve the use of any resources not previously considered in the original FES for construction.

Agencies and Persons Consulted

In accordance with its stated policy, on July 2, 2007, the staff consulted with the Pennsylvania State official, Brad Fuller, of the Pennsylvania Department of Environmental Protection, regarding the environmental impact of the proposed action. The State official had no comments.

Finding of No Significant Impact

On the basis of the Environmental Assessment, the Commission concludes that the proposed action would not have a significant effect on the quality of the human environment. Accordingly, the Commission has determined not to prepare an environmental impact statement for the proposed action.

For further details with respect to the proposed action, see the licensee's application dated October 11, 2006, as supplemented by letters dated October 25, December 4 and 26, 2006, February 13, March 14 and 22, April 13, 17, 23, 26, and 27, May 3, 9, 14, and 21, June 1, 4, 8, 14, 20, and 27, July 6, 12, 13, 30, 31, and August 3, 13, 15, 28, and October 5, 2007 (Agencywide Documents Access and Management System (ADAMS) Accession Nos. ML062900160, ML062900161, ML062900162, ML062900306, ML062900361, ML062900401, ML062900405, ML063120119, ML063460354, ML070040376, ML070610371, ML070860229, ML070890411, ML071150113, ML071150043, ML071240196, ML071700104, ML071280506, ML071300266, ML071360026, ML071360036, ML071360041, ML071420064, ML071420047, ML071500058, ML071500300, ML071620218, ML071620311, ML071620299, ML071620342, ML071620256, ML071700096, ML071710442, ML071780629, ML071860142, ML071860421, ML071870449, ML071730404, ML072010019, ML072060040, ML072060588, ML072200103, ML07220477, ML072220482, ML072220485, ML072220490, ML072280247, ML072340597, ML072340603, ML072480182, and ML072900642 respectively). Documents may be examined, and/or copied for a fee, at the NRC's Public Document Room (PDR), located at One White Flint

North, Public File Area O–1F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible electronically from the Agencywide Documents Access and Management System (ADAMS) Public Electronic Reading Room on the NRC Web site, *http://www.nrc.gov/reading-rm/adams.html*. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC PDR Reference staff at 1–800–397–4209, or 301–415–4737, or send an e-mail to *pdr@nrc.gov*.

Dated at Rockville, Maryland, this 15th day of August 2007.

For The Nuclear Regulatory Commission.

Richard V. Guzman,

Senior Project Manager, Plant Licensing Branch I–1, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

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[FR Doc. E7–23537 Filed 12–4–07; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF MANAGEMENT AND BUDGET

Information Collection; Request for Public Comments

AGENCY: Office of Management and Budget, Executive Office of the President.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*), the Office of Management and Budget (OMB) invites the general public and Federal agencies to comment on a renewal of an information collection with revisions that would affect two types of entities: (1) The reports of auditors to auditees concerning audit results, audit findings, and questioned costs, and (2) reports from auditees to the Federal Government providing information about the auditees, the awards they administer, and the audit results. These collection efforts are required by the Single Audit Act Amendments of 1996 (31 U.S.C. 7501, *et seq.*) and OMB Circular A–133, "Audits of States, Local Governments, and Non-Profit Organizations."

Included as part of this information collection is the Data Collection Form (SF–SAC). The changes being proposed are to modify the data elements collected on the SF–SAC to update the internal control terminology and related definitions used in OMB Circular A–133, "Audits of States, Local Governments, and Non-Profit Organizations," the American Institute of Certified Public Accountants and the Government Accountability Office. The current Form SF–SAC is being used for audit periods ending in 2004, 2005, 2006 and 2007. A revised Form SF–SAC will be used for audit periods ending in 2008, 2009, and 2010.

Additionally, OMB is interested in receiving comments on the requirement to submit the Data Collection Form (SF–SAC) and the single audit reporting packages electronically. Currently, more than 87% of the SF–SAC are filed electronically. Electronic submission would streamline the submission process, reduce the administrative burden and satisfy the Bureau of Census to fully comply with the Government Paperwork Elimination Act (Pub. L. 105–277).

DATES: Submit comments on or before February 4, 2008. Late comments will be considered to the extent practicable.

ADDRESSES: Due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, we

encourage respondents to submit comments electronically to ensure timely receipt. We cannot guarantee that comments mailed will be received before the comment closing date.

Electronic mail comments may be submitted to: Gilbert Tran at *hai__m.__tran@omb.eop.gov.* Please include "Form SF–SAC Comments" in the subject line and the full body of your comments in the text of the electronic message and not as an attachment. Please include your name, title, organization, postal address, telephone number, and e-mail address in the text of the message. Comments may also be submitted via facsimile to 202–395–3952.

Comments may be mailed to Gilbert Tran, Office of Federal Financial Management, Office of Management and Budget, Room 6025, New Executive Office Building, Washington, DC 20503.

Comments: All responses will be summarized and included in the request for OMB approval. All comments will also be a matter of public record.

FOR FURTHER INFORMATION CONTACT: Gilbert Tran, Office of Federal Financial Management, Office of Management and Budget, (202) 395–3052. The proposed revisions to the Information Collection Form, Form SF–SAC can be obtained by contacting the Office of Federal Financial Management as indicated above or by download from the OMB Grants Management home page on the Internet at *http://www.whitehouse.gov/OMB/grants/grants_docs.html.*

SUPPLEMENTARY INFORMATION:

OMB Control No.: 0348–0057.

Title: Data Collection Form.

Form No: SF–SAC.

Type of Review: Reinstatement with change.

Respondents: States, local governments, non-profit organizations (Non-Federal entities) and their auditors.

Estimated Number of Respondents: 72,000 (36,000 from auditors and 36,000 from auditees). The respondents' information is collected by the Federal Audit Clearinghouse (maintained by the U.S. Bureau of the Census).

Estimated Time per Respondent: 59 hours for each of 400 large respondents and 17 hours for each of 71,600 small respondents for estimated annual burden hours of 1,240,800.

Estimated Number of Responses per Respondent: 1.

Frequency of Response: Annually.

Needs and Uses: Reports from auditors to auditees and reports from auditees to the Federal government are used by non-Federal entities, pass-through entities, and Federal agencies to ensure that Federal awards are expended in accordance with applicable laws and regulations. The Federal Audit Clearinghouse (FAC) (maintained by the U.S. Bureau of the Census) uses the information on the SF–SAC to ensure proper distribution of audit reports to Federal agencies and identify non-Federal entities who have not filed the required reports. The FAC also uses the information on the SF–SAC to create a government-wide database which contains information on audit results. This database is publicly accessible on the Internet at *http://harvester.census.gov/sac/.* It is used by Federal agencies, pass-through entities, non-Federal entities, auditors, the Government Accountability Office, OMB, and the general public for management of and information about Federal awards and the results of audits. Comments are invited on: (a) Whether the proposed information collection is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the estimate of the burden of the collection of the information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who respond, including through the use of automated collection techniques or other forms of information technology.

Danny Werfel,

Acting Controller.

[FR Doc. E7–23540 Filed 12–4–07; 8:45 am]

BILLING CODE 3110–01–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

[Docket No. WTO/DS–365; WTO/DS–357]

WTO Dispute Settlement Proceedings Regarding U.S. Domestic Support for Agricultural Products

AGENCY: Office of the United States Trade Representative.

ACTION: Notice; request for comments.

SUMMARY: The Office of the United States Trade Representative ("USTR") is providing notice that on November 8, 2007, Brazil requested the establishment of a dispute settlement panel under the Marrakesh Agreement Establishing the World Trade Organization ("WTO Agreement") regarding U.S. domestic support measures for agricultural products. That request may be found at *http://www.wto.org* contained in a document designated as WT/DS365/13. USTR is also providing notice that on the same date, Canada made a revised request for the establishment of a dispute settlement panel under the WTO Agreement in a similar dispute. Canada's request may be found at *http://www.wto.org* contained in a document designated as WT/DS357/12. USTR invites written comments from the public concerning the issues raised in these disputes.

DATES: Although USTR will accept any comments received during the course of the consultations, comments should be submitted on or before February 1, 2008 to be assured of timely consideration by USTR.

ADDRESSES: Comments should be submitted (i) electronically, to *FR0705@ustr.eop.gov,* with "Agricultural Subsidies (DS357 and 365)" in the subject line, or (ii) by fax, to Sandy McKinzy at (202) 395–3640. For documents sent by fax, USTR requests that the submitter provide a confirmation copy to the electronic mail address listed above.

FOR FURTHER INFORMATION CONTACT: David Yocis, Assistant General Counsel, Office of the United States Trade Representative, 600 17th Street, NW., Washington, DC., (202) 395–6150.

SUPPLEMENTARY INFORMATION: Section 127(b) of the Uruguay Round Agreements Act (URAA) (19 U.S.C. 3537(b)(1)) requires that notice and opportunity for comment be provided after the United States submits or receives a request for the establishment of a WTO dispute settlement panel. Consistent with this obligation, USTR is providing notice that the establishment of a dispute settlement panel has been requested pursuant to the WTO *Understanding on Rules and Procedures Governing the Settlement of Disputes* ("DSU") in each of these disputes. If such a panel is established pursuant to the DSU, such panel, which would hold its meetings in Geneva, Switzerland, would be expected to issue a report on its findings and recommendations within nine months after it is established.

Major Issues Raised

In the requests for the establishment of a panel, Brazil and Canada allege that the United States has provided support to domestic agricultural producers in excess of U.S. commitments with respect to the Aggregate Measurement of Support ("AMS") as described in Article 6.2 of the WTO *Agreement on Agriculture* and the U.S. WTO schedule of commitments. According to Brazil and Canada, the United States has provided domestic support in excess of its AMS commitments in each of the

years 1999, 2000, 2001, 2002, 2004, and 2005, in breach of Article 3.2 of the WTO *Agreement on Agriculture*. The revised request for the establishment of a panel submitted by Canada supersedes Canada's prior request for the establishment of a panel from Canada (see 72 FR 39,467 (July 18, 2007)), which Canada has withdrawn.

Public Comment: Requirements for Submissions

Interested persons are invited to submit written comments concerning the issues raised in the disputes. Comments should be submitted (i) electronically, to *FR0705@ustr.eop.gov*, with "Agricultural Subsidies (DS357 and 365)" in the subject line, or (ii) by fax, to Sandy McKinzy at (202) 395–3640. For documents sent by fax, USTR requests that the submitter provide a confirmation copy to the electronic mail address listed above.

USTR encourages the submission of documents in Adobe PDF format as attachments to an electronic mail. Interested persons who make submissions by electronic mail should not provide separate cover letters; information that might appear in a cover letter should be included in the submission itself. Similarly, to the extent possible, any attachments to the submission should be included in the same file as the submission itself, and not as separate files.

Comments must be in English. A person requesting that information contained in a comment submitted by that person be treated as confidential business information must certify that such information is business confidential and would not customarily be released to the public by the submitter. Confidential business information must be clearly designated as such and the submission must be marked "Business Confidential" at the top and bottom of the cover page and each succeeding page.

Information or advice contained in a comment submitted, other than business confidential information, may be determined by USTR to be confidential in accordance with section 135(g)(2) of the Trade Act of 1974 (19 U.S.C. 2155(g)(2)). If the submitter believes that information or advice may qualify as such, the submitter—

(1) Must clearly so designate the information or advice;

(2) Must clearly mark the material as "Submitted in Confidence" at the top and bottom of the cover page and each succeeding page; and

(3) Is encouraged to provide a non-confidential summary of the information or advice.

Pursuant to section 127(e) of the URAA (19 U.S.C. 3537(e)), USTR will maintain a file on these dispute settlement proceedings, accessible to the public, in the USTR Reading Room, which is located at 1724 F Street, NW., Washington, DC 20508. The public file will include non-confidential comments received by USTR from the public with respect to the disputes; if a dispute settlement panel is convened or in the event of an appeal from such a panel, the U.S. submissions, the submissions, or non-confidential summaries of submissions, received from other participants in the dispute; the report of the panel; and, if applicable, the report of the Appellate Body. An appointment to review the public file (Docket WTO/DS–357 and DS–365, Ag Subsidies Disputes) may be made by calling the USTR Reading Room at (202) 395–6186. The USTR Reading Room is open to the public from 9:30 a.m. to noon and 1 p.m. to 4 p.m., Monday through Friday.

Daniel Brinza,

Assistant United States Trade Representative for Monitoring and Enforcement.

[FR Doc. E7–23575 Filed 12–4–07; 8:45 am]

BILLING CODE 3190–W8–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94–409, that the Securities and Exchange Commission will hold the following meeting during the week of December 3, 2007:

A Closed Meeting will be held on Thursday, December 6, 2007 at 2 p.m.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the Closed Meeting. Certain staff members who have an interest in the matters may also be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (4), (5), (7), (8), (9)(B), and (10) and 17 CFR 200.402(a)(3), (4), (5), (7), (8), 9(ii) and (10), permit consideration of the scheduled matters at the Closed Meeting.

Commissioner Casey, as duty officer, voted to consider the items listed for the closed meeting in closed session and determined that no earlier notice thereof was possible.

The subject matter of the Closed Meeting scheduled for Thursday, December 6, 2007 will be:

Formal orders of investigation;

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings of an enforcement nature;

Regulatory matters regarding financial institutions; and a

Matter involving enforcement techniques.

At times, changes in Commission priorities require alterations in the scheduling of meeting items.

For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact:

The Office of the Secretary at (202) 551–5400.

Dated: November 30, 2007.

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–23602 Filed 12–4–07; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–56855; File No. SR–CBOE–2006–90]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Order Approving Proposed Rule Change as Modified by Amendment No. 1 Thereto to List and Trade Delayed Start Option Series

November 28, 2007.

I. Introduction

On November 7, 2006, the Chicago Board Options Exchange, Incorporated ("CBOE" 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 list and trade Delayed Start Option Series™ ("DSOs") on any security index that has been approved for trading on the Exchange. On September 5, 2007, the Exchange filed Amendment No. 1 to the proposed rule change. The proposed rule change, as amended, was published for comment in the **Federal Register** on September 17, 2007.[3] The Commission received no comments on the proposal. This order approves the proposed rule change, as amended, and designates

[1] 15 U.S.C. 78s(b)(l).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 56378 (September 10, 2007), 72 FR 52944 (September 17, 2007) ("Notice").

DSOs as "standardized options" pursuant to Rule 9b–1 under the Act.[4]

II. Description of the Proposal

The Exchange is proposing to introduce for trading a new type of security index option product called DSOs. DSOs would possess all of the characteristics of existing index options with one variation: at the commencement of trading of a particular DSO, and until a predetermined date (the "strike setting date"), there would be no set exercise price. Instead, prior to the opening of a particular DSO series, a pre-established methodology would be applied to determine the strike price of the DSO, and the strike price would then be fixed on the strike setting date according to that formula. The Exchange notes that DSOs, which address the dependence of an index option's vega (volatility exposure) on the relationship between the option's strike price and the underlying index level, are designed as a tool to allow customers to manage risk associated with the volatility of a particular index.[5]

Product Description. DSOs would be identical to other option series that currently trade except that the exercise price for a DSO would be fixed based on the closing value of the underlying index on a predetermined strike setting date prior to expiration. The particular strike setting date would be specified at the time the DSO is initially opened for trading and would be no sooner than one month, and no later than twelve months, after the series' opening. The particular expiration date would also be specified at the time the DSO is initially opened for trading and would be no later than what is currently permitted under CBOE rules.[6]

Initially, CBOE proposes to establish the strike setting dates for all series of DSOs at three months prior to the option's expiration date. However, as proposed, CBOE would have the ability to issue series of DSOs with more or less time than three months between the strike setting date and expiration date. Accordingly, the particular strike setting date and the expiration date, and thus the corresponding length of the interval between the strike setting date and expiration, would be set prior to issuance of each particular series. No changes to any terms of an existing DSO series could be made once a series commences trading.

Establishment of Strike Price. On the strike setting date, the DSO would be assigned a strike price, which would be at-the-money, in-the-money, or out-of-the-money, according to the pre-established terms of the particular DSO series. A DSO's exercise price would be fixed based on the closing value of the underlying index on the strike setting date, rounded to the nearest one-eighth (.125) value, or such smaller value as the Exchange may designate at the time the DSO is listed, provided that the value cannot be smaller than 0.01.[7] For example, using a one-eighth interval, if the S&P 500® Index ("SPX") closes at 1004.12 on the strike setting date, an at-the-money DSO would be assigned a strike price of 1004.125. After the strike setting date, the DSO would trade the same as other options until expiration.

An in- or out-of-the money DSO would trade in the exact same manner as an at-the-money DSO, except that the strike price would be set to a predetermined level either in- or out-of-the-money on the strike setting date (*e.g.*, 5% in-the-money, or 5% out-of-the-money). For example, if the Exchange determines to list a 5% out-of-the-money DSO on the SPX, and the SPX closes at 1000 on the strike setting date, the strike price would be established at 1050. The amount by which the strike price of an in- or out-of-the money DSO series would be set in- or out-of-the-money on the strike setting date would be announced prior to the inception of trading of that particular series and could not change thereafter.

Exercise Style. All DSOs would feature European-style exercise until the strike setting date (*i.e.*, the option contract could not be exercised during this period). After the strike setting date, the DSO would be subject to the exercise style (*i.e.*, American or European) of the particular index option class. The period during which exercise is restricted would therefore depend upon the particular DSO's strike setting date, expiration date, and expiration style. For instance, in the case of a DSO that is subject to American-style exercise, is issued with a nine-month expiration, and has a strike setting date fixed at three-months prior to expiration, then the period of non-exercise would be six months.[8]

Trading Increments, Margin, and Trading Symbols. The Exchange proposes to list DSO puts to correspond with each DSO call in a particular index option class. As with all other options, the premium quotation would be stated in decimals, and one point would equal $100. The minimum tick for options trading below $3.00 would be 0.05 ($5.00) and for all other series, 0.10 ($10.00).

DSOs in any particular index option class would be treated the same as any other options on the same index for the purpose of determining customer margin.[9] Therefore, a buyer of DSOs would have to pay the premium in full, while a seller would have to put up the entire premium, plus 15% of the underlying value for a broad-based index option, or the premium plus 20% for a narrow-based or micro narrow-based index option.

Prior to the strike setting date, margin on any DSO would be based on the then-current level of the underlying index. For example, a DSO whose strike price would be set at-the-money would be margined as an at-the-money option in the same index option class prior to the strike setting date, because prior to the strike setting date the DSO's price would be directly related to the price of an at-the-money option. Prior to the strike setting date, in- and out-of-the-money DSOs would be margined the same as any other in- and out-of-the-money options in the same index option class.

Prior to the strike setting date, DSOs would be distinguished from existing options by a unique root symbol and a special strike price code designating an at-the-money, in-the-money, or out-of-the-money option. The Exchange intends to trade the DSO series under separate symbols from other option series on the same index option class. The exact exercise price, and a unique DSO strike price code, would be fixed on the strike setting date pursuant to the method established at the time the

[4] 17 CFR 240.9b–1.

[5] *See* Notice, *supra* note 3, at 52945.

[6] Presently, the longest term for an option series expiration is thirty-nine months from the listing date. *See* CBOE Rule 5.8(a) and proposed CBOE Rule 24.9(d)(2).

[7] Because of system limitations, the Exchange currently plans to round DSO exercise prices to the nearest .125. However, should the system functionality permit it in the future, the Exchange wants the flexibility to be able to determine to round DSO exercise prices to a smaller value, provided that the particular increment would be designated at the time the DSO is listed and that it would not be any smaller than 0.01.

[8] Similarly, a DSO that is subject to European-style exercise with a nine-month expiration and a strike setting date fixed at three months prior to expiration would have a nine-month period of non-exercisability. The strike setting interval would be publicly announced prior to the inception of trading of a particular DSO series. No changes to any terms of existing DSO series could be made once the series trades (with the exception of the establishment of the exercise price).

[9] See CBOE Rule 12.3. However, the Exchange does not initially plan to permit spread margining between DSO and non-DSO options for the time period between the initial listing of a DSO and its strike setting date. The Exchange intends to consider what spread margin would be appropriate and address the subject under a separate rule filing.

option series was originally opened for trading. The strike price code would specify the exact strike price of the particular DSO option series (rounded to the nearest eighth or smaller increment, if applicable).

Position and Exercise Limits. Positions in any DSO would be subject to the same rules governing position and exercise limits upon other options in the same index option class and, for purposes of determining position limits, DSO positions would be aggregated with positions in other series of the same option class.[10] Similarly, members and member organizations trading in DSOs would continue to be subject to the same reporting requirements and margin and clearing firm requirements as provided under Interpretations and Policies .03 and .04 to CBOE Rule 24.4.

Pricing of a DSO. Similar to other index options, the pricing of an at-the-money DSO, for example, would reflect the price of the underlying index, implied volatility, interest rates, time to expiration, and strike price. Therefore, the price for a DSO would generally approximate the concurrent price for a similar option, with one significant deviation: whereas other options are priced based on current levels of implied volatility, a DSO is priced using an expectation of implied volatility levels at the time the strike price is set, which is generally derived from the current level of implied volatility. The dependence of a particular DSO's price on expected implied volatility is what the Exchange believes would make DSOs useful to market participants that are interested in volatility trading.

Customer Suitability. Although the Exchange believes that DSOs may be suitable for all types of investors, the Exchange has proposed to limit the trading of DSOs to investors with prior options trading experience.[11] Also, prior to the commencement of trading of DSOs, the Exchange would make available on its Web site all information necessary to inform members and customers of the addition of new DSO series to a particular option class.

Surveillance. The Exchange represents that it has in place appropriate surveillance procedures to monitor trading activity in DSOs and intends to monitor trading activity in DSOs like any other option series listed in that same index option class.[12]

III. Discussion and Commission Findings

The Commission has carefully reviewed the proposed rule change and finds that it is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[13] In particular, the Commission finds that the proposed rule change is consistent with section 6(b)(5) of the Act,[14] which, among other things, requires that the rules of a national securities exchange be designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating transactions in securities, 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 notes that options similar to CBOE's proposed DSOs currently trade in the over-the-counter market. The introduction of CBOE's proposed DSOs will provide investors with an exchange-traded product to manage the risk associated with changes in volatility of a particular security index, thereby providing additional investment options to investors in the context of a transparent exchange-traded market for these products.

In addition, DSOs will be subject to CBOE's rules applicable to other standardized options. For example, positions in a DSO will be subject to CBOE's rules governing position and exercise limits and, for the purposes of determining position limits, DSO positions will be aggregated with positions in other series of the same option class. Similarly, CBOE members and member organizations trading in DSOs will be subject to the reporting requirements and clearing firm requirements provided under CBOE rules. Further, DSOs in any particular index option class will be treated the same as any other options on the same index for the purpose of determining customer margin.

The Commission notes that the Exchange has represented that it has surveillance procedures in place that are adequate to monitor trading in DSOs. In particular, the Exchange will monitor trading activity in DSOs as it does for other option series listed in the same index option class. Further, the Exchange will limit trading of DSOs to investors with prior options trading experience, and will provide information about DSOs on its Web site, including information that describes the terms and operation of DSOs.

Accordingly, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder, and should promote just and equitable principles of trade while protecting investors and the public interest.

IV. Designation of DSOs as Standardized Options Pursuant to Rule 19b-1

Rule 9b–1 under the Act establishes a disclosure framework for standardized options that are traded on a national securities exchange and cleared through a registered clearing agency.[15] Under this framework, the exchange on which a standardized option is listed and traded must prepare an Options Disclosure Document ("ODD") that, among other things, identifies the issuer and describes the uses, mechanics, and risks of options trading, in language that can be easily understood by the general investing public. The ODD is treated as a substitute for the traditional prospectus. A broker-dealer must provide a copy of the ODD to each customer at or before approving the customer's account for trading any standardized option.[16] Any amendment to the ODD must be distributed to each customer whose account is approved for trading the options class for which the ODD relates.[17]

Pursuant to Rule 9b–1 under the Act, use of the ODD is limited to "standardized options" for which there is an effective registration statement on Form S–20 under the Securities Act of 1933 ("Securities Act") or that are otherwise exempt from registration.[18]

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[10] *See* CBOE Rules 4.11, 4.12, 24.4, 24.4A, and 24.4B. In addition, the Exchange is proposing to clarify in Rule 24.4B (Position Limits for Options on Micro Narrow-Based Indexes as Defined Under Rule 24.2(d)) that position in Short Term Option Series and Quarterly Options, together with DSO positions, shall be aggregated with positions in options contracts in the same class.

[11] *See* Notice, *supra* note 3, at 52947. *See also* Proposed CBOE Rule 9.9, Interpretations and Policies .01.

[12] *See* Notice, *supra* note 3, at 52948.

[13] 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).

[14] 15 U.S.C. 78f(b)(5).

[15] "Standardized options" are defined in Rule 9b–1(a)(4) as "options contracts trading on a national securities exchange, an automated quotation system of a registered securities association, or a foreign securities exchange which relate to options classes the terms of which are limited to specific expiration dates and exercise prices, or such other securities as the Commission may, by order, designate." 17 CFR 240.9b–1(a)(4).

[16] *See* 17 CFR 240.9b–1(d)(1).

[17] *See* 17 CFR 240.9b–1(d)(2).

[18] *See* 17 CFR 240.9b–1(b)(1) and (c)(8). *See also* 17 CFR 230.238 ("Rule 238"). Rule 238 under the Securities Act provides an exemption from the Securities Act for any standardized option, as defined by Rule 9b–1(a)(4) under the Act, with limited exceptions. Rule 238 does not exempt standardized options from the anti-fraud provisions of Section 17 of the Securities Act, 15 U.S.C. 77q. Also, offers and sales of standardized options by or

Pursuant to Rule 9b–1(a)(4), the Commission may, by order, designate as "standardized options" securities that do not otherwise meet the definition of "standardized options" but which "the Commission believes should be included within the [options] disclosure framework." [19] The Commission has used this authority in the past, for example, in connection with the listing and trading of Index Participations,[20] FLEX options,[21] credit default options,[22] and credit default basket options.[23] CBOE has requested that the Commission designate DSOs as standardized options so that the ODD may be used for DSOs.[24]

The Commission hereby designates DSOs, as separately defined in the Options Clearing Corporation's ("OCC") proposal,[25] as standardized options for purposes of Rule 9b–1 under the Act. DSOs do not meet the definition of standardized options because they do not have a specific exercise price. Whereas the exercise price of a conventional standardized option is determined when the option series is first listed for trading, the exercise price for a DSO would not be determined until the strike setting date. Instead, prior to the listing of the particular DSO series, the Exchange will specify a formula to determine the strike price of the DSO on the pre-determined strike setting date according to the terms of the formula.[26] No changes to any terms of existing DSO series could be made once the series begins trading.

Aside from the determination of the exercise price, DSOs resemble standardized options in other significant respects. DSOs have an underlying security index and a specific expiration date. Like other standardized options, they also have standardized terms pertaining to the rights and obligations of holders and writers. The fact that DSOs lack a specified exercise price at the commencement of trading does not detract from their character as options. Compared with FLEX options, which the Commission has also declared to be "standardized options," [27] the terms of DSOs would be even more standardized in that a strike price formula, settlement, expiration date, and exercise style would be fixed by the Exchange for each DSO series. In addition, similar to DSOs, credit default options and credit default basket options, which were recently designated by the Commission as "standardized options," also have many characteristics of standardized options, except for exercise price.[28]

The Commission also believes that the fact that the OCC, the clearing agency for standardized options, is willing to serve as issuer of DSOs supports the view that adding DSOs to the standardized option disclosure framework is reasonable.[29]

Therefore, the Commission herein designates DSOs, such as those proposed by CBOE, as standardized options for purposes of Rule 9b–1 under the Act.[30]

IV. Conclusion

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[31] that the proposed rule change (SR–CBOE–2006–90) as modified by Amendment No. 1 thereto, be, and hereby is, approved.

It is further ordered, pursuant to Rule 9b–1(a)(4) under the Act,[32] that DSOs, as defined in proposed rule change SR–OCC–2007–13, are hereby designated as standardized options.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[33]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–23533 Filed 12–4–07; 8:45 am]

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on behalf of the issuer of the underlying security or securities, an affiliate of the issuer, or an underwriter, will constitute an offer or sale of the underlying security or securities as defined in Section 2(a)(3) of the Securities Act, 15 U.S.C. 77b(a)(3). *See also* Securities Act Release No. 8171 (December 23, 2002), 68 FR 188 (January 2, 2003) (Exemption for Standardized Options From Provisions of the Securities Act of 1933 and From Registration Requirements of the Exchange Act of 1934).

[19] *See* Securities Exchange Act Release No. 19055 (September 16, 1982), 47 FR 41950, 41954 (September 23, 1982).

[20] *See* Securities Exchange Act Release No. 26709 (April 11, 1989), 54 FR 15280 (April 17, 1989) (SR–Phlx–88–07; SR–Amex–88–10; SR–CBOE–88–09).

[21] *See* Securities Exchange Act Nos. 31910 (February 23, 1993), 58 FR 12056 (March 2, 1993) (SR–CBOE–92–17; SR–OCC–92–33; ODD 93–1) (order designating FLEX index options as standardized options under Rule 9b–1); and 36841 (February 14, 1996), 61 FR 6666 (February 21, 1996) (SR–CBOE–95–43 and SR–PSE–95–24) and 37336 (June 19, 1996), 61 FR 33558 (June 27, 1996) (SR–Amex–95–57) (orders approving the listing and trading of FLEX equity options, and designating them as standardized options pursuant to Rule 9b–1 under the Act).

[22] *See* Securities Exchange Act Release No. 55871 (June 6, 2007), 72 FR 32372 (June 12, 2007) (SR–CBOE–2006–84).

[23] *See* Securities Exchange Act Release No. 56275 (August 17, 2007), 72 FR 47097 (August 22, 2007) (SR–CBOE–2007–26).

[24] *See* Notice, *supra* note 3, at 52947.

[25] The OCC has filed with the Commission a proposed rule change to enable it to clear and settle DSOs proposed to be listed by CBOE (the "OCC Proposal"). *See* Securities Exchange Act Release No. 56856 (November 28, 2007) (SR–OCC–2007–13) (order noticing and granting accelerated approval). The OCC Proposal defines the term "delayed start option" to mean "an option that at the commencement of trading does not have an exercise price but instead has an exercise price setting formula pursuant to which the exercise price will be fixed on the exercise price setting date for the series of delayed start option." This definition of DSOs is being added to Article 1, Section 1 of the OCC's By-Laws.

[26] Prior to the opening of the particular DSO series, the Exchange will announce the strike setting date as well as the expiration date of the DSO.

[27] *See supra* note 21 (citing the applicable orders regarding FLEX equity and index options).

[28] *See supra* notes 22 and 23 (citing the approval orders for credit default options and credit default basket options, respectively).

[29] The Commission notes that CBOE presently intends to offer DSOs in early 2008, and has represented that they will not introduce DSOs before the supplement to the ODD has been submitted to the Commission pursuant to Rule 9b–1 under the Act. Telephone conversation between Richard Holley III, Senior Special Counsel, Division of Trading and Markets, Commission, and Jennifer M. Lamie, Assistant General Counsel, CBOE, on November 16, 2007.

[30] 17 CFR 240.9b–1.

[31] 15 U.S.C. 78s(b)(2).

[32] 17 CFR 240.9b–1(a)(4).

[33] 17 CFR 200.30–3(a)(12) and 17 CFR 200.30–3(a)(51).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–56854; File No. SR–NYSE–2007–53]

Self-Regulatory Organizations; The New York Stock Exchange LLC; Order Approving Proposed Rule Change, as Modified by Amendments Nos. 1 and 2 Thereto, To Amend NYSE Rule 342.13 ("Acceptability of Supervisors")

November 28, 2007.

I. Introduction

On June 20, 2007, The New York Stock Exchange LLC ("NYSE" 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 amend NYSE Rule 342.13 ("Acceptability of Supervisors") to eliminate the current requirement in the rule that the General Securities Principal Examination ("Series 24 Examination") be passed after July 1, 2001 in order to be recognized by the Exchange as an acceptable alternative to the General Securities Sales Supervisor Qualification Examination ("Series 9/10 Examination").

On September 27, 2007, NYSE filed Amendment No. 1 to the proposed rule change. On October 15, 2007, NYSE filed Amendment No. 2 to the proposed rule change. The proposed rule change, as modified by Amendments Nos. 1 and 2, was published for comment in the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Federal Register on October 29, 2007.[3] The Commission received one comment letter, which expressed support for the proposed rule change.[4] This order approves the proposed rule change, as amended.

II. Description of the Proposal

Rule 342 ("Offices—Approval, Supervision and Control") prescribes the Exchange's general supervisory requirements for member organizations. Among the requirements, Rule 342.13 ("Acceptability of Supervisors") sets forth the Exchange's qualification standards for personnel delegated supervisory responsibility. Before 2001, this provision provided, in part, that a person delegated supervisory responsibility must pass the General Securities Sales Supervisor Qualification Examination ("Series 9/10 Examination") or an historical equivalent (*i.e.*, the Series 8 Examination).

In 2002, the Exchange amended Rule 342.13[5] to recognize the National Association of Securities Dealers, Inc. ("NASD")'s[6] General Securities Principal Examination ("Series 24 Examination"), if taken and passed after July 1, 2001, as an alternative to the Series 9/10 Examination requirement for persons whose duties did not include supervision of options or municipal securities sales activities.[7] At that time, the Exchange represented that NASD, as of July 2, 2001, had enhanced the Series 24 Examination by including test questions sufficient to provide appropriate coverage of the NYSE Rules. The Commission approved the proposed rule change on October 17, 2002.[8] The Exchange is now proposing to amend Rule 342.13 to eliminate the requirement that the Series 24 Examination be passed after July 1, 2001 in order for it to be an acceptable alternative to the Series 9/10 Examination.[9]

III. Discussion and Commission Findings

The Commission has carefully reviewed the proposed rule change and finds that it is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[10] In particular, the Commission finds that the proposed rule change is consistent with section 6(b)(5) of the Act,[11] which, among other things, requires that the rules of a national securities exchange be designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating transactions in securities, 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 the proposed amendment to NYSE's rules to eliminate the requirement that the Series 24 Examination be passed after July 1, 2001 in order for it to be recognized as an acceptable alternative to the Series 9/10 Examination is consistent with the Act. The Commission notes that the NYSE and the NASD rulebooks have converged significantly in the last six years. Thus, the persons who took the Series 24 before July 1, 2001 have been subject to regulatory standards that have, to a large degree, been harmonized.[12] Further, persons who took the Series 24 Examination before July 1, 2001 have been subject to regulatory and firm element continuing education,[13] which provides ongoing training with respect to current regulatory requirements, including NYSE Rules, applicable to duties and responsibilities of those persons.

In addition, the Commission believes that the proposed amendment furthers the goals of the Exchange's and FINRA's continuing Rule Harmonization Initiative[14] in that it should result in more closely aligned requirements under Rule 342.13 and the corresponding supervisory requirements under FINRA's regulatory scheme.[15]

IV. Conclusion

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[16] that the proposed rule change, as amended (SR–NYSE–2007–53), be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E7–23532 Filed 12–4–07; 8:45 am]

BILLING CODE 8011–01–P

[3] *See* Securities Exchange Act Release No. 56686 (October 23, 2007), 72 FR 61193 (October 29, 2007) (the "Notice").

[4] *See* letter from Marian H. Desilets, President, Association of Registration Management, Inc. to Nancy M. Morris, Secretary, Commission, dated November 15, 2007.

[5] *See* Securities Exchange Act Release No. 46425 (August 28, 2002), 67 FR 56863 (September 5, 2002) (SR–NYSE–2002–24).

[6] NASD is now known as the Financial Industry Regulatory Authority, Inc. ("FINRA").

[7] The Series 24 Examination does not address these activities.

[8] *See* Securities Exchange Act Release No. 46631 (October 9, 2002), 67 FR 64187 (October 17, 2002) (order approving SR–NYSE–2002–24). *See also* NYSE Information Memo 02–51 (November 12, 2002).

[9] Prospectively, persons may continue to qualify to supervise options or municipal securities sales activity by taking and passing the Series 24 Examination and also taking and passing the Registered Options Principal (Series 4) and/or Municipal Securities Principal (Series 53) examinations.

[10] 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).

[11] 15 U.S.C. 78f(b)(5).

[12] Convergence between the NYSE Rules and FINRA Rules has included, in part, standards relating to anti-money laundering, supervision, research and internal controls, etc.

[13] *See* NYSE Rule 345A.

[14] The purpose of the Rule Harmonization Initiative is to achieve, to the extent practicable, substantive harmonization of the two regulatory schemes in an effort to reduce regulatory duplication and streamline the rules of self-regulatory organizations.

[15] *See* FINRA Rule 1022(a).

[16] 15 U.S.C. 78s(b)(2).

[17] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Additional Designations, Foreign Narcotics Kingpin Designation Act

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Treasury Department's Office of Foreign Assets Control ("OFAC") is publishing the names of additional persons whose property and interests in property have been blocked pursuant to the Foreign Narcotics Kingpin Designation Act (21 U.S.C. 1901–1908, 8 U.S.C. 1182). In addition, OFAC is publishing a change to the listing of one individual previously designated pursuant to the Foreign Narcotics Kingpin Designation Act.

DATES: The designation by the Secretary of the Treasury of the nine individuals and thirteen entities identified in this notice pursuant to section 805(b) of the Kingpin Act is effective on November 27, 2007. In addition, the change to the listing of one individual previously designated pursuant to section 804(b) of the Kingpin Act is effective on November 27, 2007.

FOR FURTHER INFORMATION CONTACT: Assistant Director, Compliance Outreach & Implementation, Office of Foreign Assets Control, Department of the Treasury, Washington, DC 20220, tel.: 202/622–2490.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

This document and additional information concerning OFAC are available on OFAC's Web site (*http://www.treas.gov/ofac*) or via facsimile through a 24-hour fax-on demand service, tel.: (202) 622–0077.

Background

The Foreign Narcotics Kingpin Designation Act ("Kingpin Act") became law on December 3, 1999. The Kingpin Act establishes a program targeting the activities of significant foreign narcotics traffickers and their organizations on a worldwide basis. It provides a statutory framework for the President to impose sanctions against significant foreign narcotics traffickers and their organizations on a worldwide basis, with the objective of denying their businesses and agents access to the U.S. financial system and to the benefits of trade and transactions involving U.S. companies and individuals.

The Kingpin Act blocks all property and interests in property, subject to U.S. jurisdiction, owned or controlled by significant foreign narcotics traffickers as identified by the President. In addition, the Kingpin Act blocks the property and interests in property, subject to U.S. jurisdiction, of foreign persons designated by the Secretary of Treasury, in consultation with the Attorney General, the Director of Central Intelligence, the Director of the Federal Bureau of Investigation, the Administrator of the Drug Enforcement Administration, the Secretary of Defense, the Secretary of State, and the Secretary of Homeland Security who are found to be: (1) Materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of a person designated pursuant to the Kingpin Act; (2) owned, controlled, or directed by, or acting for or on behalf of, a person designated pursuant to the Kingpin Act; or (3) playing a significant role in international narcotics trafficking.

On November 27, 2007, OFAC designated nine additional individuals and thirteen additional entities whose property and interests in property are blocked pursuant to section 805(b) of the Foreign Narcotics Kingpin Designation Act.

The list of additional designees follows:

Individuals:

1. AZAM, Amir (a.k.a. SHEIKH MOHAMMED, Amir Azam); c/o A A TRADING FZCO, Dubai, United Arab Emirates; Dubai, United Arab Emirates; DOB 02 Nov 1971; POB Chiswick, England; Citizen United Arab Emirates; Passport 039856039 (United Kingdom); (INDIVIDUAL) [SDNTK].

2. BEHZAD, Ahmad Abdulla Mohammad Abdulla (a.k.a. BEHZAD BSTAKI, Ahmad Abdullah Mohammed Abdullah; a.k.a. BEHZAD, Ahmad Abdulla Mohammad Abdulla; a.k.a. "Ahmed Mohammed Abdullah"; a.k.a. BAHZAD, Ahmad Abdullah Mohamed Abdullah; a.k.a. "Abdullah Mohammed Abdullah BAHZAD"; a.k.a. "Mohammed Abdullah Mohammed BAHZAD"; a.k.a. "Ahmed BEHZA"; a.k.a. BEHZAD, Ahmad Abdulla Mohd Abdulla; a.k.a. BEHZAD, Ahmed Abdullah; a.k.a. BEHZAD, Ahmad Abdulla Mohammad A; a.k.a. BEHZAD, Abdulla Mohd Abdulla; a.k.a. "Abdulla Mohamad Abdulla Mohamad BEHZAD"; a.k.a. "Abdullah Ahmad Abdullah Mohamad BAHZAD"); c/o SHAHBAZ KHAN GENERAL TRADING LLC, Dubai, United Arab Emirates; c/o FMF GENERAL TRADING LLC, Dubai, United Arab Emirates; Dubai, United Arab Emirates; Sharjah, United Arab Emirates; DOB 02 Nov 1971; POB Dubai, United Arab Emirates; Citizen United Arab Emirates; Passport A1042768 (United Arab Emirates); Passport A0269124 (United Arab Emirates); (INDIVIDUAL) [SDNTK].

3. LOAN, Waseem Rauf (a.k.a. LOUN, Waseem Rouf; a.k.a. LOUN, Waseem Raouf; a.k.a. RASHID, Abdul Majid; a.k.a. RASHI, Abdul Majid; a.k.a. BUTT, Abdul Majid; a.k.a. LOAN, Waseem Raouf; a.k.a. LOUN, Waseem Rauf; a.k.a. LON RAOUF, Wasim Raouf); c/o AL AMLOOD TRADING LLC, Dubai, United Arab Emirates; c/o FMF GENERAL TRADING LLC, Dubai, United Arab Emirates; Pakistan; DOB 03 Mar 1966; POB Lahore, Pakistan; Citizen Pakistan; Passport AA8908881 (Pakistan); Identification Number 35200–5407888–5 (Pakistan); (INDIVIDUAL) [SDNTK].

4. GHANI, Mohammad Nadeem (GHANI, Mohamed Nadim); c/o ZULEKHA GENERAL TRADING LLC, Ajman, United Arab Emirates; United Kingdom; Citizen United Kingdom; Passport 093055372 (United Kingdom); (INDIVIDUAL) [SDNTK].

5. SCHNEIDER, Simon, c/o OFFENBACH HAUSHALTWAREN B.V., Beverwijk, Netherlands; c/o BELS FLOWERS IMPORT EXPORT BVBA, Antwerpen, Belgium; Netherlands; DOB 14 Jul 1967; POB Hoorn, Netherlands; Citizen Netherlands; Passport BA0199589 (Netherlands); (INDIVIDUAL) [SDNTK].

6. MICHIELSEN, Tom (a.k.a. MICHIELSEN, Tom R.D.); Belgium; DOB 22 Dec 1975; POB Kapellen, Belgium; Citizen Belgium; Passport FF615720 (Belgium); Identification Number 1041 002019 56 (Belgium); (INDIVIDUAL) [SDNTK].

7. KHAN, Sherbaz, c/o SHAHBAZ KHAN GENERAL TRADING LLC, Dubai, United Arab Emirates; c/o SHER MATCH INDUSTRIES (PVT.) LIMITED, Peshawar, Pakistan; Peshawar, Pakistan; P.O. Box 33651, Dubai, United Arab Emirates; DOB 03 Apr 1979; POB Khyber Agency, Pakistan; Citizen Pakistan; Passport 137987 (Pakistan); (INDIVIDUAL) [SDNTK].

8. NOOR MUHAMMAD, Abdul Majeed (a.k.a. NOOR MUHAMMED, Abdul Majid; a.k.a. NOOR MOHAMMAD, Abdul Majid); c/o FMF GENERAL TRADING LLC, Dubai, United Arab Emirates; DOB 1957; POB Chagai, Pakistan; Citizen Pakistan; Passport LA097936 (Pakistan); (INDIVIDUAL) [SDNTK].

9. DUZCAN, Ceylan, United Arab Emirates; DOB 01 Mar 1975; POB Savsat, Turkey; Citizen Turkey; Passport 315408 (Turkey); Driver's License No. 11550 (Turkey); (INDIVIDUAL) [SDNTK].

Entities:

1. SHAHBAZ KHAN GENERAL TRADING LLC (a.k.a. AL SHAHBOZ KHAN GENERAL TRADING LLC.); Al Ghas Building, Baniyas Square, Al Rigga Area, Flat No. 106, Dubai, United Arab Emirates; P.O. Box 24241, Dubai, United Arab Emirates; P.O. Box 40754, Dubai, United Arab Emirates; Shop No. 16, Baniyas Centre, Dubai, United Arab Emirates; C.R. No. 52060 (United Arab Emirates); (ENTITY) [SDNTK].

2. SHER MATCH INDUSTRIES (PVT.) LIMITED, Plot Numbers 119–121, Industrial Estate, Jamrud Road, Hayatabad, Peshawar, Pakistan; Shahnawaz Traders Royal Industrial Area, Jamrud Road, Peshawar, Pakistan; C.R. No. P–01876/19981106 (Pakistan); (ENTITY) [SDNTK].

3. SHAHNAWAZ TRADERS, Shop No. 1–2, Block A, Jamrud Road, Royal Market, Peshawar, Pakistan; (ENTITY) [SDNTK].

4. SHAHBAZ TV CENTER, Shop No. 1–2, Block A, Jamrud Road, Royal Market, Peshawar, Pakistan; (ENTITY) [SDNTK].

5. DUBAI TRADING COMPANY, 44–45, Royal Shopping Plaza, Industrial Estate, Hayatabad, Peshawar, Pakistan; 53 Royal Shopping Plaza, Industrial Estate, Hayatabad, Peshawar, Pakistan; (ENTITY) [SDNTK].

6. SAF TECH S.L., Calle Serrano 52, Barcelona 08031, Spain; C.R. No. B62398060 (Spain); (ENTITY) [SDNTK].

7. KHAN & SCHIRINDEL GMBH, Schwalbacher Strasse 19, Weisbaden

65185, Germany; C.R. No. HRB20555 (Germany); (ENTITY) [SDNTK].

8. OFFENBACH HAUSHALTWAREN B.V., Rietlanden 5–A, Beverwijk 1948, Netherlands; Rietlanden 5–7, Beverwijk 1948 NE., Netherlands; C.R. No. 28094396 (Netherlands); (ENTITY) [SDNTK].

9. BELS FLOWERS IMPORT EXPORT BVBA, Lange Lobroekstraat 8, Antwerpen 2060, Belgium; C.R. No. 478351540 (Belgium); (ENTITY) [SDNTK].

10. A A TRADING FZCO, P.O. Box 37089, Dubai, United Arab Emirates; (ENTITY) [SDNTK].

11. ZULEKHA GENERAL TRADING LLC (a.k.a. ZULEIKHA GENERAL TRADING; a.k.a. ZULIKHA GENERAL TRADING); P.O. Box 5456, Ajman, United Arab Emirates; C.R. No. 32035 (United Arab Emirates); (ENTITY) [SDNTK].

12. AL AMLOOD TRADING LLC, Ali Rashid Lootah Building, Al Khaleej Street, Al Baraha Area, Dubai, United Arab Emirates; P.O. Box 3517, Dubai, United Arab Emirates; C.R. No. 79190 (United Arab Emirates); (ENTITY) [SDNTK].

13. FMF GENERAL TRADING LLC, Ahmad Abdulla Bahzad Building, Al Qusais Street, Al Qusais Industrial Area, Dubai, United Arab Emirates; P.O. Box 16542, Dubai, United Arab Emirates; C.R. No. 66488 (United Arab Emirates); (ENTITY) [SDNTK].

In addition, OFAC has made a change to the following listing of one individual previously designated pursuant to the Kingpin Act:

1. KHAN, Shahbaz (a.k.a. KHAN GALAT KHAN, Shahbaz; a.k.a. KHAN ZADRAN, Shahbaz; a.k.a. KOOCHI, Shahbaz; a.k.a. "HAJI SHAHBAZ KOOCHI"; a.k.a. "HAJI SHAHBAZ"; a.k.a. ZADRAN, Shahbaz; a.k.a. "HAJI SHABBAZ"; a.k.a. ZADRAN, Shabbaz; a.k.a. ZADRAN, Haji Shabaz; a.k.a. ZADRAN, Haji Shahbaz; a.k.a. HAN, Cellat; a.k.a. HAN, Sahbaz; a.k.a. KOCHI, Haji Shahbaz Khan; a.k.a. KHAN JALAT KHAN, Shahbaz); Dubai, United Arab Emirates; Peshawar, Pakistan; Hanover, Germany; DOB 01 Jan 1948; POB Landi Kotal, Pakistan; Citizen Pakistan; Passport AB4106401 (Pakistan); (INDIVIDUAL) [SDNTK].

The listings now appear as follows:

1. KHAN, Shahbaz (a.k.a. KHAN GALAT KHAN, Shahbaz; a.k.a. KHAN ZADRAN, Shahbaz; a.k.a. KOOCHI, Shahbaz; a.k.a. "HAJI SHAHBAZ KOOCHI"; a.k.a. "HAJI SHAHBAZ"; a.k.a. ZADRAN, Shahbaz; a.k.a. "HAJI SHABBAZ"; a.k.a. ZADRAN, Shabbaz; a.k.a. ZADRAN, Haji Shabaz; a.k.a. ZADRAN, Haji Shahbaz; a.k.a. HAN, Cellat; a.k.a. HAN, Sahbaz; a.k.a. KOCHI, Haji Shahbaz Khan; a.k.a. KHAN JALAT KHAN, Shahbaz); c/o DUBAI TRADING COMPANY, Peshawar, Pakistan; c/o KHAN & SCHIRINDEL GMBH, Weisbaden, Germany; c/o SAF TECH S.L., Barcelona, Spain; c/o SHAHBAZ KHAN GENERAL TRADING LLC, Dubai, United Arab Emirates; c/o SHAHBAZ TV CENTER, Peshawar, Pakistan; c/o SHAHNAWAZ TRADERS, Peshawar, Pakistan; c/o SHER MATCH INDUSTRIES (PVT.) LIMITED, Peshawar, Pakistan; Dubai, United Arab Emirates; Peshawar, Pakistan; Hanover, Germany; DOB 01 Jan 1948; POB Landi Kotal, Pakistan; Citizen Pakistan; Passport AB4106401 (Pakistan); (INDIVIDUAL) [SDNTK].

Dated: November 27, 2007.

Adam J. Szubin,

Director, Office of Foreign Assets Control.

[FR Doc. 07–5920 Filed 12–4–07; 8:45 am]

BILLING CODE 4811–42–P

DEPARTMENT OF THE TREASURY

United States Mint

Request for Citizens Coinage Advisory Committee Membership Applications

ACTION: Request for Citizens Coinage Advisory Committee Membership Applications.

SUMMARY: Pursuant to United States Code, Title 31, section 5135(b), the United States Mint is accepting applications for membership to the Citizens Coinage Advisory Committee (CCAC) for *two* new members: One representing the *interests of the general public* in the coinage of the United States; and one specially qualified to serve on the CCAC by virtue of his or her education, training, or experience in *numismatics*. The CCAC was established to:

- Advise the Secretary of the Treasury on any theme or design proposals relating to circulating coinage, bullion coinage, Congressional Gold Medals, and national and other medals produced by the United States Mint.
- Advise the Secretary of the Treasury with regard to the events, persons, or places that the CCAC recommends to be commemorated by the issuance of commemorative coins in each of the five calendar years succeeding the year in which a commemorative coin designation is made.
- Make recommendations with respect to the mintage level for any commemorative coin recommended.

Total membership consists of eleven voting members appointed by the Secretary of the Treasury:

- One person specially qualified by virtue of his or her education, training or experience as nationally or internationally recognized curator in the United States of a numismatic collection;
- One person specially qualified by virtue of his or her experience in the medallic arts or sculpture;
- One person specially qualified by virtue of his or her education, training, or experience in American history;
- One person specially qualified by virtue of his or her education, training, or experience in numismatics;
- Three persons who can represent the interests of the general public in the coinage of the United States; and
- Four persons appointed by the Secretary of the Treasury on the basis of the recommendations by the House and Senate leadership.

Members are appointed for a term of four years. No individual may be appointed to the CCAC while serving as an officer or employee of the Federal Government.

The CCAC is subject to the direction of the Secretary of the Treasury. Meetings of the CCAC are open to the public and are held approximately six to eight times per year. The United States Mint is responsible for providing the necessary support, technical services and advice to the CCAC. CCAC members are not paid for their time or services, but, consistent with Federal Travel Regulations, members are reimbursed for their travel and lodging expenses to attend meetings. Members are Special Government Employees and are subject to the Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR part 2653).

The United States Mint will review all submissions and will forward its recommendations to the Secretary of the Treasury for appointment consideration. Candidates should include specific skills, abilities, talents, and credentials to support their applications. The United States Mint is also interested in candidates who have demonstrated leadership skills, have received recognition by their peers in their field of interest, have a record of participation in public service or activities, and are willing to commit the time and effort to participate in the CCAC meetings and related activities. Further information about the CCAC is available at *http://www.ccac.gov.*

Application Deadline: January 31, 2008.

Receipt of Applications: Any member of the public wishing to be considered

for participation on the committee should submit a resumé and cover letter describing qualifications for membership, by fax to 202–756–6525 or by mail to the United States Mint, 801 9th Street, NW., Washington, DC 20001, Attn: Greg Weinman. Submissions must specify which position the candidate wished to be considered for, and must be postmarked no later than January 31, 2008.

Notice Concerning Delivery of First-Class and Priority Mail: The delivery of first-class mail to the United States Mint has been delayed since mid-October 2001, and delays are expected to continue. Until normal mail service resumes, please consider using alternate delivery services when sending time-sensitive material.

Some or all of the first-class and priority mail we receive may be put through an irradiation process to protect against biological contamination. Support materials put through this process may suffer irreversible damage. We encourage you to consider using alternate delivery services.

FOR FURTHER INFORMATION CONTACT: Cliff Northup, United States Mint Liaison to the CCAC; 801 Ninth Street, NW., Washington, DC 20220, or call 202–354–7463.

Dated: November 28, 2007.

Edmund C. Moy,

Director, United States Mint.

[FR Doc. E7–23546 Filed 12–4–07; 8:45 am]

BILLING CODE 4810–02–P

Corrections

Federal Register
Vol. 72, No. 233
Wednesday, December 5, 2007

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 26

[Docket No.: FAA–2004–18379; Amendment Nos. 1–60, 21–90, 25–123, 26–0, 91–297, 121–336, 125–53, 129–43]

RIN 2120–AI31

Enhanced Airworthiness Program for Airplane Systems/Fuel Tank Safety (EAPAS/FTS)

Correction

In rule document E7–21434 beginning on page 63364 in the issue of Thursday, November 8, 2007, make the following correction:

§26.11 [Corrected]

On page 63410, in §26.11(d)(5), in the first column, in the sixth line, "December 10, 2009" should read "June 7, 2010".

[FR Doc. Z7–21434 Filed 12–4–07; 8:45 am]
BILLING CODE 1505–01–D

Federal Register

Wednesday,
December 5, 2007

Part II

State Justice Institute

Grant Guideline; Notice

STATE JUSTICE INSTITUTE

Grant Guideline, Notice

AGENCY: State Justice Institute.

ACTION: Final Grant Guideline for 2008.

SUMMARY: This Guideline sets forth the administrative, programmatic, and financial requirements attendant to Fiscal Year 2008 State Justice Institute grants, cooperative agreements, and contracts.

DATES: December 5, 2007.

FOR FURTHER INFORMATION CONTACT: Janice Munsterman, Executive Director, State Justice Institute, 1650 King St. (Suite 600), Alexandria, VA 22314, (703) 684–6100 X202, *jmunsterman@statejustice.org.*

SUPPLEMENTARY INFORMATION: Pursuant to the State Justice Institute Act of 1984, 42 U.S.C. 10701, et seq., as amended, the Institute is authorized to award grants, cooperative agreements, and contracts to State and local courts, nonprofit organizations, and others for the purpose of improving the quality of justice in the State courts of the United States.

Final appropriations legislation for fiscal year (FY) 2008 is still pending. The House-passed version (H.R. 3093) includes $4,640,000 for the Institute in FY 2008; the Senate passed version (S. 1745) of the bill includes $3,500,000.

Regardless of the final amount provided to the Institute for FY 2008, the Institute's Board of Directors intends to solicit grant applications across the range of grant programs available.

The following Grant Guideline is adopted by the State Justice Institute for FY 2008:

Table of Contents

I. The Mission of the State Justice Institute

The Institute was established by Public Law 98–620 to improve the administration of justice in the State courts of the United States. Incorporated in the State of Virginia as a private, nonprofit corporation, the Institute is charged, by statute, with the responsibility to:

- Direct a national program of financial assistance designed to assure that each citizen of the United States is provided ready access to a fair and effective system of justice;
- Foster coordination and cooperation with the Federal judiciary;
- Promote recognition of the importance of the separation of powers doctrine to an independent judiciary; and
- Encourage education for judges and support personnel of State court systems through national and State organizations, including universities.

To accomplish these broad objectives, the Institute is authorized to provide funds to State courts, national organizations which support and are supported by State courts, national judicial education organizations, and other organizations that can assist in improving the quality of justice in the State courts. The Institute is supervised by a Board of Directors appointed by the President, with the consent of the Senate. The Board is statutorily composed of six judges; a State court administrator; and four members of the public, no more than two can be of the same political party.

Through the award of grants, contracts, and cooperative agreements, the Institute is authorized to perform the following activities:

A. Support technical assistance, demonstrations, special projects, research and training to improve the administration of justice in the State courts;

B. Provide for the preparation, publication, and dissemination of information regarding State judicial systems;

C. Participate in joint projects with Federal agencies and other private grantors;

D. Evaluate or provide for the evaluation of programs and projects to determine their impact upon the quality of criminal, civil, and juvenile justice and the extent to which they have contributed to improving the quality of justice in the State courts;

E. Encourage and assist in furthering judicial education; and,

F. Encourage, assist, and serve in a consulting capacity to State and local justice system agencies in the development, maintenance, and coordination of criminal, civil, and juvenile justice programs and services.

II. Eligibility for Award

The Institute is authorized by Congress to award grants, cooperative agreements, and contracts to the following entities and types of organizations:

A. *State and local courts and their agencies (42 U.S.C. 10705(b)(1)(A)).*

B. *National nonprofit organizations controlled by, operating in conjunction with, and serving the judicial branches of State governments (42 U.S.C. 10705(b)(1)(B)).*

C. *National nonprofit organizations for the education and training of judges and support personnel of the judicial branch of State governments (42 U.S.C. 10705(b)(1)(C)).* An applicant is considered a national education and training applicant under section 10705(b)(1)(C) if:

1. The principal purpose or activity of the applicant is to provide education and training to State and local judges and court personnel; and

2. The applicant demonstrates a record of substantial experience in the field of judicial education and training.

D. *Other eligible grant recipients (42 U.S.C. 10705 (b)(2)(A)–(D)).*

1. Provided that the objectives of the project can be served better, the Institute is also authorized to make awards to:

a. Nonprofit organizations with expertise in judicial administration;

b. Institutions of higher education;

c. Individuals, partnerships, firms, corporations (for-profit organizations must waive their fees); and

d. Private agencies with expertise in judicial administration.

2. The Institute may also make awards to State or local agencies and institutions other than courts for services that cannot be adequately provided through nongovernmental arrangements (42 U.S.C. 10705(b)(3)).

E. *Inter-agency Agreements.* The Institute may enter into inter-agency agreements with Federal agencies (42 U.S.C. 10705(b)(4)) and private funders to support projects consistent with the purposes of the State Justice Institute Act.

III. Scope of the Program

SJI is offering five types of grants in FY 2008: Project Grants, Technical Assistance (TA) Grants, Curriculum Adaptation and Training (CAT) Grants, Partner Grants, and Scholarships. Effective beginning in FY 2007, SJI no longer awards Continuation Grants to extend previous or future Project Grants.

A. Project Grants

Project Grants are intended to support innovative education and training, research and evaluation, demonstration, and technical assistance projects that can improve the administration of justice in State courts locally or nationwide. Project Grants may ordinarily not exceed $300,000. Grant periods for Project Grants ordinarily may not exceed 36 months. No Continuation Grants will be awarded.

Applicants for Project Grants will be required to contribute a cash match of not less than 50% of the total cost of the proposed project. In other words, grant awards by SJI must be matched at least dollar for dollar by grant applicants. Applicants may contribute the required cash match directly or in cooperation with third parties. Prospective applicants should carefully review Section VI.8. (matching requirements) and Section VI.16.a. (non-supplantation) of the Guideline prior to beginning the application process. If questions arise, applicants are strongly encouraged to consult the Institute.

As set forth in Section I., the Institute is authorized to fund projects addressing a broad range of program areas. However, the Board is likely to favor Project Grant applications focused on the Special Interest program categories described below, potential applicants are also encouraged to bring to the attention of the Institute innovative projects outside those categories. Funding will not be made available for the ordinary, routine operations of court systems, or to support ordinary operations of courts.

1. Special Interest Program Criteria and Categories

The Institute is interested in funding both innovative programs and programs of proven merit that can be replicated in other jurisdictions. The Institute is especially interested in funding projects that:

- Formulate new procedures and techniques, or creatively enhance existing procedures and techniques;
- Address aspects of the State judicial systems that are in special need of serious attention;
- Have national significance by developing products, services, and techniques that may be used in other States; and
- Create and disseminate products that effectively transfer the information and ideas developed to relevant audiences in State and local judicial systems, or provide technical assistance to facilitate the adaptation of effective programs and procedures in other State and local jurisdictions.

A project will be identified as a Special Interest project if it meets the four criteria set forth above and it falls within the scope of the Board-designated Special Interest program categories listed below. The order of listing does not imply any ranking of priorities among the categories.

a. Immigration Issues

Recent immigration growth is having a significant impact on State and local courts. Courts along the Southwest Border, and other areas of the United States with large immigrant populations, are contending with issues such as how to provide culturally appropriate services; increases in gang-crime cases involving immigrants; and the impact of federal and state immigration policies on court operations. The Institute is interested in projects that highlight the issues State and local courts face in addressing the demands of increased immigration, and potential solutions to those issues.

The Institute is also interested in judicial education or other programs that prepare judges and court officials to address immigration issues in their courts, and the development of plans of action to improve service delivery, build community coalitions, and accommodate federal and state immigration policies.

b. Courts and the Media

Recent repeated public attacks on courts have gone largely unanswered, because judges were unwilling and/or courts were unable to respond effectively. No one is better prepared than a judge to describe decision-making on the bench within the law and the Constitution. The Institute is interested in projects that explore the role of judge as public commentator within ethical and professional bounds. The Institute is also interested in judicial education or other programs that prepare judges and court officials to serve as spokesmen in short notice, high profile circumstances, especially in situations where courts lack dedicated press secretaries. Finally, the Institute is interested in promoting initiatives that improve relations between the judiciary and the media, since much of the recent rancor between the two seems based on unfamiliarity with one another's duties, responsibilities, and limitations. In particular, the Institute is interested in proposals that focus on cultivating trust and open communication between the Third Branch and the Fourth Estate on a day-to-day basis, because dialogue between strangers is rarely started and never sustained in a crisis.

c. Elder Issues

This category includes research, demonstration, evaluation, and education projects designed to improve management of guardianship, probate, fraud, Americans with Disability Act, and other types of elder-related cases. The Institute is particularly interested in projects that would develop and evaluate judicial branch education programs addressing elder law and related issues.

d. Performance Standards and Outcome Measures

This category includes projects that will develop and measure performance standards and outcomes for all aspects of court operations. The Institute is particularly interested in projects that take the National Center for State Courts' "'CourTools'" to the next level. Other initiatives designed to further professionalize court staff and operations, or to objectively evaluate the costs and benefits and cost-effectiveness of problem solving courts, are also welcome.

e. Relationship Between State and Federal Courts

This category includes research, demonstration, evaluation, and education projects designed to facilitate appropriate and effective communication, cooperation, and coordination between State and Federal courts. The Institute is also interested in projects that improve relationships between the courts, the legislative and executive branches, and the people.

B. Technical Assistance (TA) Grants

TA Grants are intended to provide State or local courts, or regional court associations, with sufficient support to obtain expert assistance to diagnose a problem, develop a response to that problem, and implement any needed changes. TA Grants may not exceed $30,000, and shall only cover the cost of obtaining the services of expert consultants. Examples of expenses not covered by TA Grants include the salaries, benefits, travel, or training costs of full- or part-time court employees. Grant periods for TA Grants ordinarily may not exceed 24 months. In calculating project duration, applicants are cautioned to fully consider the time required to issue a request for proposals, negotiate a contract with the selected provider, and execute the project.

Applicants for TA Grants will be required to contribute a match of not less than 50 percent of the grant amount requested, of which 20 percent must be cash. In other words, an applicant seeking a $30,000 TA grant must

provide a $15,000 match, of which up to $12,000 can be in-kind and not less than $3,000 must be cash. TA Grant application procedures can be found in section IV.B.

C. Curriculum Adaptation and Training (CAT) Grants

CAT Grants are intended to: (1) Enable courts and regional or national court associations to modify and adapt model curricula, course modules, or conference programs to meet States' or local jurisdictions' educational needs; train instructors to present portions or all of the curricula; and pilot-test them to determine their appropriateness, quality, and effectiveness, or (2) conduct judicial branch education and training programs, led by either expert or in-house personnel, designed to prepare judges and court personnel for innovations, reforms, and/or new technologies recently adopted by grantee courts. CAT Grants may not exceed $20,000. Grant periods for CAT Grants ordinarily may not exceed 12 months.

Applicants for CAT Grants will be required to contribute a match of not less than 50 percent of the grant amount requested, of which 20 percent must be cash. In other words, an applicant seeking a $20,000 CAT grant must provide a $10,000 match, of which up to $8,000 can be in-kind and not less than $2,000 must be cash. CAT Grant application procedures can be found in section IV.C.

D. Partner Grants

Partner Grants are intended to allow the Institute and Federal, State, or local agencies or foundations, trusts, or other private entities to combine financial resources in pursuit of common interests. Although many, if not most, Partner Grants will fall under the Special Interest program categories cited in section III.A., proposals addressing other emerging or high priority court-related problems will be considered on a case-by-case basis. The Institute and its financial partners may set any level for Partner Grants, subject to the entire amount of the grant being available at the time of the award; applicants for Partner Grants may request any amount of funding. Grant periods for Partner Grants ordinarily may not exceed 36 months.

Partner Grants are subject to the same cash match requirement as Project Grants. In other words, grant awards by the Institute must be matched at least dollar-for-dollar. Applicants may contribute the required cash match directly or in cooperation with third parties. Partner Grants are coordinated by the funding organizations. Applicants considering Partner Grants are encouraged to contact Institute staff to discuss the potential of this mechanism for project funding. Partner Grant application procedures can be found in section IV.E.

E. Scholarships for Judges and Court Managers

Scholarships are intended to enhance the skills, knowledge, and abilities of State court judges and court managers by enabling them to attend out-of-State, or to enroll in online, educational and training programs sponsored by national and State providers that they could not otherwise attend or take online because of limited State, local, and personal budgets. Scholarships may not exceed $1,500. The Institute's Board of Directors intends to reserve up to $175,000 for scholarships in FY 2008. Scholarship application procedures can be found in section IV.D.

IV. Applications

A. Project Grants

An application for a Project Grant must include an application form; budget forms (with appropriate documentation); a project abstract and program narrative; a disclosure of lobbying form, when applicable; and certain certifications and assurances (see below). See Appendix B for the Project Grant application forms.

1. Forms

a. Application Form (Form A).

The application form requests basic information regarding the proposed project, the applicant, and the total amount of funding requested from the Institute. It also requires the signature of an individual authorized to certify on behalf of the applicant that the information contained in the application is true and complete; that submission of the application has been authorized by the applicant; and that if funding for the proposed project is approved, the applicant will comply with the requirements and conditions of the award, including the assurances set forth in Form D.

b. Certificate of State Approval (Form B)

An application from a State or local court must include a copy of Form B signed by the State's Chief Justice or Chief Judge, the director of the designated agency, or the head of the designated council. The signature denotes that the proposed project has been approved by the State's highest court or the agency or council it has designated. It denotes further that if the Institute approves funding for the project, the court or the specified designee will receive, administer, and be accountable for the awarded funds.

c. Budget Form (Form C)

Applicants must submit a Form C. In addition to Form C, applicants must provide a detailed budget narrative providing an explanation of the basis for the estimates in each budget category (see subsection A.4. below).

If funds from other sources are required to conduct the project, either as match or to support other aspects of the project, the source, current status of the request, and anticipated decision date must be provided.

d. Assurances (Form D)

This form lists the statutory, regulatory, and policy requirements with which recipients of Institute funds must comply.

e. Disclosure of Lobbying Activities

Applicants other than units of State or local government are required to disclose whether they, or another entity that is part of the same organization as the applicant, have advocated a position before Congress on any issue, and to identify the specific subjects of their lobbying efforts (see section VI.A.7.).

2. Project Abstract

The abstract should highlight the purposes, goals, methods, and anticipated benefits of the proposed project. It should not exceed 1 single-spaced page on 8½ by 11 inch paper.

3. Program Narrative

The program narrative for an application may not exceed 25 double-spaced pages on 8½ by 11 inch paper. Margins must be at least 1 inch, and type size must be at least 12-point and 12 cpi. The pages should be numbered. This page limit does not include the forms, the abstract, the budget narrative, and any appendices containing resumes and letters of cooperation or endorsement. Additional background material should be attached only if it is essential to impart a clear understanding of the proposed project. Numerous and lengthy appendices are strongly discouraged.

The program narrative should address the following topics:

a. Project Objectives

The applicant should include a clear, concise statement of what the proposed project is intended to accomplish. In stating the objectives of the project, applicants should focus on the overall programmatic objective (e.g., to enhance

understanding and skills regarding a specific subject, or to determine how a certain procedure affects the court and litigants) rather than on operational objectives (e.g., provide training for 32 judges and court managers, or review data from 300 cases).

b. Program Areas To Be Covered

The applicant should note the Special Interest criteria and category addressed by the proposed project when appropriate (see section III.A.).

c. Need for the Project

If the project is to be conducted in any specific location(s), the applicant should discuss the particular needs of the project site(s) to be addressed by the project and why those needs are not being met through the use of existing programs, procedures, services, or other resources.

If the project is not site-specific, the applicant should discuss the problems that the proposed project would address, and why existing programs, procedures, services, or other resources cannot adequately resolve those problems. The discussion should include specific references to the relevant literature and to the experience in the field.

d. Tasks, Methods and Evaluations

(1) Tasks and Methods. The applicant should delineate the tasks to be performed in achieving the project objectives and the methods to be used for accomplishing each task. For example:

(a) *For research and evaluation projects*, the applicant should include the data sources, data collection strategies, variables to be examined, and analytic procedures to be used for conducting the research or evaluation and ensuring the validity and general applicability of the results. For projects involving human subjects, the discussion of methods should address the procedures for obtaining respondents' informed consent, ensuring the respondents' privacy and freedom from risk or harm, and protecting others who are not the subjects of research but would be affected by the research. If the potential exists for risk or harm to human subjects, a discussion should be included that explains the value of the proposed research and the methods to be used to minimize or eliminate such risk.

(b) *For education and training projects*, the applicant should include the adult education techniques to be used in designing and presenting the program, including the teaching/learning objectives of the educational design, the teaching methods to be used, and the opportunities for structured interaction among the participants; how faculty would be recruited, selected, and trained; the proposed number and length of the conferences, courses, seminars, or workshops to be conducted and the estimated number of persons who would attend them; the materials to be provided and how they would be developed; and the cost to participants.

(c) *For demonstration projects*, the applicant should include the demonstration sites and the reasons they were selected, or if the sites have not been chosen, how they would be identified and their cooperation obtained; and how the program or procedures would be implemented and monitored.

(d) *For technical assistance projects*, the applicant should explain the types of assistance that would be provided; the particular issues and problems for which assistance would be provided; how requests would be obtained and the type of assistance determined; how suitable providers would be selected and briefed; how reports would be reviewed; and the cost to recipients.

(2) Evaluation. Projects must include an evaluation plan to determine whether the project met its objectives. The evaluation should be designed to provide an objective and independent assessment of the effectiveness or usefulness of the training or services provided; the impact of the procedures, technology, or services tested; or the validity and applicability of the research conducted. In addition, where appropriate, the evaluation process should be designed to provide ongoing or periodic feedback on the effectiveness or utility of the project in order to promote its continuing improvement. The plan should present the qualifications of the evaluator(s); describe the criteria that would be used to evaluate the project's effectiveness in meeting its objectives; explain how the evaluation would be conducted, including the specific data collection and analysis techniques to be used; discuss why this approach would be appropriate; and present a schedule for completion of the evaluation within the proposed project period.

The evaluation plan should be appropriate to the type of project proposed. For example:

(a) An evaluation approach suited to many research projects is a review by an advisory panel of the research methodology, data collection instruments, preliminary analyses, and products as they are drafted. The panel should be comprised of independent researchers and practitioners representing the perspectives affected by the proposed project.

(b) The most valuable approaches to evaluating educational or training programs reinforce the participants' learning experience while providing useful feedback on the impact of the program and possible areas for improvement. One appropriate evaluation approach is to assess the acquisition of new knowledge, skills, attitudes, or understanding through participant feedback on the seminar or training event. Such feedback might include a self-assessment of what was learned along with the participant's response to the quality and effectiveness of faculty presentations, the format of sessions, the value or usefulness of the material presented, and other relevant factors. Another appropriate approach would be to use an independent observer who might request both verbal and written responses from participants in the program. When an education project involves the development of curricular materials, an advisory panel of relevant experts can be coupled with a test of the curriculum to obtain the reactions of participants and faculty as indicated above.

(c) The evaluation plan for a demonstration project should encompass an assessment of program effectiveness (e.g., how well did it work?); user satisfaction, if appropriate; the cost-effectiveness of the program; a process analysis of the program (e.g., was the program implemented as designed, and/or did it provide the services intended to the targeted population?); the impact of the program (e.g., what effect did the program have on the court, and/or what benefits resulted from the program?); and the replicability of the program or components of the program.

(d) For technical assistance projects, applicants should explain how the quality, timeliness, and impact of the assistance provided would be determined, and develop a mechanism for feedback from both the users and providers of the technical assistance.

Evaluation plans involving human subjects should include a discussion of the procedures for obtaining respondents' informed consent, ensuring the respondents' privacy and freedom from risk or harm, and protecting others who are not the subjects of the evaluation but would be affected by it. Other than the provision of confidentiality to respondents, human subject protection issues ordinarily are not applicable to participants evaluating an education program.

e. Project Management

The applicant should present a detailed management plan, including the starting and completion date for each task; the time commitments to the project of key staff and their responsibilities regarding each project task; and the procedures that would ensure that all tasks are performed on time, within budget, and at the highest level of quality. In preparing the project time line, Gantt Chart, or schedule, applicants should make certain that all project activities, including publication or reproduction of project products and their initial dissemination, would occur within the proposed project period. The management plan must also provide for the submission of Quarterly Progress and Financial Reports within 30 days after the close of each calendar quarter (i.e., no later than January 30, April 30, July 30, and October 30), per section VI.A.13.

Applicants should be aware that the Institute is unlikely to approve a limited extension of the grant period without very good cause. Therefore, the management plan should be as realistic as possible and fully reflect the time commitments of the proposed project staff and consultants.

f. Products

The program narrative in the application should contain a description of the products to be developed (e.g., training curricula and materials, audiotapes, videotapes, DVDs, computer software, CD–ROM disks, articles, guidelines, manuals, reports, handbooks, benchbooks, or books), including when they would be submitted to the Institute. The budget should include the cost of producing and disseminating the product to each in-State SJI library (see Appendix A), State chief justice, State court administrator, and other appropriate judges or court personnel.

(1) Dissemination Plan. The application must explain how and to whom the products would be disseminated; describe how they would benefit the State courts, including how they could be used by judges and court personnel; identify development, production, and dissemination costs covered by the project budget; and present the basis on which products and services developed or provided under the grant would be offered to the courts community and the public at large (i.e., whether products would be distributed at no cost to recipients, or if costs are involved, the reason for charging recipients and the estimated price of the product) (see section VI.A.11.b.). Ordinarily, applicants should schedule all product preparation and distribution activities within the project period.

A copy of each product must be sent to the library established in each State to collect the materials developed with Institute support (see Appendix A). Applicants proposing to develop Web-based products should provide for sending a hard-copy document to the SJI-designated libraries and other appropriate audiences to alert them to the availability of the Web site or electronic product (i.e., a written report with a reference to the Web site).

Fifteen (15) copies of all project products must be submitted to the Institute, along with an electronic version in .html or .pdf format.

(2) Types of Products and Press Releases. The type of product to be prepared depends on the nature of the project. For example, in most instances, the products of a research, evaluation, or demonstration project should include an article summarizing the project findings that is publishable in a journal serving the courts community nationally, an executive summary that would be disseminated to the project's primary audience, or both. Applicants proposing to conduct empirical research or evaluation projects with national import should describe how they would make their data available for secondary analysis after the grant period (see section VI.A.14.a.).

The curricula and other products developed through education and training projects should be designed for use outside the classroom so that they may be used again by the original participants and others in the course of their duties.

In addition, recipients of project grants must prepare a press release describing the project and announcing the results, and distribute the release to a list of national and State judicial branch organizations.

(3) Institute Review. Applicants must submit a final draft of all written grant products to the Institute for review and approval at least 30 days before the products are submitted for publication or reproduction. For products in a videotape or CD–ROM format, applicants must provide for Institute review of the product at the treatment, script, rough-cut, and final stages of development, or their equivalents. No grant funds may be obligated for publication or reproduction of a final grant product without the written approval of the Institute (see section VI.A.11.f.).

(4) Acknowledgment, Disclaimer, and Logo. Applicants must also include in all project products a prominent acknowledgment that support was received from the Institute and a disclaimer paragraph based on the example provided in section VI.A.11.a.2. in the Guideline. The "SJI" logo must appear on the front cover of a written product, or in the opening frames of a video, unless the Institute approves another placement.

g. Applicant Status

An applicant that is not a State or local court and has not received a grant from the Institute within the past three years should state whether it is either a national non-profit organization controlled by, operating in conjunction with, and serving the judicial branches of State governments, or a national non-profit organization for the education and training of State court judges and support personnel (see section II.). If the applicant is a nonjudicial unit of Federal, State, or local government, it must explain whether the proposed services could be adequately provided by non-governmental entities.

h. Staff Capability

The applicant should include a summary of the training and experience of the key staff members and consultants that qualify them for conducting and managing the proposed project. Resumes of identified staff should be attached to the application. If one or more key staff members and consultants are not known at the time of the application, a description of the criteria that would be used to select persons for these positions should be included. The applicant also should identify the person who would be responsible for managing and reporting on the financial aspects of the proposed project.

i. Organizational Capacity

Applicants that have not received a grant from the Institute within the past three years should include a statement describing their capacity to administer grant funds, including the financial systems used to monitor project expenditures (and income, if any), and a summary of their past experience in administering grants, as well as any resources or capabilities that they have that would particularly assist in the successful completion of the project.

Unless requested otherwise, an applicant that has received a grant from the Institute within the past three years should describe only the changes in its organizational capacity, tax status, or financial capability that may affect its capacity to administer a grant.

If the applicant is a non-profit organization (other than a university), it

must also provide documentation of its 501(c) tax-exempt status as determined by the Internal Revenue Service and a copy of a current certified audit report. For purposes of this requirement, "current" means no earlier than two years prior to the present calendar year.

If a current audit report is not available, the Institute will require the organization to complete a financial capability questionnaire, which must be signed by a Certified Public Accountant. Other applicants may be required to provide a current audit report, a financial capability questionnaire, or both, if specifically requested to do so by the Institute.

j. Statement of Lobbying Activities

Non-governmental applicants must submit the Institute's Disclosure of Lobbying Activities Form, which documents whether they, or another entity that is a part of the same organization as the applicant, have advocated a position before Congress on any issue, and identifies the specific subjects of their lobbying efforts (see Appendix B).

k. Letters of Cooperation or Support

If the cooperation of courts, organizations, agencies, or individuals other than the applicant is required to conduct the project, the applicant should attach written assurances of cooperation and availability to the application, or send them under separate cover. To ensure sufficient time to bring them to the Board's attention, letters of support sent under separate cover should be received two weeks in advance of the Board meeting, which can be seen on the Web-site.

4. Budget Narrative

The budget narrative should provide the basis for the computation of all project-related costs. When the proposed project would be partially supported by grants from other funding sources, applicants should make clear what costs would be covered by those other grants. Additional background information or schedules may be attached if they are essential to obtaining a clear understanding of the proposed budget. Numerous and lengthy appendices are strongly discouraged.

The budget narrative should cover the costs of all components of the project and clearly identify costs attributable to the project evaluation. Under OMB grant guidelines incorporated by reference in this Guideline, grant funds may not be used to purchase alcoholic beverages.

a. Justification of Personnel Compensation

The applicant should set forth the percentages of time to be devoted by the individuals who would staff the proposed project, the annual salary of each of those persons, and the number of work days per year used for calculating the percentages of time or daily rates of those individuals. The applicant should explain any deviations from current rates or established written organizational policies. If grant funds are requested to pay the salary and related costs for a current employee of a court or other unit of government, the applicant should explain why this would not constitute a supplantation of State or local funds in violation of 42 U.S.C. 10706(d)(1). An acceptable explanation may be that the position to be filled is a new one established in conjunction with the project or that the grant funds would support only the portion of the employee's time that would be dedicated to new or additional duties related to the project.

b. Fringe Benefit Computation

The applicant should provide a description of the fringe benefits provided to employees. If percentages are used, the authority for such use should be presented, as well as a description of the elements included in the determination of the percentage rate.

c. Consultant/Contractual Services and Honoraria

The applicant should describe the tasks each consultant would perform, the estimated total amount to be paid to each consultant, the basis for compensation rates (e.g., the number of days multiplied by the daily consultant rates), and the method for selection. Rates for consultant services must be set in accordance with section VII.I.2.c. Prior written Institute approval is required for any consultant rate in excess of $800 per day; Institute funds may not be used to pay a consultant more than $1,100 per day. Honorarium payments must be justified in the same manner as consultant payments.

d. Travel

Transportation costs and per diem rates must comply with the policies of the applicant organization. If the applicant does not have an established travel policy, then travel rates must be consistent with those established by the Federal Government. The budget narrative should include an explanation of the rate used, including the components of the per diem rate and the basis for the estimated transportation expenses. The purpose of the travel should also be included in the narrative.

e. Equipment

Grant funds may be used to purchase only the equipment necessary to demonstrate a new technological application in a court or that is otherwise essential to accomplishing the objectives of the project. Equipment purchases to support basic court operations ordinarily will not be approved. The applicant should describe the equipment to be purchased or leased and explain why the acquisition of that equipment is essential to accomplish the project's goals and objectives. The narrative should clearly identify which equipment is to be leased and which is to be purchased. The method of procurement should also be described. Purchases of automated data processing equipment must comply with section VII.I.2.b.

f. Supplies

The applicant should provide a general description of the supplies necessary to accomplish the goals and objectives of the grant. In addition, the applicant should provide the basis for the amount requested for this expenditure category.

g. Construction

Construction expenses are prohibited except for the limited purposes set forth in section VI.A.16.b. Any allowable construction or renovation expense should be described in detail in the budget narrative.

h. Telephone

Applicants should include anticipated telephone charges, distinguishing between monthly charges and long distance charges in the budget narrative. Also, applicants should provide the basis used to calculate the monthly and long distance estimates.

i. Postage

Anticipated postage costs for project-related mailings, including distribution of the final product(s), should be described in the budget narrative. The cost of special mailings, such as for a survey or for announcing a workshop, should be distinguished from routine operational mailing costs. The bases for all postage estimates should be included in the budget narrative.

j. Printing/Photocopying

Anticipated costs for printing or photocopying project documents, reports, and publications should be included in the budget narrative, along

with the bases used to calculate these estimates.

k. Indirect Costs

Recoverable indirect costs are limited to no more than 75 percent of a grantee's direct personnel costs, i.e. salaries plus fringe benefits (see section VII.I.4.).

Applicants should describe the indirect cost rates applicable to the grant in detail. If costs often included within an indirect cost rate are charged directly (e.g., a percentage of the time of senior managers to supervise project activities), the applicant should specify that these costs are not included within its approved indirect cost rate. These rates must be established in accordance with section VII.I.4. If the applicant has an indirect cost rate or allocation plan approved by any Federal granting agency, a copy of the approved rate agreement must be attached to the application.

l. Match

Applicants who do not contemplate making matching contributions continuously throughout the course of the project or on a task-by-task basis must provide a schedule within 30 days after the beginning of the project period indicating at what points during the project period the matching contributions would be made (see sections VI.A.8, and VII.E.1.).

5. Submission Requirements

a. Every applicant must submit an original and three copies of the application package consisting of Form A; Form B, if the application is from a State or local court, or a Disclosure of Lobbying Form (Form E), if the applicant is not a unit of State or local government; Form C; the Application Abstract; the Program Narrative; the Budget Narrative; and any necessary appendices.

Letters of application may be submitted at any time. Applications received by the first day of the second month in a calendar quarter will be considered at the next Board meeting for that quarter. Please mark Project Application on the application package envelope and send it to: State Justice Institute, 1650 King Street, Suite 600, Alexandria, VA 22314.

Receipt of each application will be acknowledged by letter or e-mail.

b. Applicants submitting more than one application may include material that would be identical in each application in a cover letter. This material will be incorporated by reference into each application and counted against the 25-page limit for the program narrative. A copy of the cover letter should be attached to each copy of the application.

B. Technical Assistance (TA) Grants

1. Application Procedures

Applicants for TA Grants may submit, at any time, an original and three copies of a detailed letter describing the proposed project, as well as a Forms A, "State Justice Institute Application" (see Appendix B) and Form B, Certificate of State Approval from the State Supreme Court, or its designated agency and Form C, "Project Budget in Tabular Format." Letters from regional court associations must be signed by the president of the association. The applications received by the first day of the second month in a calendar quarter will be reviewed in the Board meeting for that quarter.

2. Application Format

Although there is no prescribed form for the letter, or a minimum or maximum page limit, letters of application should include the following information:

a. Need for Funding. What is the critical need facing the applicant? How would the proposed technical assistance help the applicant meet this critical need? Why are State or local resources not sufficient to fully support the costs of the required consultant services?

b. Project Description. What tasks would the consultant be expected to perform, and how would they be accomplished? Which organization or individual would be hired to provide the assistance, and how was this consultant selected? If a consultant has not yet been identified, what procedures and criteria would be used to select the consultant (applicants are expected to follow their jurisdictions' normal procedures for procuring consultant services)? What specific tasks would the consultant(s) and court staff undertake? What is the schedule for completion of each required task and the entire project? How would the applicant oversee the project and provide guidance to the consultant, and who at the court or regional court association would be responsible for coordinating all project tasks and submitting quarterly progress and financial status reports?

If the consultant has been identified, the applicant should provide a letter from that individual or organization documenting interest in and availability for the project, as well as the consultant's ability to complete the assignment within the proposed time frame and for the proposed cost. The consultant must agree to submit a detailed written report to the court and the Institute upon completion of the technical assistance.

c. Likelihood of Implementation. What steps have been or would be taken to facilitate implementation of the consultant's recommendations upon completion of the technical assistance? For example, if the support or cooperation of specific court officials or committees, other agencies, funding bodies, organizations, or a court other than the applicant would be needed to adopt the changes recommended by the consultant and approved by the court, how would they be involved in the review of the recommendations and development of the implementation plan?

3. Budget and Matching State Contribution

A completed Form C "Project Budget, Tabular Format" and budget narrative must be included with the letter requesting technical assistance.

The budget narrative should provide the basis for all project-related costs, including the basis for determining the estimated consultant costs, if compensation of the consultant is required (e.g., the number of days per task times the requested daily consultant rate). Applicants should be aware that consultant rates above $800 per day must be approved in advance by the Institute, and that no consultant will be paid more than $1,100 per day from Institute funds. In addition, the budget should provide for submission of two copies of the consultant's final report to the Institute.

Recipients of TA Grants do not have to submit an audit report but must maintain appropriate documentation to support expenditures (see section VI.A.3.).

4. Submission Requirements

Letters of application may be submitted at any time and will be considered on a quarterly rolling basis. Applications should be received by the first day of the second month of a calendar quarter in order to be reviewed at the Board meeting for that quarter.

If the support or cooperation of agencies, funding bodies, organizations, or courts other than the applicant would be needed in order for the consultant to perform the required tasks, written assurances of such support or cooperation should accompany the application letter. Support letters also may be submitted under separate cover; however, to ensure that there is sufficient time to bring them to the attention of the Institute's Board of Directors, letters sent under separate

cover must be received by the same date as the technical assistance request being supported.

C. Curriculum Adaptation and Training (CAT) Grants

1. Application Procedures

In lieu of formal applications, applicants should submit an original and three photocopies of a detailed letter as well as a Form A, "State Justice Institute Application;" Form B, "Certificate of State Approval;" and Form C, "Project Budget, Tabular Format" (see Appendices).

2. Application Format

Although there is no prescribed format for the letter, or a minimum or maximum page limit, letters of application should include the following information:

a. For adaptation of a curriculum:

(1) Project Description. What is the title of the model curriculum to be adapted and who originally developed it? Why is this education program needed at the present time? What are the project's goals? What are the learning objectives of the adapted curriculum? What program components would be implemented, and what types of modifications, if any, are anticipated in length, format, learning objectives, teaching methods, or content? Who would be responsible for adapting the model curriculum? Who would the participants be, how many would there be, how would they be recruited, and from where would they come (e.g., from a single local jurisdiction, from across the State, from a multi-State region, from across the nation)?

(2) Need for Funding. Why are sufficient State or local resources unavailable to fully support the modification and presentation of the model curriculum? What is the potential for replicating or integrating the adapted curriculum in the future using State or local funds, once it has been successfully adapted and tested?

(3) Likelihood of Implementation. What is the proposed timeline, including the project start and end dates? On what date(s) would the judicial branch education program be presented? What process would be used to modify and present the program? Who would serve as faculty, and how were they selected? What measures would be taken to facilitate subsequent presentations of the program? Ordinarily, an independent evaluation of a curriculum adaptation project is not required; however, the results of any evaluation should be included in the final report.

(4) Expressions of Interest by Judges and/or Court Personnel. Does the proposed program have the support of the court system or association leadership, and of judges, court managers, and judicial branch education personnel who are expected to attend? Applicants may demonstrate this by attaching letters of support.

b. For training assistance:

(1) Need for Funding. What is the court reform or initiative prompting the need for training? How would the proposed training help the applicant implement planned changes at the court? Why are State or local resources not sufficient to fully support the costs of the required training?

(2) Project Description. What tasks would the trainer(s) be expected to perform, and how would they be accomplished? Which organization or individual would be hired, if in-house personnel are not the trainers, to provide the training, and how was the trainer selected? If a trainer has not yet been identified, what procedures and criteria would be used to select the trainer? [**Note:** Applicants are expected to follow their jurisdictions' normal procedures for procuring consultant services.] What specific tasks would the trainer and court staff or regional court association members undertake? What presentation methods will be used? What is the schedule for completion of each required task and the entire project? How would the applicant oversee the project and provide guidance to the trainer, and who at the court or affiliated with the regional court association would be responsible for coordinating all project tasks and submitting quarterly progress and financial status reports? If the trainer has been identified, the applicant should provide a letter from that individual or organization documenting interest in and availability for the project, as well as the trainer's ability to complete the assignment within the proposed time frame and for the proposed cost. The trainer must agree to submit a detailed written report to the court and the Institute upon completion of the technical assistance.

(3) Likelihood of Implementation. What steps have been or would be taken to coordinate the implementation of the new reform, initiative, etc. and the training to support the same? For example, if the support or cooperation of specific court or regional court association officials or committees, other agencies, funding bodies, organizations, or a court other than the applicant would be needed to adopt the reform and initiate the training proposed, how would they be involved in the review of the recommendations and development of the implementation plan?

3. Budget and Matching State Contribution

Applicants should attach a copy of budget Form C and a budget narrative (see subsection A.4. above) that describes the basis for the computation of all project-related costs and the source of the match offered.

4. Submission Requirements

Letters of application may be submitted at any time and will be considered on a quarterly rolling basis. Applications should be received by the first day of the second month of a calendar quarter in order to be reviewed at the Board meeting for that quarter. Dates of Board meetings will be available on the Web site: *www.Statejustice.org.*

For curriculum adaptation requests, applicants should allow at least 90 days between the Board meeting and the date of the proposed program to allow sufficient time for needed planning. Applicants are encouraged to call SJI staff to discuss concerns about timing of submissions.

D. Partner Grants

The Institute and its funding partners may meld, pick and choose, or waive their application procedures, grant cycles, or grant requirements to expedite the award of jointly-funded grants targeted at emerging or high priority problems confronting State and local courts. The Institute may solicit brief proposals from potential grantees to propose to fellow financial partners as a first step. Should the Institute be chosen as the lead grant manager, Project Grant application procedures will apply to the proposed Partner Grant. As with Project Grants, Partner Grants will be targeted at initiatives likely to have a significant national impact.

E. Scholarships

1. Limitations

Applicants may not receive more than one scholarship in a two-year period unless the course specifically assumes multi-year participation or the course is part of a graduate degree program in judicial studies in which the applicant is currently enrolled (neither exception should be taken as a commitment on the part of the Institute's Board of Directors to approve serial scholarships). Attendance at annual or mid-year meetings of a State or national organization does not qualify as an out-of-State educational program for

scholarship purposes, even though it may include workshops or other training sessions.

Scholarship funds may be used only to cover the costs of tuition, transportation, and reasonable lodging expenses (not to exceed $150 per night, including taxes). Transportation expenses may include round-trip coach airfare or train fare. Scholarship recipients are strongly encouraged to take advantage of excursion or other special airfares (e.g., reductions offered when a ticket is purchased 21 days in advance of the travel date) when making their travel arrangements. Recipients who drive to a program site may receive $.485/mile up to the amount of the advanced-purchase round-trip airfare between their homes and the program sites. Funds to pay tuition, transportation, and lodging expenses in excess of $1,500 and other costs of attending the program—such as meals, materials, transportation to and from airports, and local transportation (including rental cars)—at the program site must be obtained from other sources or borne by the scholarship recipient. Scholarship applicants are encouraged to check other sources of financial assistance and to combine aid from various sources whenever possible. A scholarship is not transferable to another individual. It may be used only for the course specified in the application unless the applicant's request to attend a different course that meets the eligibility requirements is approved in writing by the Institute. Decisions on such requests will be made within 30 days after the receipt of the request letter.

2. Eligibility Requirements

a. Recipients. Scholarships can be awarded only to full-time judges of State or local trial and appellate courts; full-time professional, State, or local court personnel with management responsibilities; and supervisory and management probation personnel in judicial branch probation offices. Senior judges, part-time judges, quasi-judicial hearing officers including referees and commissioners, administrative law judges, staff attorneys, law clerks, line staff, law enforcement officers, and other executive branch personnel are not eligible to receive a scholarship.

b. Courses. A scholarship can be awarded only for: (1) A course presented in a State other than the one in which the applicant resides or works, or (2) an online course. The course must be designed to enhance the skills of new or experienced judges and court managers; or be offered by a recognized graduate program for judges or court managers.

Applicants are encouraged not to wait for the decision on a scholarship to register for an educational program they wish to attend. The Institute does not submit the names of scholarship recipients to educational organizations.

3. Forms

a. Scholarship Application—Form S1 (Appendix D). The Scholarship Application requests basic information about the applicant and the educational program the applicant would like to attend. It also addresses the applicant's commitment to share the skills and knowledge gained with local court colleagues and to submit an evaluation of the program the applicant attends. The Scholarship Application must bear the original signature of the applicant. Faxed or photocopied signatures will not be accepted. Please be sure to indicate whether the State will be providing funds for the project and, if so, how much. The Institute will not supplant State funds for these scholarships: it can only provide funding above the amount to be covered by the State.

b. Scholarship Application Concurrence—Form S2 (Appendix D). Judges and court managers applying for scholarships must submit the written concurrence of the Chief Justice of the State's Supreme Court (or the Chief Justice's designee) on the Institute's Judicial Education Scholarship Concurrence form (see Appendix D). The signature of the presiding judge of the applicant's court may not be substituted for that of the Chief Justice or the Chief Justice's designee. Court managers, other than elected clerks of court, also must submit a letter of support from their immediate supervisors.

4. Submission Requirements

Scholarship applications may be submitted at any time but will be reviewed on a quarterly basis. This means scholarships will be awarded on a "first come, first considered" basis, although the Institute will attempt to award programs equitably over the year. The dates for applications to be received by the Institute for consideration in FY 08 are November 1, February 1, May 1, and August 1. (These are NOT mailing deadlines. The applications must be received by the Institute by each of these dates.) No exceptions or extensions will be granted. All the required items must be received for an application to be considered. If the Concurrence form or letter of support is sent separately from the application, the postmark date of the last item to be sent will be used in determining the review date.

All applications should be sent by mail or courier (not fax or e-mail) to: Scholarship Program Coordinator, State Justice Institute, 1650 King Street, Suite 600, Alexandria, VA 22314.

V. Application Review Procedures

A. Preliminary Inquiries

The Institute staff will answer inquiries concerning application procedures. The staff contact will be named in the Institute's letter or e-mail acknowledging receipt of the application.

B. Selection Criteria

1. Project Grant Applications

a. Project Grant applications will be rated on the basis of the criteria set forth below. The Institute will accord the greatest weight to the following criteria:

(1) The soundness of the methodology;

(2) The demonstration of need for the project;

(3) The appropriateness of the proposed evaluation design;

(4) If applicable, the key findings and recommendations of the most recent evaluation and the proposed responses to those findings and recommendations;

(5) The applicant's management plan and organizational capabilities;

(6) The qualifications of the project's staff;

(7) The products and benefits resulting from the project, including the extent to which the project will have long-term benefits for State courts across the nation;

(8) The degree to which the findings, procedures, training, technology, or other results of the project can be transferred to other jurisdictions;

(9) The reasonableness of the proposed budget; and

(10) The demonstration of cooperation and support of other agencies that may be affected by the project.

(11) The proposed project's relationship to one of the Special Interest Criteria and Categories set forth in section III.A.

b. In determining which projects to support, the Institute will also consider whether the applicant is a State court, a national court support or education organization, a non-court unit of government, or other type of entity eligible to receive grants under the Institute's enabling legislation (see section II.); the availability of financial assistance from other sources for the project; the amount of the applicant's match; the extent to which the proposed project would also benefit the Federal

courts or help State courts enforce Federal constitutional and legislative requirements; and the level of appropriations available to the Institute in the current year and the amount expected to be available in succeeding fiscal years.

2. Technical Assistance (TA) Grant Applications

TA Grant applications will be rated on the basis of the following criteria:

a. Whether the assistance would address a critical need of the applicant;

b. The soundness of the technical assistance approach to the problem;

c. The qualifications of the consultant(s) to be hired or the specific criteria that will be used to select the consultant(s);

d. The commitment of the court or association to act on the consultant's recommendations; and

e. The reasonableness of the proposed budget.

The Institute also will consider factors such as the level and nature of the match that would be provided, diversity of subject matter, geographic diversity, the level of appropriations available to the Institute in the current year, and the amount expected to be available in succeeding fiscal years.

3. Curriculum Adaptation and Training (CAT) Grant Applications

CAT Grant applications will be rated on the basis of the following criteria:

a. For curriculum adaptation projects:

(1) The goals and objectives of the proposed project;

(2) The need for outside funding to support the program;

(3) The appropriateness of the approach in achieving the project's educational objectives;

(4) The likelihood of effective implementation and integration of the modified curriculum into ongoing educational programming; and

(5) Expressions of interest by the judges and/or court personnel who would be directly involved in or affected by the project.

b. For training assistance:

(1) Whether the training would address a critical need of the court or association;

(2) The soundness of the training approach to the problem;

(3) The qualifications of the trainer(s) to be hired or the specific criteria that will be used to select the trainer(s);

(4) The commitment of the court or association to the training program; and

(5) The reasonableness of the proposed budget. The Institute will also consider factors such as the reasonableness of the amount requested, compliance with match requirements, diversity of subject matter, geographic diversity, the level of appropriations available in the current year, and the amount expected to be available in succeeding fiscal years.

4. Partner Grants

The selection criteria for Partner Grants will be driven by the collective priorities of the Institute and other organizations and their collective assessments regarding the needs and capabilities of court and court-related organizations. Having settled on priorities, the Institute and its financial partners will likely contact the courts or court-related organizations most acceptable as pilots, laboratories, consultants, or the like. Should the Institute be chosen as the lead grant manager, Project application review procedures will apply to the proposed Partner Grant.

5. Scholarships

Scholarships will be approved only for programs that either (1) enhance the skills of judges and court managers; or (2) are part of a graduate degree program for judges or court personnel. Scholarships will be awarded on the basis of:

a. The date on which the application and concurrence (and support letter, if required) were sent ("first come, first considered");

b. The unavailability of State or local funds or scholarship funds from another source to cover the costs of attending the program, or participating online;

c. The absence of educational programs in the applicant's State addressing the topic(s) covered by the educational program for which the scholarship is being sought;

d. Geographic balance among the recipients;

e. The balance of scholarships among educational providers and programs;

f. The balance of scholarships among the types of courts and court personnel (trial judge, appellate judge, trial court administrator) represented; and

g. The level of appropriations available to the Institute in the current year and the amount expected to be available in succeeding fiscal years.

The postmark or courier receipt will be used to determine the date on which the application form and other required items were sent.

C. Review and Approval Process

1. Project Grant Applications

The Institute's Board of Directors will review the applications competitively. The Institute staff will prepare a narrative summary and a rating sheet assigning points for each relevant selection criterion. The staff will present the narrative summaries and rating sheets to the Board for its review. The Board will review all application summaries and decide which projects it will fund. The decision to fund a project is solely that of the Board of Directors.

The Chairman of the Board will sign approved awards on behalf of the Institute.

2. Technical Assistance (TA) and Curriculum Adaptation and Training (CAT) Grant Applications

The Institute staff will prepare a narrative summary of each application and a rating sheet assigning points for each relevant selection criterion. The Board of Directors may delegate its authority to approve TA and CAT Grants to the committee established for each program. The Board or the committee will review the applications competitively. The Chairman of the Board will sign approved awards on behalf of the Institute.

3. Scholarships

A committee of the Institute's Board of Directors will review scholarship applications quarterly. The Board of Directors has delegated its authority to approve scholarships to the committee established for the program. The committee will review the applications competitively. In the event of a tie vote, the Chairman will serve as the tie-breaker. The Chairman of the Board will sign approved awards on behalf of the Institute.

4. Partner Grants

The Institute's internal process for the review and approval of Partner Grants will depend upon negotiations with fellow financiers. The Institute may use its procedures, a partner's procedures, a mix of both, or entirely unique procedures. All Partner Grants will be approved by the Board of Directors on whatever schedule makes sense at the time.

D. Return Policy

Unless a specific request is made, unsuccessful applications will not be returned. Applicants are advised that Institute records are subject to the provisions of the Federal Freedom of Information Act, 5 U.S.C. 552.

E. Notification of Board Decision

The Institute will send written notice to applicants concerning all Board decisions to approve, defer, or deny their respective applications. For all applications (except scholarships), the

Institute also will convey the key issues and questions that arose during the review process. A decision by the Board to deny an application may not be appealed, but it does not prohibit resubmission of a proposal based on that application in a subsequent funding cycle. The Institute will also notify the State court administrator when grants are approved by the Board to support projects that will be conducted by or involve courts in that State.

F. Response to Notification of Approval

With the exception of those approved for scholarships, applicants have 30 days from the date of the letter notifying them that the Board has approved their application to respond to any revisions requested by the Board. If the requested revisions (or a reasonable schedule for submitting such revisions) have not been submitted to the Institute within 30 days after notification, the approval may be rescinded and the application presented to the Board for reconsideration. In the event an issue will only be resolved after award, such as the selection of a consultant, the final award document will include a Special Condition that will require additional grantee reporting and Institute review and approval. Special Conditions, in the form of incentives or sanctions, may also be used in situations where past poor performance by a grantee necessitates increased grant oversight.

VI. Compliance Requirements

The State Justice Institute Act contains limitations and conditions on grants, contracts, and cooperative agreements awarded by the Institute. The Board of Directors has approved additional policies governing the use of Institute grant funds. These statutory and policy requirements are set forth below.

A. Recipients of Project Grants

1. Advocacy

No funds made available by the Institute may be used to support or conduct training programs for the purpose of advocating particular nonjudicial public policies or encouraging nonjudicial political activities (42 U.S.C. 10706(b)).

2. Approval of Key Staff

If the qualifications of an employee or consultant assigned to a key project staff position are not described in the application or if there is a change of a person assigned to such a position, the recipient must submit a description of the qualifications of the newly assigned person to the Institute. Prior written approval of the qualifications of the new person assigned to a key staff position must be received from the Institute before the salary or consulting fee of that person and associated costs may be paid or reimbursed from grant funds (see section VIII.A.7.).

3. Audit

Recipients of project grants must provide for an annual fiscal audit which includes an opinion on whether the financial statements of the grantee present fairly its financial position and its financial operations are in accordance with generally accepted accounting principles (see section VII.K. for the requirements of such audits). Scholarship recipients, Curriculum Adaptation and Training Grants, and Technical Assistance Grants are not required to submit an audit, but they must maintain appropriate documentation to support all expenditures (see section VIII.K.).

4. Budget Revisions

Budget revisions among direct cost categories that: (a) Transfer grant funds to an unbudgeted cost category, or (b) individually or cumulatively exceed five percent of the approved original budget or the most recently approved revised budget require prior Institute approval (see section VIII.A.1.).

5. Conflict of Interest

Personnel and other officials connected with Institute-funded programs must adhere to the following requirements:

a. No official or employee of a recipient court or organization shall participate personally through decision, approval, disapproval, recommendation, the rendering of advice, investigation, or otherwise in any proceeding, application, request for a ruling or other determination, contract, grant, cooperative agreement, claim, controversy, or other particular matter in which Institute funds are used, where, to his or her knowledge, he or she or his or her immediate family, partners, organization other than a public agency in which he or she is serving as officer, director, trustee, partner, or employee or any person or organization with whom he or she is negotiating or has any arrangement concerning prospective employment, has a financial interest.

b. In the use of Institute project funds, an official or employee of a recipient court or organization shall avoid any action which might result in or create the appearance of:

(1) Using an official position for private gain; or

(2) Affecting adversely the confidence of the public in the integrity of the Institute program.

c. Requests for proposals or invitations for bids issued by a recipient of Institute funds or a subgrantee or subcontractor will provide notice to prospective bidders that the contractors who develop or draft specifications, requirements, statements of work, and/or requests for proposals for a proposed procurement will be excluded from bidding on or submitting a proposal to compete for the award of such procurement.

6. Inventions and Patents

If any patentable items, patent rights, processes, or inventions are produced in the course of Institute-sponsored work, such fact shall be promptly and fully reported to the Institute. Unless there is a prior agreement between the grantee and the Institute on disposition of such items, the Institute shall determine whether protection of the invention or discovery shall be sought. The Institute will also determine how the rights in the invention or discovery, including rights under any patent issued thereon, shall be allocated and administered in order to protect the public interest consistent with "'Government Patent Policy'" (President's Memorandum for Heads of Executive Departments and Agencies, February 18, 1983, and statement of Government Patent Policy).

7. Lobbying

a. Funds awarded to recipients by the Institute shall not be used, indirectly or directly, to influence Executive Orders or similar promulgations by Federal, State or local agencies, or to influence the passage or defeat of any legislation by Federal, State or local legislative bodies (42 U.S.C. 10706(a)).

b. It is the policy of the Board of Directors to award funds only to support applications submitted by organizations that would carry out the objectives of their applications in an unbiased manner. Consistent with this policy and the provisions of 42 U.S.C. 10706, the Institute will not knowingly award a grant to an applicant that has, directly or through an entity that is part of the same organization as the applicant, advocated a position before Congress on the specific subject matter of the application.

8. Matching Requirements

All grantees other than scholarship recipients are required to provide a match. A match is the portion of project costs not borne by the Institute. Match includes both cash and in-kind contributions. Cash match is the direct

outlay of funds by the grantee or a third party to support the project. Examples of cash match are the dedication of funds to support a new employee or purchase new equipment to carry out the project or the application of project income (e.g., tuition or the proceeds of sales of grant products) generated during the grant period to grant costs. In-kind match consists of contributions of time and/or services of current staff members, space, supplies, etc., made to the project by the grantee or others (e.g., advisory board members) working directly on the project or that portion of the grantee's Federally approved indirect cost rate that exceeds the Guideline's limit of permitted charges (75% of salaries and benefits).

Under normal circumstances, allowable match may be incurred only during the project period. When appropriate, and with the prior written permission of the Institute, match may be incurred from the date of the Board of Directors' approval of an award. Match does not include the time of participants attending an education program. The amount and nature of required match depends on the type of grant (see section III.).

The grantee is responsible for ensuring that the total amount of match proposed is actually contributed. If a proposed contribution is not fully met, the Institute may reduce the award amount accordingly, in order to maintain the ratio originally provided for in the award agreement (see section VII.E.1.).

The Board of Directors looks favorably upon any unrequired match contributed by applicants when making grant decisions. The match requirement may be waived in exceptionally rare circumstances upon the request of the Chief Justice of the highest court in the State or the highest ranking official in the requesting organization and approval by the Board of Directors (42 U.S.C. 10705(d)). The Board of Directors encourages all applicants to provide the maximum amount of cash and in-kind match possible, even if a waiver is approved. The amount and nature of match are criteria in the grant selection process (see section V.B.1.b.).

9. Nondiscrimination

No person may, on the basis of race, sex, national origin, disability, color, or creed be excluded from participation in, denied the benefits of, or otherwise subjected to discrimination under any program or activity supported by Institute funds. Recipients of Institute funds must immediately take any measures necessary to effectuate this provision.

10. Political Activities

No recipient may contribute or make available Institute funds, program personnel, or equipment to any political party or association, or the campaign of any candidate for public or party office. Recipients are also prohibited from using funds in advocating or opposing any ballot measure, initiative, or referendum. Officers and employees of recipients shall not intentionally identify the Institute or recipients with any partisan or nonpartisan political activity associated with a political party or association, or the campaign of any candidate for public or party office (42 U.S.C. 10706(a)).

11. Products

a. Acknowledgment, Logo, and Disclaimer

(1) Recipients of Institute funds must acknowledge prominently on all products developed with grant funds that support was received from the Institute. The "SJI" logo must appear on the front cover of a written product, or in the opening frames of a video product, unless another placement is approved in writing by the Institute. This includes final products printed or otherwise reproduced during the grant period, as well as reprintings or reproductions of those materials following the end of the grant period. A camera-ready logo sheet is available on the Institute's web site: *www.statejustice.org.*

(2) Recipients also must display the following disclaimer on all grant products: "'This [document, film, videotape, etc.] was developed under [grant/cooperative agreement] number SJI-[insert number] from the State Justice Institute. The points of view expressed are those of the [author(s), filmmaker(s), etc.] and do not necessarily represent the official position or policies of the State Justice Institute."

b. Charges for Grant-Related Products/ Recovery of Costs

(1) When Institute funds fully cover the cost of developing, producing, and disseminating a product (*e.g.*, a report, curriculum, videotape, or software), the product should be distributed to the field without charge. When Institute funds only partially cover the development, production, or dissemination costs, the grantee may, with the Institute's prior written approval, recover its costs for developing, producing, and disseminating the material to those requesting it, to the extent that those costs were not covered by Institute funds or grantee matching contributions.

(2) Applicants should disclose their intent to sell grant-related products in the application. Grantees must obtain the written prior approval of the Institute of their plans to recover project costs through the sale of grant products. Written requests to recover costs ordinarily should be received during the grant period and should specify the nature and extent of the costs to be recouped, the reason that such costs were not budgeted (if the rationale was not disclosed in the approved application), the number of copies to be sold, the intended audience for the products to be sold, and the proposed sale price. If the product is to be sold for more than $25, the written request also should include a detailed itemization of costs that will be recovered and a certification that the costs were not supported by either Institute grant funds or grantee matching contributions.

(3) In the event that the sale of grant products results in revenues that exceed the costs to develop, produce, and disseminate the product, the revenue must continue to be used for the authorized purposes of the Institute-funded project or other purposes consistent with the State Justice Institute Act that have been approved by the Institute (see section VII.G.).

c. Copyrights

Except as otherwise provided in the terms and conditions of an Institute award, a recipient is free to copyright any books, publications, or other copyrightable materials developed in the course of an Institute-supported project, but the Institute shall reserve a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use, and to authorize others to use, the materials for purposes consistent with the State Justice Institute Act.

d. Due Date

All products and, for TA and CAT grants, consultant and/or trainer reports (see section VI.B.1 & 2) are to be completed and distributed (see below) not later than the end of the award period, not the 90-day close out period. The latter is only intended for grantee final reporting and to liquidate obligations (see section VII.L.).

e. Distribution

In addition to the distribution specified in the grant application, grantees shall send:

(1) Fifteen (15) copies of each final product developed with grant funds to

the Institute, unless the product was developed under either a Technical Assistance or a Curriculum Adaptation and Training Grant, in which case submission of 2 copies is required;

(2) An electronic version of the product in .html or .pdf format to the Institute; and

(3) One copy of each final product developed with grant funds to the library established in each State to collect materials prepared with Institute support. A list of the libraries is contained in Appendix A. Labels for these libraries are available on the Institute's Web site, *http://www.statejustice.org.*

(4) Bound copies of products, where possible and cost-effective, rather than hard copies in ring binders, to SJI depository libraries. Grantees that develop Web-based electronic products must send a hard-copy document to the SJI-designated libraries and other appropriate audiences to alert them to the availability of the Web site or electronic product. Recipients of Technical Assistance and Curriculum Adaptation and Training Grants are not required to submit final products to State libraries.

(5) A press release describing the project and announcing the results to a list of national and State judicial branch organizations provided by the Institute.

f. Institute Approval

No grant funds may be obligated for publication or reproduction of a final product developed with grant funds without the written approval of the Institute. Grantees shall submit a final draft of each written product to the Institute for review and approval. The draft must be submitted at least 30 days before the product is scheduled to be sent for publication or reproduction to permit Institute review and incorporation of any appropriate changes required by the Institute. Grantees must provide for timely reviews by the Institute of videotape, DVD or CD'ROM products at the treatment, script, rough cut, and final stages of development or their equivalents.

g. Original Material

All products prepared as the result of Institute-supported projects must be originally-developed material unless otherwise specified in the award documents. Material not originally developed that is included in such products must be properly identified, whether the material is in a verbatim or extensive paraphrase format.

12. Prohibition Against Litigation Support

No funds made available by the Institute may be used directly or indirectly to support legal assistance to parties in litigation, including cases involving capital punishment.

13. Reporting Requirements

a. Recipients of Institute funds other than scholarships must submit Quarterly Progress and Financial Status Reports within 30 days of the close of each calendar quarter (that is, no later than January 30, April 30, July 30, and October 30). The Quarterly Progress Reports shall include a narrative description of project activities during the calendar quarter, the relationship between those activities and the task schedule and objectives set forth in the approved application or an approved adjustment thereto, any significant problem areas that have developed and how they will be resolved, and the activities scheduled during the next reporting period. Failure to comply with the requirements of this provision could result in the termination of a grantee's award.

b. The quarterly Financial Status Report must be submitted in accordance with section VII.H.2. of this Guideline. A final project Progress Report and Financial Status Report shall be submitted within 90 days after the end of the grant period in accordance with section VII.L.1. of this Guideline.

14. Research

a. Availability of Research Data for Secondary Analysis

Upon request, grantees must make available for secondary analysis a diskette(s) or data tape(s) containing research and evaluation data collected under an Institute grant and the accompanying code manual. Grantees may recover the actual cost of duplicating and mailing or otherwise transmitting the data set and manual from the person or organization requesting the data. Grantees may provide the requested data set in the format in which it was created and analyzed.

b. Confidentiality of Information

Except as provided by Federal law other than the State Justice Institute Act, no recipient of financial assistance from SJI may use or reveal any research or statistical information furnished under the Act by any person and identifiable to any specific private person for any purpose other than the purpose for which the information was obtained. Such information and copies thereof shall be immune from legal process, and shall not, without the consent of the person furnishing such information, be admitted as evidence or used for any purpose in any action, suit, or other judicial, legislative, or administrative proceedings.

c. Human Subject Protection

Human subjects are defined as individuals who are participants in an experimental procedure or who are asked to provide information about themselves, their attitudes, feelings, opinions, and/or experiences through an interview, questionnaire, or other data collection technique. All research involving human subjects shall be conducted with the informed consent of those subjects and in a manner that will ensure their privacy and freedom from risk or harm and the protection of persons who are not subjects of the research but would be affected by it, unless such procedures and safeguards would make the research impractical. In such instances, the Institute must approve procedures designed by the grantee to provide human subjects with relevant information about the research after their involvement and to minimize or eliminate risk or harm to those subjects due to their participation.

15. State and Local Court Applications

Each application for funding from a State or local court must be approved, consistent with State law, by the State's Supreme Court, or its designated agency or council. The Supreme Court or its designee shall receive, administer, and be accountable for all funds awarded on the basis of such an application (42 U.S.C. 10705(b)(4)). See section VII.C.2.

16. Supplantation and Construction

To ensure that funds are used to supplement and improve the operation of State courts, rather than to support basic court services, funds shall not be used for the following purposes:

a. To supplant State or local funds supporting a program or activity (such as paying the salary of court employees who would be performing their normal duties as part of the project, or paying rent for space which is part of the court's normal operations);

b. To construct court facilities or structures, except to remodel existing facilities or to demonstrate new architectural or technological techniques, or to provide temporary facilities for new personnel or for personnel involved in a demonstration or experimental program; or

c. Solely to purchase equipment.

17. Suspension or Termination of Funding

After providing a recipient reasonable notice and opportunity to submit written documentation demonstrating why fund termination or suspension should not occur, the Institute may terminate or suspend funding of a project that fails to comply substantially with the Act, the Guideline, or the terms and conditions of the award (42 U.S.C. 10708(a)).

18. Title to Property

At the conclusion of the project, title to all expendable and nonexpendable personal property purchased with Institute funds shall vest in the recipient court, organization, or individual that purchased the property if certification is made to and approved by the Institute that the property will continue to be used for the authorized purposes of the Institute-funded project or other purposes consistent with the State Justice Institute Act. If such certification is not made or the Institute disapproves such certification, title to all such property with an aggregate or individual value of $1,000 or more shall vest in the Institute, which will direct the disposition of the property.

B. Recipients of Technical Assistance (TA) and Curriculum Adaptation and Training (CAT) Grants

Recipients of TA and CAT Grants must comply with the requirements listed in section VI.A. (except the requirements pertaining to audits in subsection A.3. above and product dissemination and approval in subsection A.11.e. and f. above) and the reporting requirements below:

1. Technical Assistance (TA) Grant Reporting Requirements

Recipients of TA Grants must submit to the Institute one copy of a final report that explains how it intends to act on the consultant's recommendations, as well as two copies of the consultant's written report.

2. Curriculum Adaptation and Training (CAT) Grant Reporting Requirements

Recipients of CAT Grants must submit one copy of the agenda or schedule, outline of presentations and/or relevant instructor's notes, copies of overhead transparencies, power point presentations, or other visual aids, exercises, case studies and other background materials, hypotheticals, quizzes, and other materials involving the participants, manuals, handbooks, conference packets, evaluation forms, and suggestions for replicating the program, including possible faculty or the preferred qualifications or experience of those selected as faculty, developed under the grant at the conclusion of the grant period, along with a final report that includes any evaluation results and explains how the grantee intends to present the educational program in the future, as well as two copies of the consultant's or trainer's report.

C. Scholarship Recipients

1. Scholarship recipients are responsible for disseminating the information received from the course to their court colleagues locally and, if possible, throughout the State (*e.g.*, by developing a formal seminar, circulating the written material, or discussing the information at a meeting or conference).

Recipients also must submit to the Institute a certificate of attendance at the program, an evaluation of the educational program they attended, and a copy of the notice of any scholarship funds received from other sources. A copy of the evaluation must be sent to the Chief Justice of the scholarship recipient's State. A State or local jurisdiction may impose additional requirements on scholarship recipients.

2. To receive the funds authorized by a scholarship award, recipients must submit a Scholarship Payment Voucher (Form S3) together with a tuition statement from the program sponsor, a transportation fare receipt (or statement of the driving mileage to and from the recipient's home to the site of the educational program), and a lodging receipt.

Scholarship Payment Vouchers must be submitted within 90 days after the end of the course, which the recipient attended.

3. Scholarship recipients are encouraged to check with their tax advisors to determine whether the scholarship constitutes taxable income under Federal and State law.

D. Partner Grants

The compliance requirements for Partner Grant recipients will depend upon the agreements struck between the grant financiers and between lead financiers and grantees. Should SJI be the lead, the compliance requirements for Project Grants will apply.

VII. Financial Requirements

A. Purpose

The purpose of this section is to establish accounting system requirements and offer guidance on procedures to assist all grantees, subgrantees, contractors, and other organizations in:

1. Complying with the statutory requirements for the award, disbursement, and accounting of funds;

2. Complying with regulatory requirements of the Institute for the financial management and disposition of funds;

3. Generating financial data to be used in planning, managing, and controlling projects; and

4. Facilitating an effective audit of funded programs and projects.

B. References

Except where inconsistent with specific provisions of this Guideline, the following circulars are applicable to Institute grants and cooperative agreements under the same terms and conditions that apply to Federal grantees. The circulars supplement the requirements of this section for accounting systems and financial record-keeping and provide additional guidance on how these requirements may be satisfied (circulars may be obtained on the OMB Web site at *http://www.whitehouse.gov/omb*).

1. *Office of Management and Budget (OMB) Circular A–21*, Cost Principles for Educational Institutions.

2. *Office of Management and Budget (OMB) Circular A–87*, Cost Principles for State and Local Governments.

3. *Office of Management and Budget (OMB) Circular A–102*, Uniform Administrative Requirements for Grants-in-Aid to State and Local Governments.

4. *Office of Management and Budget (OMB) Circular A–110*, Grants and Agreements with Institutions of Higher Education, Hospitals and Other Non-Profit Organizations.

5. *Office of Management and Budget (OMB) Circular A–122*, Cost Principles for Non-profit Organizations.

6. *Office of Management and Budget (OMB) Circular A–133*, Audits of States, Local Governments and Non-profit Organizations.

C. Supervision and Monitoring Responsibilities

1. Grantee Responsibilities

All grantees receiving awards from the Institute are responsible for the management and fiscal control of all funds. Responsibilities include accounting for receipts and expenditures, maintaining adequate financial records, and refunding expenditures disallowed by audits.

2. Responsibilities of State Supreme Court

a. Each application for funding from a State or local court must be approved,

consistent with State law, by the State's Supreme Court, or its designated agency or council.

b. The State Supreme Court or its designee shall receive all Institute funds awarded to such courts; be responsible for assuring proper administration of Institute funds; and be responsible for all aspects of the project, including proper accounting and financial record-keeping by the subgrantee. These responsibilities include:

(1) Reviewing Financial Operations. The State Supreme Court or its designee should be familiar with, and periodically monitor, its subgrantees' financial operations, records system, and procedures. Particular attention should be directed to the maintenance of current financial data.

(2) Recording Financial Activities. The subgrantee's grant award or contract obligation, as well as cash advances and other financial activities, should be recorded in the financial records of the State Supreme Court or its designee in summary form. Subgrantee expenditures should be recorded on the books of the State Supreme Court OR evidenced by report forms duly filed by the subgrantee. Matching contributions provided by subgrantees should likewise be recorded, as should any project income resulting from program operations.

(3) Budgeting and Budget Review. The State Supreme Court or its designee should ensure that each subgrantee prepares an adequate budget as the basis for its award commitment. The State Supreme Court should maintain the details of each project budget on file.

(4) Accounting for Match. The State Supreme Court or its designee will ensure that subgrantees comply with the match requirements specified in this Guideline (see section VI.A.8.).

(5) Audit Requirement. The State Supreme Court or its designee is required to ensure that subgrantees meet the necessary audit requirements set forth by the Institute (see sections K. below and VI.A.3.).

(6) Reporting Irregularities. The State Supreme Court, its designees, and its subgrantees are responsible for promptly reporting to the Institute the nature and circumstances surrounding any financial irregularities discovered.

D. Accounting System

The grantee is responsible for establishing and maintaining an adequate system of accounting and internal controls and for ensuring that an adequate system exists for each of its subgrantees and contractors. An acceptable and adequate accounting system:

1. Properly accounts for receipt of funds under each grant awarded and the expenditure of funds for each grant by category of expenditure (including matching contributions and project income);

2. Assures that expended funds are applied to the appropriate budget category included within the approved grant;

3. Presents and classifies historical costs of the grant as required for budgetary and evaluation purposes;

4. Provides cost and property controls to assure optimal use of grant funds;

5. Is integrated with a system of internal controls adequate to safeguard the funds and assets covered, check the accuracy and reliability of the accounting data, promote operational efficiency, and assure conformance with any general or special conditions of the grant;

6. Meets the prescribed requirements for periodic financial reporting of operations; and

7. Provides financial data for planning, control, measurement, and evaluation of direct and indirect costs.

E. Total Cost Budgeting and Accounting

Accounting for all funds awarded by the Institute must be structured and executed on a *"Total Project Cost"* basis. That is, total project costs, including Institute funds, State and local matching shares, and any other fund sources included in the approved project budget serve as the foundation for fiscal administration and accounting. Grant applications and financial reports require budget and cost estimates on the basis of total costs.

1. Timing of Matching Contributions

Matching contributions need not be applied at the exact time of the obligation of Institute funds. Ordinarily, the full matching share must be obligated during the award period; however, with the written permission of the Institute, contributions made following approval of the grant by the Institute's Board of Directors but before the beginning of the grant may be counted as match. Grantees that do not contemplate making matching contributions continuously throughout the course of a project, or on a task-by-task basis, are required to submit a schedule within 30 days after the beginning of the project period indicating at what points during the project period the matching contributions will be made. If a proposed cash or in-kind match is not fully met, the Institute may reduce the award amount accordingly to maintain the ratio of grant funds to matching funds stated in the award agreement.

2. Records for Match

All grantees must maintain records that clearly show the source, amount, and timing of all matching contributions. In addition, if a project has included, within its approved budget, contributions which exceed the required matching portion, the grantee must maintain records of those contributions in the same manner as it does Institute funds and required matching shares. For all grants made to State and local courts, the State Supreme Court has primary responsibility for grantee/subgrantee compliance with the requirements of this section (see subsection C.2. above).

F. Maintenance and Retention of Records

All financial records, including supporting documents, statistical records, and all other information pertinent to grants, subgrants, cooperative agreements, or contracts under grants, must be retained by each organization participating in a project for at least three years for purposes of examination and audit. State Supreme Courts may impose record retention and maintenance requirements in addition to those prescribed in this section.

1. Coverage

The retention requirement extends to books of original entry, source documents supporting accounting transactions, the general ledger, subsidiary ledgers, personnel and payroll records, canceled checks, and related documents and records. Source documents include copies of all grant and subgrant awards, applications, and required grantee/subgrantee financial and narrative reports. Personnel and payroll records shall include the time and attendance reports for all individuals reimbursed under a grant, subgrant or contract, whether they are employed full-time or part-time. Time and effort reports are required for consultants.

2. Retention Period

The three-year retention period starts from the date of the submission of the final expenditure report.

3. Maintenance

Grantees and subgrantees are expected to see that records of different fiscal years are separately identified and maintained so that requested information can be readily located. Grantees and subgrantees are also obligated to protect records adequately

against fire or other damage. When records are stored away from the grantee's/subgrantee's principal office, a written index of the location of stored records should be on hand, and ready access should be assured.

4. Access

Grantees and subgrantees must give any authorized representative of the Institute access to and the right to examine all records, books, papers, and documents related to an Institute grant.

G. Project-Related Income

Records of the receipt and disposition of project-related income must be maintained by the grantee in the same manner as required for the project funds that gave rise to the income and must be reported to the Institute (see subsection H.2. below). The policies governing the disposition of the various types of project-related income are listed below.

1. Interest

A State and any agency or instrumentality of a State, including institutions of higher education and hospitals, shall not be held accountable for interest earned on advances of project funds. When funds are awarded to subgrantees through a State, the subgrantees are not held accountable for interest earned on advances of project funds. Local units of government and nonprofit organizations that are grantees must refund any interest earned. Grantees shall ensure minimum balances in their respective grant cash accounts.

2. Royalties

The grantee/subgrantee may retain all royalties received from copyrights or other works developed under projects or from patents and inventions, unless the terms and conditions of the grant provide otherwise.

3. Registration and Tuition Fees

Registration and tuition fees may be considered as cash match with the prior written approval of the Institute. Estimates of registration and tuition fees, and any expenses to be offset by the fees, should be included in the application budget forms and narrative.

4. Income from the Sale of Grant Products

If the sale of products occurs during the project period, the income may be treated as cash match with the prior written approval of the Institute. The costs and income generated by the sales must be reported on the Quarterly Financial Status Reports and documented in an auditable manner. Whenever possible, the intent to sell a product should be disclosed in the application or reported to the Institute in writing once a decision to sell products has been made. The grantee must request approval to recover its product development, reproduction, and dissemination costs as specified in section VI.A.11.b.

5. Other

Other project income shall be treated in accordance with disposition instructions set forth in the grant's terms and conditions.

H. Payments and Financial Reporting Requirements

1. Payment of Grant Funds

The procedures and regulations set forth below are applicable to all Institute grant funds and grantees.

a. Request for Advance or Reimbursement of Funds. Grantees will receive funds on a "check-issued" basis. Upon receipt, review, and approval of a Request for Advance or Reimbursement by the Institute, a check will be issued directly to the grantee or its designated fiscal agent. A request must be limited to the grantee's immediate cash needs. The Request for Advance or Reimbursement, along with the instructions for its preparation, will be included in the official Institute award package.

b. Termination of Advance and Reimbursement Funding. When a grantee organization receiving cash advances from the Institute:

(1) Demonstrates an unwillingness or inability to attain program or project goals, or to establish procedures that will minimize the time elapsing between cash advances and disbursements, or cannot adhere to guideline requirements or special conditions;

(2) Engages in the improper award and administration of subgrants or contracts; or

(3) Is unable to submit reliable and/or timely reports; the Institute may terminate advance financing and require the grantee organization to finance its operations with its own working capital. Payments to the grantee shall then be made by check to reimburse the grantee for actual cash disbursements. In the event the grantee continues to be deficient, the Institute may suspend reimbursement payments until the deficiencies are corrected. In extreme cases, grants may be terminated.

c. Principle of Minimum Cash on Hand. Grantees should request funds based upon immediate disbursement requirements. Grantees should time their requests to ensure that cash on hand is the minimum needed for disbursements to be made immediately or within a few days.

2. Financial Reporting

a. General Requirements. To obtain financial information concerning the use of funds, the Institute requires that grantees/subgrantees submit timely reports for review.

b. Due Dates and Contents. A Financial Status Report is required from all grantees, other than scholarship recipients, for each active quarter on a calendar-quarter basis. This report is due within 30 days after the close of the calendar quarter. It is designed to provide financial information relating to Institute funds, State and local matching shares, project income, and any other sources of funds for the project, as well as information on obligations and outlays. A copy of the Financial Status Report, along with instructions for its preparation, is included in each official Institute Award package. If a grantee requests substantial payments for a project prior to the completion of a given quarter, the Institute may request a brief summary of the amount requested, by object class, to support the Request for Advance or Reimbursement.

3. Consequences of Non-Compliance With Submission Requirement

Failure of the grantee to submit required financial and progress reports may result in suspension or termination of grant payments.

I. Allowability of Costs

1. General

Except as may be otherwise provided in the conditions of a particular grant, cost allowability is determined in accordance with the principles set forth in *OMB Circulars A–21*, Cost Principles Applicable to Grants and Contracts with Educational Institutions; *A–87*, Cost Principles for State and Local Governments; and *A–122*, Cost Principles for Non-profit Organizations.

No costs may be recovered to liquidate obligations incurred after the approved grant period. Circulars may be obtained on the OMB Web site at *http://www.whitehouse.gov/omb*.

2. Costs Requiring Prior Approval

a. Pre-agreement Costs. The written prior approval of the Institute is required for costs considered necessary but which occur prior to the start date of the project period.

b. Equipment. Grant funds may be used to purchase or lease only that equipment essential to accomplishing the goals and objectives of the project.

The written prior approval of the Institute is required when the amount of automated data processing (ADP) equipment to be purchased or leased exceeds $10,000 or software to be purchased exceeds $3,000.

c. Consultants. The written prior approval of the Institute is required when the rate of compensation to be paid a consultant exceeds $800 a day. Institute funds may not be used to pay a consultant more than $1,100 per day.

d. Budget Revisions. Budget revisions among direct cost categories that (i) transfer grant funds to an unbudgeted cost category or (ii) individually or cumulatively exceed five percent (5%) of the approved original budget or the most recently approved revised budget require prior Institute approval (see section VIII.A.1.).

3. Travel Costs

Transportation and per diem rates must comply with the policies of the grantee. If the grantee does not have an established written travel policy, then travel rates must be consistent with those established by the Institute or the Federal Government. Institute funds may not be used to cover the transportation or per diem costs of a member of a national organization to attend an annual or other regular meeting of that organization.

4. Indirect Costs

These are costs of an organization that are not readily assignable to a particular project but are necessary to the operation of the organization and the performance of the project. The cost of operating and maintaining facilities, depreciation, and administrative salaries are examples of the types of costs that are usually treated as indirect costs. Although the Institute's policy requires all costs to be budgeted directly, it will accept indirect costs if a grantee has an indirect cost rate approved by a Federal agency as set forth below. However, recoverable indirect costs are limited to no more than 75% of a grantee's direct personnel costs (salaries plus fringe benefits).

a. Approved Plan Available.

(1) A copy of an indirect cost rate agreement or allocation plan approved for a grantee during the preceding two years by any Federal granting agency on the basis of allocation methods substantially in accord with those set forth in the applicable cost circulars must be submitted to the Institute.

(2) Where flat rates are accepted in lieu of actual indirect costs, grantees may not also charge expenses normally included in overhead pools, e.g., accounting services, legal services, building occupancy and maintenance, etc., as direct costs.

b. Establishment of Indirect Cost Rates. To be reimbursed for indirect costs, a grantee must first establish an appropriate indirect cost rate. To do this, the grantee must prepare an indirect cost rate proposal and submit it to the Institute within three months after the start of the grant period to assure recovery of the full amount of allowable indirect costs. The rate must be developed in accordance with principles and procedures appropriate to the type of grantee institution involved as specified in the applicable OMB Circular.

c. No Approved Plan. If an indirect cost proposal for recovery of indirect costs is not submitted to the Institute within three months after the start of the grant period, indirect costs will be irrevocably disallowed for all months prior to the month that the indirect cost proposal is received.

J. Procurement and Property Management Standards

1. Procurement Standards

For State and local governments, the Institute has adopted the standards set forth in Attachment O of *OMB Circular A–102*. Institutions of higher education, hospitals, and other non-profit organizations will be governed by the standards set forth in Attachment O of *OMB Circular A–110*.

2. Property Management Standards

The property management standards as prescribed in Attachment N of *OMB Circulars A–102 and A–110* apply to all Institute grantees and subgrantees except as provided in section VI.A.18. All grantees/subgrantees are required to be prudent in the acquisition and management of property with grant funds. If suitable property required for the successful execution of projects is already available within the grantee or subgrantee organization, expenditures of grant funds for the acquisition of new property will be considered unnecessary.

K. Audit Requirements

1. Implementation

Each recipient of a Project Grant must provide for an annual fiscal audit. This requirement also applies to a State or local court receiving a subgrant from the State Supreme Court. The audit may be of the entire grantee or subgrantee organization or of the specific project funded by the Institute. Audits conducted in accordance with the Single Audit Act of 1984 and *OMB Circular A–133*, will satisfy the requirement for an annual fiscal audit. The audit must be conducted by an independent Certified Public Accountant, or a State or local agency authorized to audit government agencies. Grantees must send two copies of the audit report to the Institute. Grantees that receive funds from a Federal agency and satisfy audit requirements of the cognizant Federal agency must submit two copies of the audit report prepared for that Federal agency to the Institute in order to satisfy the provisions of this section.

2. Resolution and Clearance of Audit Reports

Timely action on recommendations by responsible management officials is an integral part of the effectiveness of an audit. Each grantee must have policies and procedures for acting on audit recommendations by designating officials responsible for: (1) Follow-up, (2) maintaining a record of the actions taken on recommendations and time schedules, (3) responding to and acting on audit recommendations, and (4) submitting periodic reports to the Institute on recommendations and actions taken.

3. Consequences of Non-Resolution of Audit Issues

Ordinarily, the Institute will not make a subsequent grant award to an applicant that has an unresolved audit report involving Institute awards. Failure of the grantee to resolve audit questions may also result in the suspension or termination of payments for active Institute grants to that organization.

L. Close-Out of Grants

1. Grantee Close-Out Requirements

Within 90 days after the end date of the grant or any approved extension thereof (see subsection L.2. below), the following documents must be submitted to the Institute by grantees (other than scholarship recipients):

a. Financial Status Report. The final report of expenditures must have no unliquidated obligations and must indicate the exact balance of unobligated funds. Any unobligated/unexpended funds will be deobligated from the award by the Institute. Final payment requests for obligations incurred during the award period must be submitted to the Institute prior to the end of the 90-day close-out period. Grantees on a check-issued basis, who have drawn down funds in excess of their obligations/expenditures, must return any unused funds as soon as it is determined that the funds are not

required. In no case should any unused funds remain with the grantee beyond the submission date of the final Financial Status Report.

b. Final Progress Report. This report should describe the project activities during the final calendar quarter of the project and the close-out period, including to whom project products have been disseminated; provide a summary of activities during the entire project; specify whether all the objectives set forth in the approved application or an approved adjustment have been met and, if any of the objectives have not been met, explain why not; and discuss what, if anything, could have been done differently that might have enhanced the impact of the project or improved its operation. These reporting requirements apply at the conclusion of every grant other than a scholarship.

2. Extension of Close-out Period

Upon the written request of the grantee, the Institute may extend the close-out period to assure completion of the grantee's close-out requirements. Requests for an extension must be submitted at least 14 days before the end of the close-out period and must explain why the extension is necessary and what steps will be taken to assure that all the grantee's responsibilities will be met by the end of the extension period.

VIII. Grant Adjustments

All requests for programmatic or budgetary adjustments requiring Institute approval must be submitted by the project director in a timely manner (ordinarily 30 days prior to the implementation of the adjustment being requested). All requests for changes from the approved application will be carefully reviewed for both consistency with this Guideline and the enhancement of grant goals and objectives. Failure to submit adjustments in a timely manner may result in the termination of a grantee's award.

A. Grant Adjustments Requiring Prior Written Approval

The following grant adjustments require the prior written approval of the Institute:

1. Budget revisions among direct cost categories that (a) transfer grant funds to an unbudgeted cost category or (b) individually or cumulatively exceed five percent (5%) of the approved original budget or the most recently approved revised budget (see section VII.I.2.d.).

2. A change in the scope of work to be performed or the objectives of the project (see subsection D. below).

3. A change in the project site.

4. A change in the project period, such as an extension of the grant period and/or extension of the final financial or progress report deadline (see subsection E. below).

5. Satisfaction of special conditions, if required.

6. A change in or temporary absence of the project director (see subsections F. and G. below).

7. The assignment of an employee or consultant to a key staff position whose qualifications were not described in the application, or a change of a person assigned to a key project staff position (see section VI.A.2.).

8. A change in or temporary absence of the person responsible for managing and reporting on the grant's finances.

9. A change in the name of the grantee organization.

10. A transfer or contracting out of grant-supported activities (see subsection H. below).

11. A transfer of the grant to another recipient.

12. Preagreement costs (see section VII.I.2.a.).

13. The purchase of automated data processing equipment and software (see section VII.I.2.b.).

14. Consultant rates (see section VII.I.2.c.).

15. A change in the nature or number of the products to be prepared or the manner in which a product would be distributed.

B. Requests for Grant Adjustments

All grantees must promptly notify their SJI program managers, in writing, of events or proposed changes that may require adjustments to the approved project design. In requesting an adjustment, the grantee must set forth the reasons and basis for the proposed adjustment and any other information the program manager determines would help the Institute's review.

C. Notification of Approval/Disapproval

If the request is approved, the grantee will be sent a Grant Adjustment signed by the Executive Director or his or her designee. If the request is denied, the grantee will be sent a written explanation of the reasons for the denial.

D. Changes in the Scope of the Grant

Major changes in scope, duration, training methodology, or other significant areas must be approved in advance by the Institute. A grantee may make minor changes in methodology, approach, or other aspects of the grant to expedite achievement of the grant's objectives with subsequent notification of the SJI program manager.

E. Date Changes

A request to change or extend the grant period must be made at least 30 days in advance of the end date of the grant. A revised task plan should accompany a request for an extension of the grant period, along with a revised budget if shifts among budget categories will be needed. A request to change or extend the deadline for the final financial report or final progress report must be made at least 14 days in advance of the report deadline (see section VII.L.2.).

F. Temporary Absence of the Project Director

Whenever an absence of the project director is expected to exceed a continuous period of one month, the plans for the conduct of the project director's duties during such absence must be approved in advance by the Institute. This information must be provided in a letter signed by an authorized representative of the grantee/subgrantee at least 30 days before the departure of the project director, or as soon as it is known that the project director will be absent. The grant may be terminated if arrangements are not approved in advance by the Institute.

G. Withdrawal of/Change in Project Director

If the project director relinquishes or expects to relinquish active direction of the project, the Institute must be notified immediately. In such cases, if the grantee/subgrantee wishes to terminate the project, the Institute will forward procedural instructions upon notification of such intent. If the grantee wishes to continue the project under the direction of another individual, a statement of the candidate's qualifications should be sent to the Institute for review and approval. The grant may be terminated if the qualifications of the proposed individual are not approved in advance by the Institute.

H. Transferring or Contracting Out of Grant-Supported Activities

No principal activity of a grant-supported project may be transferred or contracted out to another organization without specific prior approval by the Institute. All such arrangements must be formalized in a contract or other written agreement between the parties involved. Copies of the proposed contract or agreement must be submitted for prior

approval of the Institute at the earliest possible time. The contract or agreement must state, at a minimum, the activities to be performed, the time schedule, the policies and procedures to be followed, the dollar limitation of the agreement, and the cost principles to be followed in determining what costs, both direct and indirect, will be allowed. The contract or other written agreement must not affect the grantee's overall responsibility for the direction of the project and accountability to the Institute.

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Janice Munsterman,

Executive Director.

Appendix A—SJI Libraries: Designated Sites and Contacts

Alabama

Supreme Court Library

Mr. Timothy A. Lewis, State Law Librarian, Alabama Supreme Court, Judicial Building, 300 Dexter Avenue, Montgomery, AL 36104, (334) 242–4347, *director@alalinc.net.*

Alaska

Anchorage Law Library

Ms. Cynthia S. Fellows, State Law Librarian, Alaska State Court Law Library, 303 K Street, Anchorage, AK 99501, (907) 264–0583, *cfellows@courts.state.ak.us.*

Arizona

Supreme Court Library

Ms. Lani Orosco, Staff Assistant, Arizona Supreme Court, Staff Attorney's Office Library, 1501 W. Washington, Suite 445, Phoenix, AZ 85007, (602) 542–5028, *lorosco@supreme.sp.state.az.us.*

Arkansas

Administrative Office of the Courts

Mr. James D. Gingerich, Director, Administrative Office of the Courts, Supreme Court of Arkansas, Justice Building, 625 Marshall Street, Little Rock, AR 72201, (501) 682–9400, *jd.gingerich@arkansas.gov.*

California

Administrative Office of the Courts

Mr. William C. Vickrey, Administrative Director of the Courts, Administrative Office of the Courts, 455 Golden Gate Avenue, San Francisco, CA 94102, (415) 865–4235, *william.vickrey@jud.ca.gov.*

Colorado

Supreme Court Library

Ms. Linda Gruenthal, Deputy Supreme Court Law Librarian, 2 East 14th Avenue, Denver, CO 80203, (303) 837–3720, *cscltech@state.co.us.*

Connecticut

State Library

Ms. Denise D. Jernigan, Law Librarian, Connecticut State Library, 231 Capitol Avenue, Hartford, CT 06106, (860) 757–6598, *djernigan@cslib.org.*

Delaware

Administrative Office of the Courts

Mr. Michael E. McLaughlin, Deputy Director, Administrative Office of the Courts, Carvel State Office Building, 820 North French Street, 11th Floor, P.O. Box 8911, Wilmington, DE 19801, (302) 577–8481, *michael.mclaughlin@state.de.us.*

District of Columbia

Executive Office, District of Columbia Courts

Ms. Anne B. Wicks, Executive Officer, District of Columbia Courts, 500 Indiana Avenue, NW., Suite 1500, Washington, DC 20001, (202) 879–1700, *Wicksab@dcsc.gov.*

Florida

Administrative Office of the Courts

Ms. Elisabeth H. Goodner, State Courts Administrator, Office of the State Courts Administrator, Florida Supreme Court, Supreme Court Building, 500 South Duval Street, Tallahassee, FL 32399, (850) 922–5081, *goodnerl@flcourts.org.*

Georgia

Administrative Office of the Courts

Mr. David Ratley, Director, Administrative Office of the Courts 244 Washington Street S.W., Suite 300, Atlanta, GA 30334, (404) 656–5171, *ratleydl@gaaoc.us.*

Hawaii

Supreme Court Library

Ms. Ann Koto, State Law Librarian, The Supreme Court Law Library, 417 South King St., Room 119, Honolulu, HI 96813, (808) 539–4964, *Ann.S.Koto@courts.state.hi.us.*

Idaho

AOC Judicial Education Library/State Law Library

Mr. Richard Visser, State Law Librarian, Idaho State Law Library, Supreme Court Building 451 West State St., Boise, ID 83720, (208) 334–3316, *lawlibrary@isc.state.id.us.*

Illinois

Supreme Court Library

Ms. Brenda Larison, Supreme Court of Illinois Library, 200 East Capitol Avenue, Springfield, IL 62701–1791, (217) 782–2425, *blarison@court.state.il.us.*

Indiana

Supreme Court Library

Ms. Terri L. Ross, Supreme Court Librarian, Supreme Court Library, State House, Room 316, Indianapolis, IN 46204, (317) 232–2557, *tross@courts.state.in.us.*

Iowa

Administrative Office of the Court

Dr. Jerry K. Beatty, Director of Judicial Branch Education, Iowa Judicial Branch, Iowa Judicial Branch Building, 1111 East Court Avenue, Des Moines, IA 50319, (515) 242–0190, *jerry.beatty@jb.state.ia.us.*

Kansas

Supreme Court Library

Mr. Fred Knecht, Law Librarian, Kansas Supreme Court Library, Kansas Judicial Center, 301 S.W. 10th Avenue, Topeka, KS 66612, (785) 296–3257, *knechtf@kscourts.org.*

Kentucky

State Law Library

Ms. Vida Vitagliano, Cataloging and Research Librarian, Kentucky Supreme Court Library, 700 Capitol Avenue, Suite 200, Frankfort, KY 40601, (502) 564–4185, *vidavitagliano@mail.aoc.state.ky.us.*

Louisiana

State Law Library

Ms. Carol Billings, Director, Louisiana Law Library, Louisiana Supreme Court Building, 400 Royal Street, New Orleans, LA 70130, (504) 310–2401, *cbillings@lasc.org.*

Maine

State Law and Legislative Reference Library

Ms. Lynn E. Randall, State Law Librarian, 43 State House Station, Augusta, ME 04333, (207) 287–1600, *lynn.randall@legislature.maine.gov.*

Maryland

State Law Library

Mr. Steve Anderson, Director, Maryland State Law Library, Court of Appeal Building, 361 Rowe Boulevard, Annapolis, MD 21401, (410) 260–1430, *steve.anderson@courts.state.md.us.*

Massachusetts

Middlesex Law Library

Ms. Linda Hom, Librarian, Middlesex Law Library, Superior Court House, 40 Thorndike Street, Cambridge, MA 02141, (617) 494–4148, *midlawlib@yahoo.com.*

Michigan

Michigan Judicial Institute

Dawn F. McCarty, Director, Michigan Judicial Institute, P.O. Box 30205, Lansing, MI 48909, (517) 373–7509, *mccartyd@courts.mi.gov.*

Minnesota

State Law Library (Minnesota Judicial Center)

Ms. Barbara L. Golden, State Law Librarian, G25 Minnesota Judicial Center, 25 Rev. Dr. Martin Luther King Jr. Boulevard, St. Paul, MN 55155, (612) 297–2089, *barb.golden@courts.state.mn.us.*

Mississippi

Mississippi Judicial College

Hon. Leslie G. Johnson, Executive Director, Mississippi Judicial College, P.O. Box 8850, University, MS 38677, (662) 915–5955, *lwleslie@olemiss.edu.*

Montana

State Law Library

Ms. Judith Meadows, State Law Librarian, State Law Library of Montana, P.O. Box 203004, Helena, MT 59620, (406) 444–3660, *jmeadows@mt.gov.*

Nebraska

Administrative Office of the Courts

Mr. Philip D. Gould, Director, Judicial Branch Education, Administrative Office of the Courts/Probation, 521 South 14th St., Suite 200, Lincoln, NE 68508–2707, (402) 471–3072 (office)/(402) 471–3071 (fax), *pgould@nsc.state.ne.us.*

Nevada

Ms. Kathleen Harrington, Law Librarian, Nevada Supreme Court Law Library, 201 S. Carson Street, Suite 100, Carson City, Nevada 89701–4702, (775)684–1715.

New Hampshire

New Hampshire Law Library

Ms. Mary Searles, Technical Services Law Librarian, New Hampshire Law Library, Supreme Court Building, One Noble Drive, Concord, NH 03301–6160, (603) 271–3777, *msearles@courts.state.nh.us.*

New Jersey

New Jersey State Library

Mr. Thomas O'Malley, Supervising Law Librarian, New Jersey State Law Library, 185 West State Street, P.O. Box 520, Trenton, NJ 08625–0250, (609) 292–6230, *tomalley@njstatelib.org.*

New Mexico

Supreme Court Library

Mr. Thaddeus Bejnar, Librarian, Supreme Court Library, Post Office Drawer L, Santa Fe, NM 87504, (505) 827–4850.

New York

Supreme Court Library

Ms. Barbara Briggs, Law Librarian, Syracuse Supreme Court Law Library, 401 Montgomery Street, Syracuse, NY 13202, (315) 671–1150, *bbriggs@courts.state.ny.us.*

North Carolina

Supreme Court Library

Mr. Thomas P. Davis, Librarian, North Carolina Supreme Court Library, 500 Justice Building, 2 East Morgan Street, Raleigh, NC 27601, (919) 733–3425, *tpd@sc.state.nc.us.*

North Dakota

Supreme Court Library

Ms. Marcella Kramer, Assistant Law Librarian, Supreme Court Law Library, 600 East Boulevard Avenue, Dept. 182, 2nd Floor Judicial Wing, Bismarck, ND 58505–0540, (701) 328–2229, *mkramer@ndcourts.com.*

Northern Mariana Islands

Supreme Court of the Northern Mariana Islands

Ms. Margarita M. Palacios, Director of Courts, Supreme Court of the Commonwealth of the Northern Mariana Islands, P.O. Box 502165, Saipan, MP 96950, (670) 235–9700, *supremecourt@saipan.com.*

Ohio

Supreme Court Library

Mr. Ken Kozlowski, Director, Law Library, Supreme Court of Ohio, 65 South Front Street, 11th Floor, Columbus, OH 43215–3431, (614) 387–9666, *kozlowsk@sconet.state.oh.us.*

Oklahoma

Administrative Office of the Courts

Mr. Michael D. Evans, State Court Administrator, Administrative Office of the Courts, 1915 North Stiles Avenue, Suite 305, Oklahoma City, OK 73105, (405) 521–2450, *mike.evans@oscn.net.*

Oregon

Administrative Office of the Courts

Ms. Kingsley W. Click, State Court Administrator, Oregon Judicial Department, Supreme Court Building, 1163 State Street, Salem, OR 97301, (503) 986–5500, *kingsley.w.click@ojd.state.or.us.*

Pennsylvania

State Library of Pennsylvania

Ms. Kathleen Kline, Collection Management Librarian, State Library of Pennsylvania, Bureau of State Library, 333 Market Street, Harrisburg, PA 17126–1745, (717) 787–5718, *kakline@state.pa.us.*

Puerto Rico

Office of Court Administration

Alfredo Rivera-Mendoza, Esq., Director, Area of Planning and Management, Office of Court Administration, P.O. Box 917, Hato Rey, PR 00919.

Rhode Island

Roger Williams University

Ms. Gail Winson, Director of Law Library/ Associate Professor of Law, Roger Williams University, School of Law Library, 10 Metacom Avenue, Bristol, RI 02809, 401/ 254–4531, *gwinson@law.rwu.edu.*

South Carolina

Coleman Karesh Law Library (University of South Carolina School of Law)

Mr. Steve Hinckley, Director, Coleman Karesh Law Library, University of South Carolina, Main and Green Streets, Columbia, SC 29208, (803) 777–5944, *hinckley@law.sc.edu.*

South Dakota

State Law Library

Librarian, South Dakota State Law Library, 500 East Capitol, Pierre, South Dakota 57501, (605) 773–4898, *donnis.deyo@ujs.state.sd.ud.*

Tennessee

Tennessee State Law Library

Hon. Cornelia A. Clark, Executive Director, Administrative Office of the Courts, 511 Union Street, Suite 600, Nashville, TN 37219, (615) 741–2687, *cclark@tscmail.state.tn.us.*

Texas

State Law Library

Mr. Marcelino A. Estrada, Director, State Law Library, P.O. Box 12367, Austin, TX 78711, (512) 463–1722, *tony.estrada@sll.state.tx.us.*

U.S. Virgin Islands

Library of the Territorial Court of the Virgin Islands (St. Thomas)

Librarian, The Library, Territorial Court of the Virgin Islands, Post Office Box 70, Charlotte Amalie, St. Thomas, Virgin Islands 00804.

Utah

Utah State Judicial Administration Library

Ms. Jessica Van Buren, Utah State Library, 450 South State Street, P.O. Box 140220, Salt Lake City, UT 84114–0220, (801) 238–7991, *jessicavb@e-mail.utcourts.gov.*

Vermont

Supreme Court of Vermont

Mr. Paul J. Donovan, Law Librarian, Vermont Department of Libraries, 109 State Street, Pavilion Office Building, Montpelier, VT 05609, (802) 828–3268, *paul.donovan@dol.state.vt.us.*

Virginia

Administrative Office of the Courts

Ms. Gail Warren, State Law Librarian, Virginia State Law Library, Supreme Court of Virginia, 100 North Ninth Street, 2nd Floor, Richmond, VA 23219–2335, (804) 786–2075, *gwarren@courts.state.va.us.*

Washington

Washington State Law Library

Ms. Kay Newman, State Law Librarian, Washington State Law Library, Temple of Justice, P.O. Box 40751, Olympia, WA 98504–0751, (360) 357–2136, *kay.newman@courts.wa.gov.*

West Virginia

Supreme Court of Appeals Library

Ms. Kaye Maerz, State Law Librarian, West Virginia Supreme Court of Appeals Library, 1900 Kanawha Boulevard East, Building 1, Room E–404, Charleston, WV 25305, (304) 558–2607, *kaye.maerz@courts.wv.org.*

Wisconsin

State Law Library

Ms. Jane Colwin, State Law Librarian, State Law Library, 120 M.L.K. Jr. Boulevard, Madison, WI 53703, (608) 261–2340, *jane.colwin@wicourts.gov.*

Wyoming

Wyoming State Law Library

Ms. Kathy Carlson, Law Librarian, Wyoming State Law Library, Supreme Court Building, 2301 Capitol Avenue, Cheyenne, WY 82002, (307) 777-7509, *Kcarlson@courts.state.wy.us.*

National

American Judicature Society

Ms. Deborah Sulzbach, Acquisitions Librarian, Drake University Law Library, Opperman Hall, 2507 University Avenue, Des Moines, IA 50311–4505, (515) 271–3784, *deborah.sulzbach@drake.edu.*

National Center for State Courts

Ms. Joan Cochet, Library Specialist, National Center for State Courts, 300 Newport Avenue, Williamsburg, VA 23185–4147, (757) 259–1826, *library@ncsc.dni.us.*

National Judicial College

Mr. Randall Snyder, Law Librarian, National Judicial College, Judicial College Building MS 358, Reno, NV 89557, (775) 327–8278, *snyder@judges.org.*

BILLING CODE 6820–SC–P

STATE JUSTICE INSTITUTE
APPLICATION

1. APPLICANT
a. Organization Name _____
b. Street/P.O. Box _____
c. City _____
d. State _____ e. Zip Code _____
f. Phone Number _____
g. Fax Number _____
h. Web Site Address _____
i. Name & Phone Number of Contact Person
_____
j. Title _____
k. E-Mail Address _____

2. TYPE OF APPLICANT (Check appropriate box)

- ☐ State Court
- ☐ National organization operating in conjunction with State court
- ☐ National State court support organization
- ☐ College or university
- ☐ Other non-profit organization or agency
- ☐ Individual
- ☐ Corporation or partnership
- ☐ Other unit of government
- ☐ Other _____ (Specify) _____

3. PROPOSED START DATE _____

4. PROJECT DURATION (months) _____

5. APPLICANT FINANCIAL CONTACT
a. Organization Name _____
b. Street/P.O. Box _____
c. City _____
d. State _____ e. Zip Code _____
f. Phone Number _____
g. Fax Number _____
h. Web Site Address _____
i. Name & Phone Number of Contact Person
_____
j. Title _____
k. E-Mail Address _____

6. IF THIS APPLICATION HAS BEEN SUBMITTED TO OTHER FUNDING SOURCES, PLEASE PROVIDE THE FOLLOWING INFORMATION:
Source _____
Date Submitted _____
Amount Requested _____
Disposition (if any) or Current Status _____
_____

7. a. AMOUNT REQUESTED FRON SJI $ _____
b. AMOUNT OF MATCH
Cash match $ _____
Non-cash Match $ _____
c. TOTAL MATCH $ _____
d. OTHER CASH $ _____
e. TOTAL PROJECT COST $ _____

8. TITLE OF PROPOSED PROJECT

9. CONGRESSIONAL DISTRICT OF: _____ (Name of Representative, District Number) _____ (Project location (if different from applicant location) Name of Representative, District Number)

10. CERTIFICATION
On behalf of the applicant, I hereby certify that to the best of my knowledge the information in this application is true and complete. I have read the attached assurances (Form D) and understand that if this application is approved for funding, the award will be subject to those assurances. I certify that the applicant will comply with the assurances if the application is approved, and that I am lawfully authorized to make these representations on the behalf of the applicant.

_____ SIGNATURE OF RESPONSIBLE OFFICIAL
_____ TITLE
_____ DATE
(For applications from State and local courts, Form B - Certificate of State Approval, must be attached)

Form A 08/07

STATE JUSTICE INSTITUTE
INSTRUCTIONS FOR APPLICATION FORM A

1. Legal **name of applicant** (court, entity or individual); **name of the organizational unit**, if any, that will conduct the project; complete **address** of the applicant, including phone and fax numbers and website addresses; and name, phone number, title, and e-mail address of a **contact person** who can provide further information about this application.

2. Type of Applicant:

   a. **State court** includes all appellate, general jurisdiction, limited jurisdiction, and special jurisdiction courts, as well as all offices that are supervised by, or report for, administrative purposes to the chief or presiding justice or judge, or his or her designee.

   b. **National organizations operating in conjunction with State court** include national non-profit organization controlled by, operating in conjunction with, and serving State courts.

   c. **National state court support organization** include national non-profit organizations with primary mission of supporting, serving, or educating judges and other personnel of the judicial branch of State government.

   d. **College or university** includes all institutions of higher education.

   e. **Other non-profit organization or agency** includes those non-profit organizations and private agencies not included in sub-paragraphs (b)-(d).

   f. **Individual** means a person not applying in conjunction with or on behalf of an entity identified in one of the other categories.

   g. **Corporation or partnership** includes for-profit and not-for-profit entities not falling within one of the other categories.

   h. **Other unit of government** includes any governmental agency, office, or organization that is not a State or local court.

3. The **proposed start date** of the project should be the earliest feasible date on which applicant will be able to begin project activities following the date of award (example: 08/01/2007).

4. **Project duration** refers to the number of months the applicant estimates will be needed to complete all project tasks after the proposed start date.

5. The **applicant financial contact** is the court or organization employee that will administer and account for any funding awarded.

6. If this application, or an application requesting support for the same project or a similar project, has been previously submitted to another funding source (Federal or private), enter the name of the **source**, the **date** of submission, the **amount** of funding sought, and the **disposition** (if any) or current status.

7. Requested funding:

   a. Insert the **amount requested** from the State Justice Institute to conduct the project.

   b. The **amount of match** is the amount, if any, to be contributed to the project by the applicant, a unit of State or local government, or private sources.
   See 42 U.S.C. 10705 (d).

   Cash match refers to funds directly contributed by the applicant, a unit of State or local government, or private sources to support the project.

   Non-cash match refers to in-kind contributions by the applicant, a unit of State or local government or private sources to support the project.

   c. **Total match** refers to the sum of the cash and in-kind contributions to the project.

   d. **Other cash** refers to other funds that may not serve as a match but can be used for a project.

   e. **Total project cost** represents the sum of the amount requested from the Institute and all other contributions to the project.

8. The **title of the proposed project** should reflect the objectives of the activities to be conducted.

9. Enter the name of the applicant's Congressional Representative and the number of the applicant's **Congressional district**, along with the number of the Congressional district(s) in which most of the project activities will take place and the name(s) of the Representative(s) from those districts. If the project activities are not site-specific (for example, a series of training workshops that will bring together participants from around the State, the country, or from a particular region), enter *Statewide*, *national*, or *regional*, as appropriate, in the space provided.

10. **Signature** and title of a duly authorized representative of the applicant and the **date** the application was signed. For applications from State and local courts, Form B, Certificate of State Approval, must be attached.

(Form B)

STATE JUSTICE INSTITUTE

Certificate of State Approval

The _____
Name of State Supreme Court or Designated Agency or Council

has reviewed the application entitled _____

prepared by _____,
Name of Applicant

approves its submission to the State Justice Institute, and

☐ agrees to receive and administer and be accountable for all funds awarded by the Institute pursuant to the application.

☐ designates _____
Name of Trial or Appellate Court or Agency

as the entity to receive, administer, and be accountable for all funds awarded by the Institute pursuant to the application.

_____ _____
Signature *Date*

_____
Name

_____
Title

INSTRUCTIONS

The State Justice Act requires that:

Each application for funding by a State or local court shall be approved, consistent with State law, by the State's Supreme Court, or its designated agency or council, which shall receive, administer, and be accountable for all funds awarded by the Institute to such courts. 42 U.S.C. 10705(b)(4).

FORM B should be signed by the Chief Judge or Chief Justice of the State Supreme Court, or by the director of the designated agency or chair of the designated council.

The term "State Supreme Court" refers to the court of last resort of a State. "Designated agency or council" refers to the office or judicial body which is authorized under State law or by delegation from the State Supreme Court to approve applications for funds and to receive, administer, and be accountable for those funds.

STATE JUSTICE INSTITUTE

PROJECT BUDGET

(TABULAR FORMAT)

Applicant:
Project Title:
For Project Activity from/to:
Total Amount Requested for Project from SJI:

ITEM	SJI FUNDS	STATE FUNDS	FEDERAL FUNDS	APPLICANT FUNDS	OTHER FUNDS	IN-KIND FUNDS	TOTAL
Direct Costs							
Personnel							$ -
Fringe Benefits							$ -
Consultant / Contractual							$ -
Travel							$ -
Equipment							$ -
Supplies							$ -
Telephone							$ -
Postage							$ -
Printing / Photocopying							$ -
Audit							$ -
Other (specify)							$ -
Subtotal, Direct Costs	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Subtotal, Indirect Costs							$ -
Grand Total	$ -	$ -	$ -	$ -	$ -	$ -	$ -

Remarks:

Application Budget Instructions

If the proposed project period is for more than 12 months, separate totals should be submitted for each succeeding twelve-month period or portion thereof beyond 12 months. However, a grand total project budget must also be included for multi-year projects. In addition to Form C, applicants must provide a detailed budget narrative that explains the basis for the estimates in each budget category. If the applicant is requesting indirect costs and has an indirect cost rate that has been approved by a Federal agency, the basis for that rate, together with a copy of the letter or other official document stating that it has been approved, should be attached. Recoverable indirect costs are limited to no more than 75% of personnel and fringe benefit costs. If matching funds from other sources are being sought, the source, current status of the request, and anticipated decision date must be provided.

STATE JUSTICE INSTITUTE

ASSURANCES

The applicant hereby assures and certifies that it possesses legal authority to apply for the award, and that if funds are awarded by the State Justice Institute pursuant to this application, it will comply with all applicable provisions of law and the regulations, policies, guidelines and requirements of the Institute as they relate to the acceptance and use of Institute funds pursuant to this application. The applicant further assures and certifies with respect to this application, that:

1. No person will, on the basis of race, sex, national origin, disability, color, or creed be excluded from participation in, denied the benefits of, or otherwise subjected to discrimination under any program or activity supported by Institute funds, and that the applicant will immediately take any measures necessary to effectuate this assurance.

2. In accordance with 42 U.S.C. 10706(a), funds awarded to the applicant by the Institute will not be used, directly or indirectly, to influence the issuance, amendment, or revocation of any Executive order or similar promulgation by Federal, State or local agencies, or to influence the passage or defeat of any legislation or constitutional amendment by any Federal, State or local legislative body.

3. In accordance with 42 U.S.C. 10706(a) and 10707(c):

   a. It will not contribute or make available Institute funds, project personnel, or equipment to any political party or association, to the campaign of any candidate for public or party office, or to influence the passage or defeat of any ballot measure, initiative, or referendum;

   b. No officer or employee of the applicant will intentionally identify the Institute or the applicant with any partisan or nonpartisan political activity or the campaign of any candidate for public or party office; and,

   c. No officer or employee of the applicant will engage in partisan political activity while engaged in work supported in whole or in part by the Institute.

4. In accordance with 42 U.S.C. 10706(b), no funds awarded by the Institute will be used to support or conduct training programs for the purpose of advocating particular nonjudicial public policies or encouraging nonjudicial political activities.

5. In accordance with 42 U.S.C. 10706(d), no funds awarded by the Institute will be used to supplant State or local funds supporting a program or activity; to construct court facilities or structures, except to remodel existing facilities or to demonstrate new architectural or technological techniques, or to provide temporary facilities for new personnel or for personnel involved in a demonstration or experimental program; or to solely purchase equipment for a court system.

6. It will provide for an annual fiscal audit of the project.

7. It will give the Institute, through any authorized representative, access to and the right to examine all records, books, papers, or documents related to the award.

8. In accordance with 42 U.S.C. 10708 (b) (as amended), research or statistical information that is furnished during the course of the project and that is identifiable to any specific individual, shall not be used or revealed for any purpose other than the purpose for which it was obtained. Such information and copies thereof shall be immune from legal process, and shall not be offered as evidence or used for any purpose in any action suit, or other judicial, legislative, or administrative proceeding without the consent of the person who furnished the information.

9. All research involving human subjects will be conducted with the informed consent of those subjects and in a manner that will ensure their privacy and freedom from risk or harm and the protection of persons who are not subjects of the research but would be affected by it, unless such procedures and safeguards would make the research impractical. In such instances, the Institute must approve procedures designed by the grantee to provide human subjects with relevant information about the research after their involvement and to minimize or eliminate risk or harm to those subjects due to their participation.

10. All products prepared as the result of the project will be originally-developed material unless otherwise specifically provided for in the award documents, and that material not originally developed that is included in such projects must by properly identified, whether the material is in a verbatim or extensive paraphrase format.

11. No funds will be obligated for publication or reproduction of a final product developed with Institute funds without the written approval of the Institute. The recipient will submit a final draft of each such product to the Institute for review and approval prior to submitting that product for publication or reproduction.

12. The following statement will be prominently displayed on all products prepared as a result of the project:
    This [document, film, videotape, etc.] was developed under a [grant, cooperative agreement, contract] from the State Justice Institute. Points of view expressed herein are those of the [author(s), filmmaker(s), etc.] and do not necessarily represent the official position or policies of the State Justice Institute.

13. THE "SJI" logo will appear on the front cover of a written product or in the opening frames of a video production produced with SJI funds, unless another placement is approved in writing by the Institute.

14. Except as otherwise provided in the terms and conditions of an Institute award, the recipient is free to copyright any books, publications, or other copyrightable materials developed in the course of an Institute-supported project, but the Institute shall reserve a royalty-free, non-exclusive and irrevocable right to reproduce, publish, or otherwise use, and to authorize others to use, the materials for purposes consistent with the State Justice Institute Act.

15. It will submit quarterly progress and financial reports within 30 days of the close of each calendar quarter during the funding period (that is, no later than January 30, April 30, July 30, and October 30); that progress reports will include a narrative description of project activities during the calendar quarter, the relationship between those activities and the task schedule and objectives set forth in the approved application or an approved adjustment thereto, any significant problem areas that have developed and how they will be resolved, and the activities scheduled during the next reporting period; and that financial reports will contain the information requested on the financial report form included in the award documents.

16. At the conclusion of the project, title to all expendable and nonexpendable personal property purchased with Institute funds shall vest in the court, organization or individual that purchased the property if certification is made to the Institute that the property will continue to be used for the authorized purposes of the Institute-funded project or other purposes consistent with the State Justice Institute Act, as approved by the Institute. If such certification is not made or the Institute disapproves such certification, title to all such property with an aggregate or individual value of $1,000 or more shall vest in the Institute, which will direct the disposition of the property.

17. The person signing the application is authorized to do so on behalf of the applicant and to obligate the applicant to comply with the assurances enumerated above.

DISCLOSURE OF LOBBYING ACTIVITIES

The State Justice Institute Act prohibits grantees from using funds awarded by the Institute to directly or indirectly influence the passage or defeat of any legislation by Federal, State of local legislative bodies. 42 U.S.C. 10706 (a). It also is the policy of the Institute to award funds only to support applications submitted by organizations that would carry out the objectives of their applications in an unbiased manner.

Consistent with this policy and the provisions of 42 U.S.C. 10706 (a), the Institute will not knowingly award a grant to an applicant that has, directly or through an entity that is part of the same organization as the applicant, advocated a position before Congress on the specific subject matter of the application. As a means of implementing that prohibition, SJI requires organizations submitting applications to the Institute to disclose whether they, or another entity that is part of the same organization as the applicant, have advocated a position before Congress on any issue, and to identify the specific subjects of their lobbying efforts. This form must be submitted with your application.

Name of Applicant: _____

Title of Application: _____

_____

☐ Yes ☐ No **Has the applicant (or an entity that is part of the same organization as the applicant) directly or indirectly advocated a position before Congress on any issue within the past five years?**

SPECIFIC SUBJECTS OF LOBBYING EFFORTS

If you answered **YES** above, please list the specific subjects on which your organization (or another entity that is part of your organization) has directly or indirectly advocated a position before Congress within the past five years. If necessary, you may continue on the back of this form or on an attached sheet.

Subject	Year

STATEMENT OF VERIFICATION

I declare under penalty of perjury that the information contained in this disclosure statement is correct and that I am authorized to make this verification on behalf of the applicant.

_____

Signature **Name (Typed)**

_____

Title **Date**

SJI Scholarship Application

This application does not serve as a registration for the course. Please contact the education provider.

APPLICANT INFORMATION:

1. Applicant Name: _____
(Last) (First) (M.I.)

2. Position: _____

3. Name of Court: _____

4. Address: _____
Street/P.O. Box

_____
City State Zip Code

5. Telephone No. _____

6. Email Address: _____

7. Congressional District: _____

PROGRAM INFORMATION:

☐ On-site ☐ Online

8. Course Name: _____

9. Course Dates: _____

10. Course Provider: _____

11. Location Offered: _____

ESTIMATED EXPENSES:

Please note: Scholarships are limited to tuition (excluding the conference fee), reasonable lodging up to $150 per night (including taxes), and transportation expenses to and from the site of the course, up to a maximum of $1,500.

Tuition: $ _____ Transportation: $ _____
(Airfare, train fare, or, if you plan to drive, an amount equal to the approximate distance and mileage rate.)

Lodging: $ _____ Total Amount Requested: $ _____

Are you seeking/have you received a scholarship for this course from another source? ☐ Yes ☐ No

If yes, please specify the source(s) and amount(s), and status (received or pending) _____

_____

Are State or local funds available to support your attendance at the proposed course? ☐ Yes ☐ No

If yes, what amount(s) will be provided? _____

Form S1 (8/07)

SJI Scholarship Application Page 2

ADDITIONAL INFORMATION:

Please attach a current resume or professional summary, and provide the information requested below.
(You may attach additional pages if necessary.)

1. Please describe your need to acquire the skills and knowledge taught in this course.

2. Please describe how taking this course will benefit you, your court, and the State's courts generally.

3. Is there an educational program currently available through your State on this topic?

4. How long have you served as a judge or court manager?

5. How long do you anticipate serving as a judge or court manager, assuming reelection or reappointment?

6. What continuing professional education programs have you attended in the past year? Please indicate which were mandatory and which were non-mandatory.

STATEMENT OF APPLICANT'S COMMITMENT

If a scholarship is awarded, I will share the skills and knowledge I have gained with my court colleagues locally and, if possible, state-wide, and I will submit an evaluation of the educational program to the State Justice Institute and to the Chief Justice of my State.

Signature Date

Please return this form and Form S-2 to:
Scholarship Coordinator, State Justice Institute, 1650 King Street, Suite 600, Alexandria, VA 22314

SJI Scholarship Application

Concurrence

I, _____,

Name of Chief Justice (or Chief Justice's Designee)

have reviewed the application for a scholarship to attend the program entitled: _____

_____,

prepared by _____,
and concur in its submission to the State Justice Institute. The applicant's participation in the program would benefit the State. The applicant's absence to attend the program would not present an undue hardship to the court.

Check box that applies:

❑ 1. Public funds **are not** available to enable the applicant to attend this course, and receipt of a scholarship would not diminish the amount of funds made available by the State for judicial branch education.

❑ 2. Public funds **are** available to support the applicant, but are insufficient to cover total costs. Therefore funding from the Institute is requested.

_____
Signature

_____
Name

_____
Title

_____
Date

Form S2 (8/07)

[FR Doc. 07–5921 Filed 12–4–07; 8:45 am]
BILLING CODE 6820–SC–C

Federal Register

Wednesday,
December 5, 2007

Part III

Department of Housing and Urban Development

Office of Federal Housing Enterprise Oversight

12 CFR Part 1750
Risk-Based Capital Regulation—Loss Severity Amendments; Proposed Rule

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of Federal Housing Enterprise Oversight

12 CFR Part 1750

RIN 2550–AA38

Risk-Based Capital Regulation—Loss Severity Amendments

AGENCY: Office of Federal Housing Enterprise Oversight, HUD.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: The Office of Federal Housing Oversight (OFHEO) is amending Appendix A to Subpart B of 12 CFR part 1750 Risk-Based Capital (Risk-Based Capital Regulation). The amendments are intended to enhance the accuracy and transparency of the calculation of the risk-based capital requirement for the Federal National Mortgage Association (Fannie Mae) and the Federal Home Loan Mortgage Corporation (Freddie Mac) (collectively the Enterprises). OFHEO proposes to amend further the Risk-Based Capital Regulation to change the loss severity equations that understate losses on defaulted single-family conventional and government guaranteed loans. OFHEO also proposes to amend the treatment of Federal Housing Administration (FHA) insurance in the Risk-Based Capital Regulation in order to conform the treatment to current law.

DATES: Comments regarding this Notice of Proposed Rulemaking must be received in writing on or before March 4, 2008. For additional information, see **SUPPLEMENTARY INFORMATION.**

ADDRESSES: You may submit your comments on the proposed rulemaking, identified by "RIN 2550–AA38," by any of the following methods:

- *U.S. Mail, United Parcel Post, or other Mail Service:* The mailing address for comments is: Alfred M. Pollard, General Counsel, Attention: Comments/RIN 2550–AA38, Office of Federal Housing Enterprise Oversight, Fourth Floor, 1700 G Street, NW., Washington, DC 20552.
- *Hand Delivery/Courier:* The hand delivery address is: Alfred M. Pollard, General Counsel, Attention: Comments/RIN 2550–AA38, Office of Federal Housing Enterprise Oversight, Fourth Floor, 1700 G Street, NW., Washington, DC 20552. The package should be logged at the Guard Desk, First Floor, on business days between 9 a.m. and 5 p.m.
- *E-mail:* Comments to Alfred M. Pollard, General Counsel, may be sent by e-mail at *RegComments@OFHEO.gov*. Please include "RIN 2550–AA38" in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: David A. Felt, Deputy General Counsel, telephone (202) 414–3750, or Jamie Schwing, Associate General Counsel, telephone (202) 414–3787 (not toll free numbers), Office of Federal Housing Enterprise Oversight, Fourth Floor, 1700 G Street, NW., Washington, DC 20552. The telephone number for the Telecommunications Device for the Deaf is (800) 877–8339.

SUPPLEMENTARY INFORMATION:

I. Comments

OFHEO invites comment on all aspects of the proposed amendments to the Risk-Based Capital Regulation, and will take all relevant comments into consideration before issuing the final regulation. OFHEO requests that comments submitted in hard copy also be accompanied by the electronic version in Microsoft® Word or in a portable document format (PDF) on 3.5″ disk or CD–ROM.

Copies of all comments will be posted on the OFHEO Internet Web site at *http://www.OFHEO.gov*. In addition, copies of all comments received will be available for examination by the public on business days between the hours of 10 a.m. and 3 p.m. at the Office of Federal Housing Enterprise Oversight, Fourth Floor, 1700 G Street, NW., Washington, DC 20552. To make an appointment to inspect comments, please call the Office of General Counsel at (202) 414–3751.

II. Background

Title XIII of the Housing and Community Development Act of 1992, Pub. L. 102–550, titled the Federal Housing Enterprise Financial Safety and Soundness Act of 1992 (the Act) (12 U.S.C. 4501 *et seq.*) established OFHEO as an independent office within the Department of Housing and Urban Development to ensure that the Enterprises are adequately capitalized, operate safely and soundly, and comply with applicable laws, rules and regulations. The Act provides that the Director of OFHEO (the Director) is authorized to make such determinations and take such actions as the Director determines necessary with respect to the issuance of regulations regarding, among other things, the required capital levels for the enterprises.[1] The Act further provides that the Director shall issue regulations establishing the risk-based capital test and that the Risk-Based Capital Regulation, subject to certain confidentiality provisions, shall be sufficiently specific to permit an individual other than the Director to apply the risk-based capital test in the same manner as the Director.[2]

Pursuant to the Act, OFHEO published a final regulation setting forth a risk-based capital test which forms the basis for determining the risk-based capital requirement for each Enterprise.[3] The Risk-Based Capital Regulation has been amended to incorporate corrective and technical amendments that enhance the accuracy and transparency of the calculation of the risk-based capital requirement.[4]

Consistent with the Act, OFHEO proposes to amend further the Risk-Based Capital Regulation to change certain loss severity equations that understate losses on defaulted single-family conventional and government guaranteed loans. OFHEO also proposes to amend the treatment of FHA insurance in the Risk-Based Capital Regulation in order to conform the treatment to current law.

As currently specified, certain loss severity equations allow the Enterprises to record negative losses (i.e., profits) on foreclosed mortgages during the calculation of the risk-based capital requirement. Unaltered, the current loss severity equations overestimate Enterprise recoveries for defaulted government-guaranteed and low loan-to-value (LTV) loans. The results generated by the current loss severity equations are not consistent with the goals of the Risk-Based Capital Regulation and result in significant reductions in the risk-based capital requirements of the Enterprises. The amendments to the relevant equations are set forth below.

A. Loss Severity

Loss Severity is the net cost to an Enterprise of a mortgage loan default. The Risk-Based Capital Regulation uses the costs associated with different events following the default of a mortgage to determine the total loss or cost to an Enterprise. Loss severity rates are computed as of the date of default and are expressed as a percentage of the unpaid principal balance of a defaulting loan. In general, losses on a loan include the unpaid principal balance of the loan, lost interest, foreclosure costs, and expenses related to real-estate-owned. *See* paragraph 3.6.3.6.1, *Calculation of*

[1] 12 U.S.C. 4513(a), (b)(1), (b)(3).

[2] 12 U.S.C. 1361(e)(1), (e)(3).

[3] Risk-Based Capital, 66 FR 44730 (September 13, 2001), 12 CFR part 1750.

[4] Risk-Based Capital, 66 FR 44730 (September 13, 2001), 12 CFR part 1750, *as amended*, 67 FR 11850 (March 15, 2002), 67 FR 19321 (April 19, 2002), 67 FR 66533 (November 1, 2002), 68 FR 7309 (February 13, 2003), 71 FR 75085 (December 14, 2006).

Single Family and Multifamily Mortgage Losses Overview.[5] Losses may be reduced by mortgage insurance proceeds, pool-level credit enhancement proceeds, and recovery proceeds from the sale of the foreclosed property, as set forth at paragraph 3.6.1[h], subtitled *Specification of Mortgage Default and Loss* and paragraph 3.6.3.6.2.1, subtitled, *Single Family Gross Loss Severity Overview.*[6]

Since the adoption of the Risk-Based Capital Regulation, OFHEO has gained extensive operating experience with the administration of the rule. A review of the loss severity equations as currently specified indicates that changes are required to correct deficiencies in the equations related to the calculation of loss severity rates for single-family conventional and FHA mortgages and single-family Department of Veterans Affairs (VA) mortgages. In addition, the current treatment of FHA insurance associated with single-family loans with an LTV below 78% is inconsistent with current law and should be corrected as detailed below.

i. Conventional Single-Family Loan Groups

The current treatment for calculating loss severity rates for conventional single-family loan groups is set forth in the Risk-Based Capital Regulation, paragraph 3.6.3.6.5.1, as a subtopic under the general heading of *Single Family and Multifamily Net Loss Severity Procedures.*[7] The following equation shows the loss severity model for conventional and FHA mortgages in the RBC regulation:

$$LS_m^{SF} = \frac{1}{\left(1+\frac{DR_m}{2}\right)^{\frac{MQ}{6}}} + \frac{\left(\frac{MQ}{12}\times PTR_m\right)+F-MI_m}{\left(1+\frac{DR_m}{2}\right)^{\frac{MF}{6}}} + \frac{R-RP_m-ALCE_m}{\left(1+\frac{DR_m}{2}\right)^{\frac{MF+MR}{6}}}$$

Where:

LS_m^{SF} = Net loss severity for conventional and FHA single-family loans in month m
MI_m = Mortgage insurance proceeds in month m
$ALCE_m$ = Aggregate limit credit enhancement in month m
MR = Months to recovery
F = Foreclosure costs
MQ = Months delinquent
PTR_m = Pass through rate for payments in month m
R = REO expenses
$RP_m = (0.61/LTV_q)$ = Recovery proceeds in month m. The 0.61 is the recovery rate on defaulted loans in the benchmark loss experience as a percentage of the predicted house price using the HPI.
LTV_q = Loan to value ratio in month q (current LTV)
DR_m = Discount rate in month m

This equation produces negative losses (profits) for low LTV loans. This result, profits on defaults, is inconsistent with the stress environment envisioned by the statute. Specifically, the problem arises with the term used to estimate the value of recovery proceeds as a percentage of the loan amount outstanding, RP_m, which is set equal to $0.61/LTV_q$. This term yields a value greater than one when LTV_q falls below 61%, resulting in the projected recovery proceeds exceeding the defaulted UPB. If the projected recovery proceeds exceed the other costs as well as the defaulted UPB, the result is a negative loss (profit).

More specifically, RP_m is problematic because it relies on LTV_q, which represents the estimated current LTV of a loan, assuming the mortgaged property has appreciated in value at the mean rate for the Census Division. Because LTV_q incorporates mean rather than actual house price appreciation, using LTV_q to measure how the loan amount compares to the property value can be misleading. Not all property values change at the mean rate; some perform less well. Loans with low LTV_q values that default generally are collateralized by properties whose values appreciated much less than properties securing other loans originated at the same time, and in the same Census Division. Such loans would normally only default rather than prepay if the defaulting borrowers cannot fully pay off the loan by selling the house because their actual current LTV ratio is higher than LTV_q. Thus the recovery rate generally is less than 61% on these defaulted loans.

The problem with the estimate of recovery proceeds has become acute, because the volume of loans in the Enterprises' portfolios with low LTV_q has increased sharply in recent years due to rapidly rising house prices. While only a very small percentage of loans with low values of LTV_q default in the RBC model, there are now so many loans with low LTV_q values that the effects are pronounced. When this model specification was selected, this problem was relatively small, as there were few defaulting loans generating gains. Alternative specifications that avoided this issue added considerable complexity to the model and had other problems.

Profiting on defaults also is not consistent with the credit stress environment envisioned in the Risk-Based Capital Regulation. Despite having a low LTV, a homeowner may face unemployment and an illiquid housing market in the RBC stress environment. Upon foreclosure, the Enterprise would face the challenge of selling the property in the same illiquid market, making the prospect of a profit highly unlikely. Substantial profits on defaulted loans would be unlikely in any event because the law in a number of states requires any "extra" proceeds from a foreclosure to revert to the mortgagee, not the holder of the mortgage.

OFHEO proposes to correct the loss severity equation for conventional and FHA mortgages such that the results of the equation are constrained to be non-negative. This change will eliminate the possibility of the Enterprises profiting on defaulted mortgages in the stress test model. The change addresses the weakness in the recovery equation and produces results that are more consistent with the credit stress environment envisioned in the RBC Regulation.

As part of its analysis, OFHEO considered two alternatives. One alternative would have restricted recovery proceeds to 120% of the outstanding loan amount.[8] Another alternative considered would have required the loss severity equation to be non-negative, except that MI and aggregate level credit enhancements payments would be received in full. These alternatives were not proposed

[5] 12 CFR part 1750 (2006), Subpart B, Appendix A, ¶ 3.6.3.6.1[c].

[6] Id. ¶ 3.6.1[h] and ¶ 3.6.3.6.2.1.

[7] Id. ¶ 3.6.3.6.5.1[a].

[8] The 120% figure reflects the total costs observed on defaulted loans in the benchmark loss experience (the loan amount (100%), the foreclosure expenses (3.7%) and real estate-owned (REO) expenses (16.3%).

because they would produce gains on defaults for certain loans.

ii. Veterans Administration Mortgages

The current treatment for calculating loss severities for single-family VA-guaranteed mortgages is set forth in the Risk-Based Capital Regulation at paragraph 3.6.3.6.5.1 as a subtopic under the general heading of *Single Family and Multifamily Net Loss Severity Procedures.*[9] The current loss severity equation for VA loans utilizes the same equation for recovery proceeds as the conventional and FHA loss severity equation, and thus may also generate negative losses. In order to address this issue, OFHEO proposes an amendment to revise the loss severity equation for VA loans such that the results of the equation are constrained to be non-negative.

During the development of this proposed amendment, OFHEO considered removing the recovery proceeds term from the VA loss severity equation in order to reduce the negative losses. However, this alternative does not accurately reflect the VA guarantee program, which may allow both recovery proceeds and the VA guarantee to be used to offset losses.

iii. Federal Housing Administration Insurance

The current treatment for consideration of FHA insurance in the calculation of loss severities is set forth in the Risk-Based Capital Regulation. See paragraph 3.6.3.6.4.3, as a subtopic under the general heading *Mortgage Credit Enhancement Procedures.*[10] The current equation cancels mortgage insurance for all loans when the LTV falls below 78%. Although this treatment is appropriate for loans with private mortgage insurance, FHA insurance remains in force irrespective of the LTV of a mortgage. OFHEO proposes not to cancel FHA insurance by amending the current equation.

B. Capital Impact of Proposed Amendments

The following table shows the estimated capital impact of all of the proposed amendments at September 30 and December 31, 2006.

TABLE 1.—ESTIMATED CAPITAL IMPACT OF PROPOSED AMENDMENTS

[Billions of dollars]

	Quarter	Interest rate scenario	RBC requirement		
			Current regulation	Current regulation with proposed amendments	Change *
Fannie Mae	2006 3Q	Up-Rate	$22.5	$32.0	$9.5
		Down-Rate	16.4	25.1	8.6
	2006 4Q	Up-Rate	26.9	36.6	9.8
		Down-Rate	9.1	16.6	7.5
Freddie Mac	2006 3Q	Up-Rate	14.9	19.4	4.5
		Down-Rate	13.8	18.2	4.4
	2006 4Q	Up-Rate	15.3	20.7	5.4
		Down-Rate	12.9	17.5	4.5

* Figures may not sum precisely due to rounding.

The proposed amendments substantially increase the RBC Requirement in both the up and down interest rate scenarios for both Enterprises for the two quarters analyzed. However, if the proposed amendments had been in effect during the analyzed periods, total capital would have exceeded the RBC Requirement and the capital classifications of the Enterprises would not have changed.

Regulatory Impacts

Executive Order 12866, Regulatory Planning and Review

The proposed amendments to the Risk-Based Capital Regulation incorporate corrections to the loss severity equations used to calculate the risk-based capital requirements of the Enterprises. The proposed amendments to the Risk-Based Capital Regulation are not classified as an economically significant rule under Executive Order 12866 because they do not result in an annual effect on the economy of $100 million or more or a major increase in costs or prices for consumers, individual industries, Federal, state or local government agencies, or geographic regions; or have any significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in foreign or domestic markets. Accordingly, no regulatory impact assessment is required. However, as a regulatory action with significant policy implications, the proposed amendments were submitted to the Office of Management and Budget for review under applicable provisions of Executive Order 12866.

Executive Order 13132, Federalism

Executive Order 13132 requires that Executive departments and agencies identify regulatory actions that have significant federalism implications. A regulation has federalism implications if it has substantial direct effects on the states, on the relationship or distribution of power between the Federal Government and the states, or on the distribution of power and responsibilities among various levels of government. The Enterprises are federally chartered entities supervised by OFHEO. The proposed amendments to the Risk-Based Capital Regulation address matters with which the Enterprises must comply for Federal regulatory purposes. The proposed amendments to the Risk-Based Capital Regulation address matters regarding the risk-based capital calculation for the Enterprises and therefore does not affect in any manner the powers and authorities of any state with respect to the Enterprises or alter the distribution of power and responsibilities between Federal and state levels of government. Therefore, OFHEO has determined that the proposed amendments to the Risk-

[9] 12 CFR part 1750 (2006), Subpart B, Appendix A, ¶ 3.6.3.6.5.1[b]2.

[10] Id. ¶ 3.6.3.6.4.3[a]1.

Based Capital Regulation have no federalism implications that warrant preparation of a Federalism Assessment in accordance with Executive Order 13132.

Paperwork Reduction Act

The proposed amendments do not contain any information collection requirement that requires the approval of OMB under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires that a regulation that has a significant economic impact on a substantial number of small entities, small businesses, or small organizations must include an initial regulatory flexibility analysis describing the regulation's impact on small entities. Such an analysis need not be undertaken if the agency has certified that the regulation does not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 605(b). OFHEO has considered the impact of the proposed amendments to the Risk-Based Capital Regulation under the Regulatory Flexibility Act. The General Counsel of OFHEO certifies that the proposed amendments to the Risk-Based Capital Regulation are not likely to have a significant economic impact on a substantial number of small business entities because the regulation is applicable only to the Enterprises, which are not small entities for purposes of the Regulatory Flexibility Act.

List of Subjects in 12 CFR Part 1750

Capital classification, Mortgages, Risk-based capital.

Accordingly, for the reasons stated in the preamble, OFHEO is amending 12 CFR part 1750 as follows:

PART 1750—CAPITAL

1. The authority citation for part 1750 continues to read as follows:

Authority: 12 U.S.C. 4513, 4514, 4611, 4612, 4614, 4618.

2. Amend Appendix A to subpart B of part 1750 as follows:

a. In paragraph 3.6.3.6.4.3[a]1, revise the explanation following the equation;

b. In paragraph 3.6.3.6.5.1[a] revise equation;

c. In paragraph 3.6.3.6.5.1[b]2 revise equation.

Appendix A to Subpart B of Part 1750—Risk-Based Capital Text Methodology and Specifications

* * * * *

3.6.3.6.4.3 * * *

[a] * * *

1. * * *

Where:

m′ = m, except for counterparties rated below BBB, where m′ = 120

$$\text{MIExp}_m^{LG} = 1 \text{ if } \left(\left(\text{LTV}_{ORIG} \times \frac{\text{UPB}_m^{LG}}{\text{UPB}_{ORIG}^{LG}} \right) < 0.78 \right) \text{ and conventional loan}$$

$$\text{MIExp}_m^{LG} = 0 \text{ otherwise}$$

0.78 (78%) = the LTV at which MI is cancelled if payments are current

* * * * *

3.6.3.6.5.1 * * *

[a] * * *

$$LS_m^{SF} = MAX\left[\left(\frac{1}{\left(1+\frac{DR_m}{2}\right)^{\frac{MQ}{6}}} + \frac{\left(\frac{MQ}{12}\times PTR_m\right)+F-MI_m}{\left(1+\frac{DR_m}{2}\right)^{\frac{MF}{6}}} + \frac{R-RP_m-ALCE_m}{\left(1+\frac{DR_m}{2}\right)^{\frac{MF+MR}{6}}}\right), 0\right]$$

[b] * * *

2. * * *

$$LS_m^{VA} = \max\left[\frac{1+F+\left(\frac{MQ}{12}\times PTR_m\right)+(R-RP_m)-0.30}{\left(1+\frac{DR_m}{2}\right)^{\frac{MF}{6}}}, 0\right]$$

* * * * *

Dated: October 11, 2007.

James B. Lockhart III,

Director, Office of Federal Housing Enterprise Oversight.

[FR Doc. 07–5101 Filed 12–4–07; 8:45 am]

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Federal Register

Wednesday,
December 5, 2007

Part IV

Environmental Protection Agency

40 CFR Part 180
Dichlorvos (DDVP); Order Denying NRDC's Petition to Revoke All Tolerances; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2002–0302; FRL–8341–9]

Dichlorvos (DDVP); Order Denying NRDC's Petition to Revoke All Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Order.

SUMMARY: In this Order, EPA denies a petition requesting that EPA revoke all pesticide tolerances for dichlorvos (DDVP) under section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA). The petition was filed on June 2, 2006, by the Natural Resources Defense Council (NRDC).

DATES: This order is effective December 5, 2007. Objections and requests for hearings must be received on or before February 4, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2002-0302. To access the electronic docket, go to *http://www.regulations.gov*, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (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 in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Susan Bartow, Special Review and Reregistration Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 603-0065; e-mail address: *bartow.susan@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

In this document EPA denies a petition by the Natural Resources Defense Council ("NRDC") to revoke pesticide tolerances. This action may also be of interest to agricultural producers, food manufacturers, or pesticide manufacturers. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (North American Industrial Classification System (NAICS) code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The NAICS codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?.

Under section 408(g) of FFDCA, any person may file an objection to any aspect of this order and may also request a hearing on those objections. You must file your objection or request a hearing on this order in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2002-0302 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before February 4, 2008.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2002-0302, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Introduction

A. What Action Is the Agency Taking?

On June 2, 2006, the Natural Resources Defense Council (NRDC) filed a petition with EPA which, among other things, requested that EPA revoke all tolerances for the pesticide dichlorvos (DDVP) established under section 408 of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. 346a. (Ref. 1). NRDC's petition asserts that the DDVP tolerances are unsafe and should be revoked for numerous reasons, including: EPA has improperly assessed the toxicity of DDVP; EPA has erred in

estimating dietary and residential exposure to DDVP; and EPA has unlawfully removed the additional safety factor for the protection of infants and children. This order finds NRDC's claims regarding the DDVP tolerances to be without merit and, accordingly, denies that aspect of NRDC petition. The other aspects of NRDC's petition are addressed in another EPA action.

B. What Is the Agency's Authority for Taking This Action?

Under section 408(d)(4) of the FFDCA, EPA is authorized to respond to a section 408(d) petition to revoke tolerances either by issuing a final rule revoking the tolerances, issuing a proposed rule, or issuing an order denying the petition. (21 U.S.C. 346a(d)(4)).

III. Statutory and Regulatory Background

A. Statutory Background

1. *In general.* EPA establishes maximum residue limits, or "tolerances," for pesticide residues in food under section 408 of the FFDCA. (21 U.S.C. 346a). Without such a tolerance or an exemption from the requirement of a tolerance, a food containing a pesticide residue is "adulterated" under section 402 of the FFDCA and may not be legally moved in interstate commerce. (21 U.S.C. 331, 342). Monitoring and enforcement of pesticide tolerances are carried out by the U.S. Food and Drug Administration and the U. S. Department of Agriculture. Section 408 was substantially rewritten by the Food Quality Protection Act of 1996 (FQPA), which added the provisions discussed below establishing a detailed safety standard for pesticides, additional protections for infants and children, and the estrogenic substances screening program.

EPA also regulates pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), (7 U.S.C. 136 et seq). While the FFDCA authorizes the establishment of legal limits for pesticide residues in food, FIFRA requires the approval of pesticides prior to their sale and distribution, (7 U.S.C. 136a(a)), and establishes a registration regime for regulating the use of pesticides. FIFRA regulates pesticide use in conjunction with its registration scheme by requiring EPA review and approval of pesticide labels and specifying that use of a pesticide inconsistent with its label is a violation of Federal law. (7 U.S.C. 136j(a)(2)(G)). In the FQPA, Congress integrated action under the two statutes by requiring that the safety standard under the FFDCA be used as a criterion in FIFRA registration actions as to pesticide uses which result in dietary risk from residues in or on food, (7 U.S.C. 136(bb)), and directing that EPA coordinate, to the extent practicable, revocations of tolerances with pesticide cancellations under FIFRA. (21 U.S.C. 346a(l)(1)).

2. *Safety standard for pesticide tolerances.* A pesticide tolerance may only be promulgated by EPA if the tolerance is "safe." (21 U.S.C. 346a(b)(2)(A)(i)). "Safe" is defined by the statute to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." (21 U.S.C. 346a(b)(2)(A)(ii)). Section 408(b)(2)(D) directs EPA, in making a safety determination, to:

> consider, among other relevant factors- ....
> (v) available information concerning the cumulative effects of such residues and other substances that have a common mechanism of toxicity;
> (vi) available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances, including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue, and exposure from other non-occupational sources;
> (viii) such information as the Administrator may require on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects. ...

(21 U.S.C. 346a(b)(2)(D)(v), (vi) and (viii)).

Section 408(b)(2)(C) requires EPA to give special consideration to risks posed to infants and children. Specifically, this provision states that EPA:

> shall assess the risk of the pesticide chemical based on— ...
> (II) available information concerning the special susceptibility of infants and children to the pesticide chemical residues, including neurological differences between infants and children and adults, and effects of *in utero* exposure to pesticide chemicals; and
> (III) available information concerning the cumulative effects on infants and children of such residues and other substances that have a common mechanism of toxicity. ...

(21 U.S.C. 346a(b)(2)(C)(i)(II) and (III)).

This provision further directs that "[i]n the case of threshold effects, ... an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children." (21 U.S.C. 346a(b)(2)(C)). EPA is permitted to "use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children." (Id.). The additional safety margin for infants and children is referred to throughout this Order as the "children's safety factor."

3. *Procedures for establishing, amending, or revoking tolerances.* Tolerances are established, amended, or revoked by rulemaking under the unique procedural framework set forth in the FFDCA. Generally, the rulemaking is initiated by the party seeking to establish, amend, or revoke a tolerance by means of filing a petition with EPA. (See 21 U.S.C. 346a(d)(1)). EPA publishes in the **Federal Register** a notice of the petition filing and requests public comment. (21 U.S.C. 346a(d)(3)). After reviewing the petition, and any comments received on it, EPA may issue a final rule establishing, amending, or revoking the tolerance, issue a proposed rule to do the same, or deny the petition. (21 U.S.C. 346a(d)(4)). Once EPA takes final action on the petition by either establishing, amending, or revoking the tolerance or denying the petition, any affected party has 60 days to file objections with EPA and seek an evidentiary hearing on those objections. (21 U.S.C. 346a(g)(2)). EPA's final order on the objections is subject to judicial review. (21 U.S.C. 346a(h)(1)).

4. *Tolerance Reassessment and FIFRA Reregistration.* The FQPA requires, among other things, that EPA reassess the safety of all pesticide tolerances existing at the time of its enactment. (21 U.S.C. 346a(q)). In this reassessment, EPA is required to review existing pesticide tolerances under the new "reasonable certainty that no harm will result" standard set forth in section 408(b)(2)(A)(i). (21 U.S.C. 346a(b)(2)(A)(i)). This reassessment was substantially completed by the August 3, 2006 deadline. Tolerance reassessment is generally handled in conjunction with a similar program involving reregistration of pesticides under FIFRA. (7 U.S.C. 136a-1). Reassessment and reregistration decisions are generally combined in a document labeled a Reregistration Eligibility Decision ("RED").

5. *Estrogenic Substances Screening Program.* Section 408(p) of the FFDCA creates the estrogenic substances screening program. This provision gives EPA 2 years from enactment of the FQPA to "develop a screening program ... to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring

estrogen, or such other endocrine effect as the Administrator may designate." This screening program must use "appropriate validated test systems and scientifically relevant information." (21 U.S.C. 346a(p)(1)). Once the program is developed, EPA is required to take public comment and seek independent scientific review of it. Following the period for public comment and scientific review, and not later than 3 years following enactment of the FQPA, EPA is directed to "implement the program." (21 U.S.C. 346a(p)(2)).

The scope of the estrogenic screening program was expanded by an amendment to the Safe Drinking Water Act (SDWA) passed contemporaneously with FQPA. That amendment gave EPA the authority to provide for the testing, under the FQPA estrogenic screening program, "of any other substance that may be found in sources of drinking water if the Administrator determines that a substantial population may be exposed to such substance." (42 U.S.C. 300j-17).

B. Setting and Reassessing Pesticide Tolerances Under the FFDCA

1. *In general.* The process EPA follows in setting and reassessing tolerances under the FFDCA includes two steps. First, EPA determines an appropriate residue level value for the tolerance taking into account data on levels that can be expected in food. Second, EPA evaluates the safety of the tolerance relying on toxicity and exposure data and guided by the statutory definition of "safety" and requirements concerning risk assessment. Only on completion of the second step can a tolerance be established or reassessed. Both stages of this process are relevant to EPA's analysis of petitions to revoke tolerances based on risk concerns because both stages bear on the assessment of risk.

2. *Choosing a tolerance value.* In the first step of the tolerance setting or reassessment process (choosing a tolerance value), EPA evaluates data from experimental crop field trials in which the pesticide has been used in a manner, consistent with the draft FIFRA label, that is likely to produce the highest residue in the crop in question (e.g., maximum application rate, maximum number of applications, minimum pre-harvest interval between last pesticide application and harvest). (Refs. 2 and 3). These crop field trials are generally conducted in several fields at several geographical locations. (Id. at 5, 7 and Tables 1 and 5). Several samples are then gathered from each field and analyzed. (Id. at 53). Generally, the results from such field trials show that the residue levels for a given pesticide use will vary from as low as non-detectable to measurable values in the parts per million (ppm) range with the majority of the values falling at the lower part of the range. EPA uses a statistical procedure to analyze the field trial results and identify the upper bound of expected residue values. This upper bound value is used as the tolerance value. (Ref. 4). (As discussed below, the safety of the tolerance value chosen is separately evaluated.).

There are three main reasons for closely linking tolerance values to the maximum value that could be present from maximum label usage of the pesticide. First, EPA believes it is important to coordinate its actions under the two statutory frameworks governing pesticides. (See 61 FR 2378, 2379 (January 25, 1996)). It would be illogical for EPA to set a pesticide tolerance under the FFDCA without considering what action is being taken under FIFRA with regard to registration of that pesticide use. (Cf. 40 CFR 152.112(g) (requiring all necessary tolerances to be in place before a FIFRA registration may be granted)). In coordinating its actions, one basic tenet that EPA follows is that a grower who applies a pesticide consistent with the FIFRA label directions should not run the risk that his or her crops will be adulterated under the FFDCA because the residues from that legal application exceed the tolerance associated with that use. Crop field trials require application of the pesticide in the manner most likely to produce maximum residues to further this goal. Second, choosing tolerance values based on FIFRA label rates helps to ensure that tolerance levels are established no higher than necessary. If tolerance values were selected solely in consideration of health risks, in some circumstances, tolerance values might be set so as to allow much greater application rates than necessary for effective use of the pesticide. This could encourage misuse of the pesticide. Finally, closely linking tolerance values to FIFRA labels helps EPA to police compliance with label directions by growers because detection of an over-tolerance residue is indicative of use of a pesticide at levels, or in a manner, not permitted on the label.

3. *The safety determination - risk assessment.* Once a tolerance value is chosen, EPA then evaluates the safety of the pesticide tolerance using the process of risk assessment. To assess risk of a pesticide, EPA combines information on pesticide toxicity with information regarding the route, magnitude, and duration of exposure to the pesticide.

In evaluating toxicity or hazard, EPA examines both short-term (e.g., "acute") and longer-term (e.g., "chronic") adverse effects from pesticide exposure. (Ref. 2 at 8-10). EPA also considers whether the "effect" has a threshold - a level below which exposure has no appreciable chance of causing the adverse effect. For non-threshold effects, EPA assumes that any exposure to the substance increases the risk that the adverse effect may occur. At present, EPA only considers one adverse effect, the chronic effect of cancer, to potentially be a non-threshold effect. (Ref. 2 at 8-9). Not all carcinogens, however, pose a risk at any exposure level (i.e., "a non-threshold effect or risk"). Advances in the understanding of carcinogenesis have increasingly led EPA to conclude that some pesticides that cause carcinogenic effects only cause such effects above a certain threshold of exposure. EPA has traditionally considered adverse effects on the endocrine system to be a threshold effect; that determination is being reexamined in conjunction with the endocrine disruptor screening program.

Once the hazard for a durational scenario is identified, EPA must determine the toxicological level of concern and then compare estimated human exposure to this level of concern. This comparison is done through either calculating a safe dose in humans (incorporating all appropriate safety factors) and expressing exposure as a percentage of this safe dose (the reference dose ("RfD") approach) or dividing estimated human exposure into an appropriate dose from the relevant studies at which no adverse effects from the pesticide are seen (the margin of exposure ("MOE") approach). How EPA determines the level of concern and assesses risk under these two approaches is explained in more detail below. EPA's general approach to estimating exposure is also briefly discussed.

a. *Levels of concern and risk assessment*—i. *Threshold effects.* In assessing the risk from a pesticide's threshold effects, EPA evaluates an array of toxicological studies on the pesticide. In each of these studies, EPA attempts to identify the lowest observed adverse effect level ("LOAEL") and the next lower dose at which there are no observed adverse affect levels ("NOAEL"). Generally, EPA will use the lowest NOAEL from the available studies as a starting point in estimating the level of concern for humans. In estimating and describing the level of

concern, however, the chosen NOAEL is at times manipulated differently depending on whether the risk assessment addresses dietary or non-dietary exposures.

For dietary risks, EPA uses the chosen NOAEL to calculate a safe dose or RfD. The RfD is calculated by dividing the chosen NOAEL by all applicable safety or uncertainty factors. Typically, a combination of safety or uncertainty factors providing a hundredfold (100X) margin of safety is used: 10X to account for uncertainties inherent in the extrapolation from laboratory animal data to humans and 10X for variations in sensitivity among members of the human population as well as other unknowns. Additional safety factors may be added to address data deficiencies or concerns raised by the existing data. Further, under the FQPA, an additional safety factor of 10X is presumptively applied to protect infants and children, unless reliable data support selection of a different factor. In implementing FFDCA section 408, EPA's Office of Pesticide Programs, also calculates a variant of the RfD referred to as a Population Adjusted Dose ("PAD"). A PAD is the RfD divided by any portion of the FQPA safety factor that does not correspond to one of the traditional additional safety factors used in general Agency risk assessments. (Ref. 5 at 13-16). The reason for calculating PADs is so that other parts of the Agency, which are not governed by FFDCA section 408, can, when evaluating the same or similar substances, easily identify which aspects of a pesticide risk assessment are a function of the particular statutory commands in FFDCA section 408. Today, RfDs and PADs are generally calculated for both acute and chronic dietary risks although traditionally a RfD or PAD was only calculated for chronic dietary risks. Throughout this document general references to EPA's calculated safe dose are denoted as a RfD/PAD.

To quantitatively describe risk using the RfD/PAD approach, estimated exposure is expressed as a percentage of the RfD/PAD. Dietary exposures lower than 100 percent of the RfD are generally not of concern.

For non-dietary, and often for combined dietary and non-dietary, risk assessments of threshold effects, the toxicological level of concern is not expressed as a safe dose or RfD/PAD but rather as the margin of exposure (MOE) that is necessary to be sure that exposure to a pesticide is safe. A safe MOE is generally considered to be a margin at least as high as the product of all applicable safety factors for a pesticide. For example, if a pesticide needs a 10X factor to account for interspecies differences, 10X factor for intraspecies differences, and 10X factor for FQPA, the safe or target MOE would be a MOE of at least 1,000. To calculate the MOE for a pesticide, human exposure to the pesticide is divided into the lowest NOAEL from the available studies. In contrast to the RfD/PAD approach, the higher the MOE, the safer the pesticide. Accordingly, if the level of concern for a pesticide is 1,000, MOEs exceeding 1,000 would generally not be of concern. Like RfD/PADs, specific MOEs are calculated for exposures of different durations. For non-dietary exposures, EPA typically examines short-term, intermediate-term, and long-term exposures. Additionally, non-dietary exposure often involves exposures by various routes including dermal, inhalation, and oral.

The RfD/PAD and MOE approaches are fundamentally equivalent. For a given risk and given exposure of a pesticide, if the pesticide were found to be safe under an RfD/PAD analysis it would also pass under the MOE approach, and vice-versa.

ii. *Non-threshold effects.* For risk assessments for non-threshold effects, EPA does not use the RfD/PAD or MOE approach if quantitation of the risk is deemed appropriate. Rather, EPA calculates the slope of the dose-response curve for the non-threshold effects from relevant studies using a model that assumes that any amount of exposure will lead to some degree of risk. The slope of the dose-response curve can then be used to estimate the probability of occurrence of additional adverse effects as a result of exposure to the pesticide. For non-threshold cancer risks, EPA generally is concerned if the probability of increased cancer cases exceeds the range of 1 in 1 million.

b. *Estimating human exposure.* Equally important to the risk assessment process as determining the toxicological level of concern is estimating human exposure. Under FFDCA section 408, EPA is concerned not only with exposure to pesticide residues in food but also exposure resulting from pesticide contamination of drinking water supplies and from use of pesticides in the home or other non-occupational settings. (See 21 U.S.C. 346a(b)(2)(D)(vi)).

i. *Exposure from food.* (A) *In General.* There are two critical variables in estimating exposure in food: (1) The types and amount of food that is consumed; and (2) the residue level in that food. Consumption is estimated by EPA based on scientific surveys of individuals' food consumption in the United States conducted by the U.S. Department of Agriculture. (Ref. 2 at 12). Information on residue values comes from a range of sources including crop field trials, data on pesticide reduction due to processing, cooking, and other practices, information on the extent of usage of the pesticide, and monitoring of the food supply. (Id. at 17).

In assessing exposure from pesticide residues in food, EPA, for efficiency's sake, follows a tiered approach in which it, in the first instance, conducts its exposure assessment using the extreme case assumptions that 100 percent of the crop in question is treated with the pesticide and 100 percent of the food from that crop contains pesticide residues at the tolerance level. (Id. at 11). When such an assessment shows no risks of concern, a more complex risk assessment is unnecessary. By avoiding a more complex risk assessment, EPA's resources are conserved and regulated parties are spared the cost of any additional studies that may be needed. If, however, a first tier assessment suggests there could be a risk of concern, EPA then attempts to refine its exposure assumptions to yield a more realistic picture of residue values through use of data on the percent of the crop actually treated with the pesticide and data on the level of residues that may be present on the treated crop. These latter data are used to estimate what has been traditionally referred to by EPA as "anticipated residues."

Use of percent crop treated data and anticipated residue information is appropriate because EPA's worst-case assumptions of 100 percent treatment and residues at tolerance value significantly overstate residue values. There are several reasons this is true. First, all growers of a particular crop would rarely choose to apply the same pesticide to that crop; generally, the proportion of the crop treated with a particular pesticide is significantly below 100 percent. Second, as discussed above, the tolerance value is set above the highest value observed in crop field trials using maximum use rates. There may be some commodities from a treated crop that approach the tolerance value where the maximum label rates are followed, but most generally fall significantly below the tolerance value. If less than the maximum legal rate is applied, residues will be even lower. Third, residue values in the field do not take into account the lowering of residue values that frequently occurs as a result of degradation over time and through food processing and cooking.

EPA uses several techniques to refine residue value estimates. (Id. at 17-28).

First, where appropriate, EPA will take into account all the residue values reported in the crop field trials, either through use of an average or individually. Second, EPA will consider data showing what portion of the crop is not treated with the pesticide. Third, data can be produced showing pesticide degradation and decline over time, and the effect of commercial and consumer food handling and processing practices. Finally, EPA can consult monitoring data gathered by the Food and Drug Administration, the U.S. Department of Agriculture, or pesticide registrants, on pesticide levels in food at points in the food distribution chain distant from the farm, including retail food establishments.

Another critical component of the exposure assessment is how data on consumption patterns are combined with data on pesticide residue levels in food. Traditionally, EPA has calculated exposure by simply multiplying average consumption by average residue values for estimating chronic risks and high-end consumption by maximum residue values for estimating acute risks. Although using average residues is a realistic approach for chronic risk assessment due to the fact that variations in residue levels and consumption amounts average out over time, using maximum residue values for acute risk assessment tends to greatly overstate exposure in narrow increments of time where it matters how much of each treated food a given consumer eats and what the residue levels are in the particular foods consumed. To take into account the variations in short-term consumption patterns and food residue values for acute risk assessments, EPA has more recently begun using probabilistic modeling techniques for estimating exposure when more simplistic models appear to show risks of concerns.

All of these refinements to the exposure assessment process, from use of food monitoring data through probabilistic modeling, can have dramatic effects on the level of exposure predicted, reducing worst case estimates by 1 or 2 orders of magnitude or more.

(B) Computer modeling of dietary exposure. EPA uses a computer program known as the Dietary Exposure Evaluation Model – Food Commodity Intake Database ("DEEM-FCID") to estimate exposure by combining data on human consumption amounts with residue values in food commodities. DEEM-FCID also compares exposure estimates to appropriate RfD/PAD values to estimate risk. DEEM-FCID can estimate exposure for the general U.S. population as well as 32 subgroups based on age, sex, ethnicity, and region. DEEM-FCID is closely modeled on its predecessor program DEEM. DEEM-FCID includes the DEEM software modeling program but has revised inputs bearing on consumption patterns that were developed by EPA to insure that all underlying aspects of the model are publicly available. (Ref. 6).

EPA uses a computer program to make exposure and risk estimates because EPA has great volumes of data on human consumption amounts and residue levels. Matching consumption and residue data can be done more efficiently by computer. Additionally, certain risk assessment techniques involve thousands of repeated analyses of the consumption database and this cannot practically be done by hand. However, the actual structure and logic of DEEM-FCID is relatively simple.

DEEM-FCID contains consumption and demographic information on the individuals who participated in the USDA's Continuing Surveys of Food Intake by Individuals ("CSFII") in 1994-1996 and 1998. The 1998 survey was a special survey required by the FQPA to supplement the number of children survey participants. DEEM-FCID also contains translation factors that convert foods as consumed (e.g., pizza) back into their component raw agricultural commodities. This is necessary because residue data are generally gathered on raw agricultural commodities rather than on finished ready-to-eat food. Data on residue values for a particular pesticide and the RfD/PADs for that pesticide have to be inputted into the DEEM-FCID program to estimate exposure and risk.

DEEM-FCID can make three types of risk estimates: a single point estimate; a simple distribution; or a probabilistic distribution. A point estimate provides a single exposure and risk value for each population subgroup. Generally, these exposure and risk values are derived by combining single values for consumption and residue amount on consumed commodities. For example, point estimates are commonly computed for chronic exposure and risk by combining data on average consumption with data on average residue levels. (Ref. 7-).

In contrast to a point estimate, DEEM-FCID can also do two types of distributional analyses. A simple distribution combines a single residue value for each food with the full range of data on individual consumption amounts to create a distribution of exposure and risk levels. More specifically, DEEM-FCID creates this distribution by calculating an exposure value for each reported day of consumption per person ("person/day") in CSFII assuming that all foods potentially bearing the pesticide residue contain such residue at the chosen value. The exposure amounts for the thousands of person/days in the CSFII are then collected in a frequency distribution.

Added complexity is introduced if DEEM-FCID computes a distribution taking into account both the full range of data on consumption levels and the full range of data on potential residue levels in food. Combining these two independent variables (consumption and residue levels) into a distribution of potential exposures and risk requires use of probabilistic techniques.

The probabilistic technique that DEEM-FCID uses to combine differing levels of consumption and residues involves the following steps:

1. for each person/day in the CSFII, identification of any food(s) that could possibly bear the residue of the pesticide in question;

2. calculation of an exposure level for each person/day based on the foods identified in Step #1 by randomly selecting residue values for the foods from the residue database;

3. repetition of Step #2 one thousand times for each person/day; and

4. collection of all of the hundreds of thousands of potential exposures estimated in Steps #2 and #3 in a frequency distribution.

In this manner, a probabilistic assessment presents a range of exposure/risk estimates.

Point estimates are used for chronic risk assessments. EPA does not use DEEM-FCID to calculate distributional assessments for chronic risk because EPA's current view is that its consumption database is not sufficiently robust to support a distributional analysis for chronic exposure. Both simple and probabilistically-derived distributions are used for acute risk assessment. EPA generally estimates exposure and risk from a simple distribution based on the 95th percentile of such a distribution. EPA's reason for relying on the 95th percentile with simple distribution assessments is that for these assessments EPA typically uses very conservative assumptions regarding residue levels (100 percent of the crop is treated and all treated food bears residues at the tolerance level) and thus the 95th percentile is protective of the general population as well as all major, identifiable population subgroups. Because probabilistic assessments generally use more realistic residue levels, EPA's starting point for estimating exposure and risk for such assessments is the 99.9th percentile.

This value can change depending on the degree of conservatism in the residue estimates. (Ref. 8).

ii. *Exposure from water.* EPA may use either or both field monitoring data and mathematical water exposure models to generate pesticide exposure estimates in drinking water. Monitoring and modeling are both important tools for estimating pesticide concentrations in water and can provide different types of information. Monitoring data can provide estimates of pesticide concentrations in water that are representative of specific agricultural or residential pesticide practices and under environmental conditions associated with a sampling design. Although monitoring data can provide a direct measure of the concentration of a pesticide in water, it does not always provide a reliable estimate of exposure because sampling may not occur in areas with the highest pesticide use, and/or the sampling may not occur when the pesticides are being used.

In estimating pesticide exposure levels in drinking water, EPA most frequently uses mathematical water exposure models. EPA's models are based on extensive monitoring data and detailed information on soil properties, crop characteristics, and weather patterns. (69 FR 30042, 30058-30065 (May 26, 2004)). These models calculate estimated environmental concentrations of pesticides using laboratory data that describe how fast the pesticide breaks down to other chemicals and how it moves in the environment. These concentrations can be estimated continuously over long periods of time, and for places that are of most interest for any particular pesticide. Modeling is a useful tool for characterizing vulnerable sites, and can be used to estimate peak concentrations from infrequent, large storms.

EPA has developed models for estimating exposure in both surface water and ground water. EPA uses a two-tiered approach to modeling pesticide exposure in surface water. In the initial tier, EPA uses the FQPA Index Reservoir Screening Tool (FIRST) model. FIRST replaces the GENeric Estimated Environmental Concentrations (GENEEC) model that was used as the first tier screen by EPA from 1995-1999. If the first tier model suggests that pesticide levels in water may be unacceptably high, a more refined model is used as a second tier assessment. The second tier model is actually a combination of the models, Pesticide Root Zone Model (PRZM) and the Exposure Analysis Model System (EXAMS). For estimating pesticide residues in groundwater, EPA uses the Screening Concentration In Ground Water (SCI-GROW) model. Currently, EPA has no second tier groundwater model.

EPA's water exposure models have been extensively peer-reviewed and/or validated, and have proved highly conservative in practice. In fact, an evaluation conducted in conjunction with NRDC objections to tolerances for other pesticides found that EPA's surface water models never under-estimated the highest values measured in monitoring studies, and that EPA's groundwater model had only rarely under-estimated such results, and those underestimations were relatively small. (69 FR at 30061-30064).

Whether EPA estimates pesticide exposure in drinking water through monitoring data or modeling, EPA uses the higher of the two values from surface and ground water in quantifying overall exposure to the pesticide. In most cases, pesticide concentrations in surface water are significantly higher than in groundwater.

iii. *Residential exposures.* Generally, in assessing residential exposure to pesticides EPA relies on its Residential Standard Operating Procedures ("SOPs"). The SOPs establish models for estimating application and post-application exposures in a residential setting where pesticide-specific monitoring data are not available. SOPs have been developed for many common exposure scenarios including pesticide treatment of lawns, garden plants, trees, swimming pools, pets, and indoor surfaces including crack and crevice treatments. The SOPs are based on existing monitoring and survey data including information on activity patterns, particularly for children. Where available, EPA relies on pesticide-specific data in estimating residential exposures.

C. EPA Policy on Cholinesterase Inhibition as a Regulatory Endpoint

On August 18, 2000, EPA issued a science policy document entitled "The Use of Data on Cholinesterase Inhibition for Risk Assessments of Organophosphorous and Carbamate Pesticides." (Ref. 9). Although assessing the risk from organophosphorous and carbamate pesticides was a primary reason for updating EPA guidance on cholinesterase inhibition, the policy addressed the topic generally and not just in the context of these two families of pesticides.

Cholinesterase inhibition is a disruption of the normal enzymatic process in the body by which the nervous system chemically communicates with muscles and glands. Communication between nerve cells and a target cell (i.e., another nerve cell, a muscle fiber, or a gland) is facilitated by the enzyme, acetylcholine. When a nerve cell is stimulated it releases acetylcholine into the synapse (or space) between the nerve cell and the target cell. The released acetylcholine binds to receptors in the target cell, stimulating the target cell in turn. As the policy explains, "the end result of the stimulation of cholinergic pathway(s) includes, for example, the contraction of smooth (e.g., in the gastrointestinal tract) or skeletal muscle, changes in heart rate or glandular secretion (e.g., sweat glands) or communication between nerve cells in the brain or in the autonomic ganglia of the peripheral nervous system." (Id. at 10).

Acetylcholinesterase is an enzyme that breaks down acetylcholine and terminates its stimulating action in the synapse between nerve cells and target cells. When acetylcholinesterase is inhibited, acetylcholine builds up prolonging the stimulation of the target cell. This excessive stimulation potentially results in a broad range of adverse effects on many bodily functions including muscle cramping or paralysis, excessive glandular secretions, or effects on learning, memory, or other behavioral parameters. Depending on the degree of inhibition these effects can be serious, even fatal.

The cholinesterase inhibition policy statement explains EPA's approach to evaluating the hazard posed by cholinesterase-inhibiting pesticides. The policy focuses on three types of effects associated with cholinesterase-inhibiting pesticides that may be assessed in animal and human toxicological studies: (1) Physiological and behavioral/functional effects; (2) cholinesterase inhibition in the central and peripheral nervous system; and (3) cholinesterase inhibition in red blood cells and blood plasma. The policy discusses how such data should be integrated in deriving a safe dose (RfD/PAD) for a cholinesterase-inhibiting pesticide.

Clinical signs or symptoms of cholinesterase inhibition in humans, the policy concludes, provide the most direct evidence of the adverse consequences of exposure to cholinesterase-inhibiting pesticides. Due to strict ethical limitations, however, studies in humans are "quite limited." (Id. at 19). Although animal studies can also provide direct evidence of cholinesterase inhibition effects, animal studies cannot easily measure cognitive effects of cholinesterase inhibition such as effects on perception, learning, and memory. For these

reasons, the policy recommends that "functional data obtained from human and animal studies should not be relied on solely, to the exclusion of other kinds of pertinent information, when weighing the evidence for selection of the critical effect(s) that will be used as the basis of the RfD or RfC." (Id. at 20).

After clinical signs or symptoms, cholinesterase inhibition in the nervous system provides the next most important endpoint for evaluating cholinesterase-inhibiting pesticides. Although cholinesterase inhibition in the nervous system is not itself regarded as a direct adverse effect, it is "generally accepted as a key component of the mechanism of toxicity leading to adverse cholinergic effects." (Id. at 25). As such, the policy states that it should be treated as "direct evidence of potential adverse effects" and "data showing this response provide valuable information in assessing potential hazards posed by anticholinesterase pesticides." (Id.). Unfortunately, useful data measuring cholinesterase inhibition in the central and peripheral nervous systems has only been relatively rarely captured by standard toxicology testing, particularly as to peripheral nervous system effects. For central nervous system effects, however, more recent neurotoxicity studies "have sought to characterize the time course of inhibition in ... [the] brain, including brain regions, after acute and 90–day exposures." (Id. at 27).

Cholinesterase inhibition in the blood is one step further removed from the direct harmful consequences of cholinesterase-inhibiting pesticides. According to the policy, inhibition of blood cholinesterases "is not an adverse effect, but may indicate a potential for adverse effects on the nervous system." (Id. at 28). The policy states that "[a]s a matter of science policy, blood cholinesterase data are considered appropriate surrogate measures of potential effects on peripheral nervous system acetylcholinesterase activity in animals, for central nervous system (CNS) acetylcholinesterase activity in animals when CNS data are lacking and for both peripheral and central nervous system acetylcholinesterase in humans." (Id. at 29). The policy notes that "there is often a direct relationship between a greater magnitude of exposure [to a cholinesterase-inhibiting pesticide] and an increase in incidence and severity of clinical signs and symptoms as well as blood cholinesterase inhibition." (Id. at 30). Thus, the policy regards blood cholinesterase data as "appropriate endpoints for derivation of reference doses or concentrations when considered in a weight-of-the-evidence analysis of the entire database ...." (Id. at 29). Between cholinesterase inhibition measured in red blood cell ("RBC") or blood plasma, the policy states a preference for reliance on RBC acetylcholinesterase measurements because plasma is composed of a mixture of acetylcholinesterase and butyrylcholinesterase, and inhibition of the latter is less clearly tied to inhibition of acetylcholinesterase in the nervous system. (Id. at 29, 32).

The policy advises that, in selection of a Point of Departure for deriving a RfD/PAD, all data on clinical signs and cholinesterase inhibition should be considered in a weight-of-the-evidence analysis. This weight-of-the-evidence analysis should focus, according to the policy, on (1) "[a] comparison of the pattern of doses required to produce physiological and behavioral effects and cholinesterase inhibition" in the central and peripheral nervous systems and in blood; (2) "comparisons of the temporal aspects (e.g., time of onset and peak effects and duration of effects) of each relevant endpoint;" and (3) "the potential for differential sensitivity/susceptibility of adult versus young animals (i.e., effects following perinatal or postnatal exposures)." (Id. at 35). This analysis can lead EPA to "select as the critical effects any one or more of the behavioral and physiological changes or enzyme measures listed above." (Id.). In comparing studies across the entire database to select an endpoint for the Point of Departure, the policy stresses that "parallel analyses of the dose-response (i.e., changes in magnitude of enzyme inhibition or of a different effect with increasing dose) and the temporal pattern of all relevant effects will be compared across all of the different compartments affected (e.g., plasma, RBC, peripheral nervous system, brain), and for the functional changes to the extent the database permits." (Id. at 38). Further, the policy states that "[t]he consistency (or, the lack thereof) of LOAELs, NOAELs, or BMDs for each category of effects (e.g., clinical signs, cholinesterase inhibition in the various compartments, etc.) for the test species/strains/sex available and for each duration and route of exposure should be noted." (Id.).

D. EPA Policy on the Children's Safety Factor

As the above brief summary of EPA's risk assessment practice indicates, the use of safety factors plays a critical role in the process. This is true for traditional 10X safety factors to account for differences between animals and humans when relying on studies in animals (inter-species safety factor) and differences among humans (intra-species safety factor) as well as the additional 10X children's safety factor added by the FQPA.

In applying the children's safety factor provision, EPA has interpreted it as imposing a presumption in favor of applying an additional 10X safety factor. (Ref. 5 at 4, 11). Thus, EPA generally refers to the additional 10X factor as a presumptive or default 10X factor. EPA has also made clear, however, that this presumption or default in favor of the additional 10X is only a presumption. The presumption can be overcome if reliable data demonstrate that a different factor is safe for children. (Id.). In determining whether a different factor is safe for children, EPA focuses on the three factors listed in section 408(b)(2)(C) - the completeness of the toxicity database, the completeness of the exposure database, and potential pre- and post-natal toxicity. In examining these factors, EPA strives to make sure that its choice of a safety factor, based on a weight-of-the-evidence evaluation, does not understate the risk to children. (Id. at 24-25, 35).

E. Endocrine Disruptor Screening Program

To aid in the design of the endocrine screening program called for in the FQPA and SDWA amendments, EPA created the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), which was comprised of members representing the commercial chemical and pesticides industries, Federal and State agencies, worker protection and labor organizations, environmental and public health groups, and research scientists. (63 FR 71542, 71544, Dec. 28, 1998). The EDSTAC presented a comprehensive report in August 1998 addressing both the scope and elements of the endocrine screening program. (Ref. 10). The EDSTAC's recommendations were largely adopted by EPA.

As recommended by EDSTAC, EPA expanded the scope of the program from focusing only on estrogenic effects to include androgenic and thyroid effects as well. (63 FR at 71545). Further, EPA, again on the EDSTAC's recommendation, chose to include both human and ecological effects in the program. (Id.). Finally, based on EDSTAC's recommendation, EPA established the universe of chemicals to be screened to include not just pesticides but also a wide range of other chemical substances. (Id.). As to the program elements, EPA adopted

EDSTAC's recommended two-tier approach with the first tier involving screening "to identify substances that have the potential to interact with the endocrine system" and the second tier involving testing "to determine whether the substance causes adverse effects, identify the adverse effects caused by the substance, and establish a quantitative relationship between the dose and the adverse effect." (Id.). Tier 1 screening is limited to evaluating whether a substance is "capable of interacting with" the endocrine system, and is "not sufficient to determine whether a chemical substance may have an effect in humans that is similar to an effect produced by naturally occurring hormones." (Id. at 71550). Based on the results of Tier 1 screening, EPA will decide whether Tier 2 testing is needed. Importantly, "[t]he outcome of Tier 2 is designed to be conclusive in relation to the outcome of Tier 1 and any other prior information. Thus, a negative outcome in Tier 2 will supersede a positive outcome in Tier 1." (Id. at 71554-71555).

The EDSTAC provided detailed recommendations for Tier 1 screening and Tier 2 testing. The panel of the EDSTAC that devised these recommendations was comprised of distinguished scientists from academia, government, industry, and the environmental community. (Endocrine Disruptor Screening and Testing Advisory Committee Final Report, Appendix B). As suggested by the EDSTAC, EPA has proposed a battery of short-term *in vitro* and *in vivo* assays for the Tier 1 screening exercise. (63 FR at 71550-71551). Validation of these assays, however, is not yet complete. As to Tier 2 testing, EPA, on the recommendation of the EDSTAC, has proposed using five longer-term reproduction studies that, with one exception, "are routinely performed for pesticides with widespread outdoor exposures that are expected to affect reproduction." (Id. at 71555). EPA is examining, pursuant to the suggestion of the EDSTAC, modifications to these studies to enhance their ability to detect endocrine effects.

Recently, EPA has published a draft list of the first group of chemicals that will be tested under the Agency's endocrine disruptor screening program. (72 FR 33486 (June 18, 2007)). The draft list was produced based solely on the exposure potential of the chemicals and EPA has emphasized that "[n]othing in the approach for generating the initial list provides a basis to infer that by simply being on this list these chemicals are suspected to interfere with the endocrine systems of humans or other species, and it would be inappropriate to do so." (Id.)

IV. DDVP Tolerances

A. Regulatory Background

Dichlorvos (2, 2-dichlorovinyl dimethyl phosphate), also known as DDVP, is an insecticide used in controlling flies, mosquitoes, gnats, cockroaches, fleas, and other insect pests. DDVP is registered for use on agricultural sites; commercial, institutional, and industrial sites; and for domestic use in and around homes. Agricultural and other commercial uses include in greenhouses; mushroom houses; storage areas for bulk, packaged and bagged raw and processed agricultural commodities; food manufacturing/processing plants; animal premises; and non-food areas of food-handling establishments. It is also registered for treatment of cattle, poultry and swine. DDVP is not registered for direct use on any field grown commodities. Currently, there are 27 tolerances listed in 40 CFR 108.235 for DDVP on agricultural (food and feed) crops and animal commodities. DDVP is applied with aerosols, fogging equipment, and spray equipment, and through use of impregnated materials such as resin strips which result in slow release of the pesticide.

DDVP is closely related to the pesticides naled and trichlorfon. Naled and trichlorfon both metabolize or degrade to DDVP in food, water, or the environment. All three pesticides are within a family of pesticides known as the organophosphates. EPA has classified the organophosphate pesticides and their common cholinesterase-inhibiting degradates as having a common mechanism of toxicity and thus, in addition to assessing the risks posed by exposure to these pesticides individually, EPA has assessed the potential cumulative effects from concurrent exposure to organophosphate pesticides.

B. FFDCA Tolerance Reassessment and FIFRA Pesticide Reregistration

As required by the Food Quality Protection Act of 1996, EPA reassessed the safety of the DDVP tolerances under the new safety standard established in the FQPA. In the Interim Reregistration Eligibility Document ("IRED") for DDVP, EPA determined that aggregate exposure to DDVP as a result of use of DDVP, naled, and trichlorfon, complied with the FQPA safety standard. (Ref. 11). Separately, EPA determined that cumulative effects from exposure to all organophosphate residues were safe. (Ref. 12). In combination, these findings satisfied EPA's obligation to review the DDVP tolerances under the new safety standard.

As a result of the FIFRA reregistration and FFDCA tolerance reassessment process, there were numerous changes made to DDVP's registration that affect non-occupational exposure to DDVP. Specifically, on May 9, 2006, EPA received from the only technical product registrant, Amvac Corporation ("Amvac"), an irrevocable request to cancel certain uses and include additional pest strip label restrictions on the DDVP technical product labels. Pursuant to section 6(f) of FIFRA, on June 30, 2006, the Agency published a notice in the **Federal Register** that it had received the request and sought comment on EPA's intention to grant the request and cancel the specified uses. (71 FR 37570 (June 30, 2006)). On October 20, 2006, EPA issued the final cancellation order. (71 FR 61968 (October 20, 2006)). The added restrictions on the use of the pest strip products were approved on October 11, 2006, and provided, among other things, that large pest strips could no longer be used in homes except for garages, attics, crawl spaces, and sheds that are occupied for less than 4 hours per day. Additionally, in early March, 2007, Amvac requested the voluntary cancellation of all its pet collar and bait registrations and deletion of those uses from its technical label. Pursuant to section 6(f) of FIFRA, Amvac's requests to cancel the pet collar and bait registrations as well as deleting such uses from the technical label were published in the **Federal Register** on March 23, 2007. (72 FR 13786 (March 23, 2007)). On June 27, 2007, EPA issued the final cancellation notice for the pet collar and bait registrations. (72 FR 35235 (June 27, 2007)).

C. Toxicity Overview

Animal and human studies with DDVP demonstrate that the toxic effect of concern for DDVP is inhibition of cholinesterase activity. These studies showed decreases in cholinesterase activity in plasma, red blood cell, and the brain. These effects were consistently found whether the exposure duration was acute or chronic and across all tested routes of exposure. Studies involving *in utero*, as well as pre- and post-natal, exposure of young animals showed no evidence of increased sensitivity in the young to these effects. Cholinesterase inhibition was also the effect used to assess potential cumulative effects from exposure to organophosphate pesticides. Based on numerous cancer studies with DDVP, EPA has classified the evidence

on DDVP's potential carcinogenicity as "suggestive;" however, due to the lack of relevance to humans of the tumors identified, EPA has determined that DDVP poses a negligible cancer risk to humans.

D. Exposure Overview

Exposure to DDVP can occur through the consumption of food treated with DDVP, naled, or trichlorfon, consumption of drinking water bearing DDVP residues, or from exposure in the residential setting from use of DDVP or trichlorfon. EPA has extensive food monitoring data on DDVP. These data show that with one exception, strawberries, DDVP is rarely found at detectable amounts in food. About 5 percent of sampled strawberries have shown detectable DDVP residues. These monitoring results are consistent with metabolism data on DDVP which shows that it is rapidly degraded into non-toxic substances. EPA has limited water monitoring data showing no detectable residues of DDVP. Due to the fact that these data do not identify whether they were collected from areas of DDVP, naled, or trichlorfon usage and the lack of data from shallow groundwater wells, EPA has relied upon conservative modeling estimates of drinking water. EPA has estimated residential exposure to DDVP based primarily on one of several monitoring studies conducted using DDVP pest strips in houses.

V. The Petition to Revoke Tolerances

On June 2, 2006, the Natural Resources Defense Council (NRDC) filed a petition with EPA which, among other things, requested that EPA (1) conclude the DDVP Special Review by August 3, 2006, with a finding that DDVP causes unreasonable adverse effects on the environment; (2) conclude the DDVP FIFRA reregistration process by August 3, 2006, with a finding that DDVP is not eligible for reregistration; (3) submit draft notices of intent to cancel all DDVP registrations to the SAP and USDA by August 3, 2006, and issue those notices 60 days thereafter; (4) conclude the DDVP tolerance reassessment process by August 3, 2006, with a finding that the DDVP tolerances do not meet the FFDCA safety standard; and (5) issue a final rule by August 3, 2006, revoking all DDVP tolerances. (Ref. 1). Shortly after the petition was filed, on June 30, 2006, EPA released the Interim Reregistration Eligibility Decision ("IRED") for DDVP which addressed DDVP's eligibility for reregistration under FIFRA and assessed whether DDVP's tolerances met the new safety standard enacted by the FQPA. NRDC submitted comments on the IRED and some of these comments bore on issues in its petition. (Ref. 13).

NRDC asserted numerous grounds as to why the DDVP tolerances do not meet the FQPA safety standard and should be revoked. EPA has divided NRDC's grounds for revocation into four categories – toxicology; dietary exposure; residential exposure; and risk characterization – and addressed separately each claim under these categories. Each specific claim of NRDC is summarized in Unit VII immediately prior to EPA's response to the claim.

VI. Public Comment

In response to the aspects of the petition addressing the DDVP tolerances, EPA published notice of the petition for comment on October 11, 2006. (71 FR 59784, October 11, 2006). EPA received roughly 1,500 brief comments in support of the petition. These comments added no new information pertaining to whether the tolerances were in compliance with the FFDCA. Detailed comments in opposition to the petition were submitted by Amvac, the party holding the registration for DDVP under FIFRA. (Ref. 14). Amvac's comments on the specific claims by NRDC are summarized in Unit VII immediately following the summary of NRDC's claim but prior to EPA's response to the claim.

VII. Ruling on Petition

This order addresses NRDC's petition to revoke DDVP tolerances. As noted, in responding to NRDC's petition, EPA has broken the issues into four categories — toxicology; dietary exposure; residential exposure; and risk characterization. Below, EPA addresses each of the claims raised in these categories and explains why they do not support revocation of the tolerances.

EPA has not addressed claims that concern DDVP uses that have been canceled since the time of the petition. Specific uses cancelled were the largest (100 gram) pest strip; lawn, turf, and ornamentals; pet collars; and in-home crack and crevice. Additionally, the remaining "large" pest strips (80 and 65 grams) were limited to unoccupied portions of the home. The only pest strips permitted in occupied areas were smaller strips (16, 10.5, 5.25 grams) for use in closets, wardrobes, and cupboards.

A. Toxicological Issues

1. *Cancer*—a. *NRDC's claims.* NRDC claims that "the rejection by EPA of the 'probable carcinogen' cancer classification of previous Agency reviews is inadequately supported .. .." (Ref. 1 at 17). According to NRDC, EPA has not explained why its prior analysis was "flawed," and the reasons EPA has given for the change in cancer classification are "speculative, at best." (Id.). NRDC urges EPA to drop its new classification of DDVP as having "suggestive" evidence of carcinogenicity and restore the "original classification." (Id. at 18).

Specifically, NRDC argues with EPA's decision to discount, in its weight-of-the-evidence evaluation for DDVP, mononuclear cell leukemia (MCL) seen in a rat study and forestomach tumors identified in a mouse study. NRDC claims that EPA's assertion that a finding of MCL in the Fischer rat is of limited usefulness due to variability of occurrence of this cancer in the Fischer rat "may be an artifact of the design of such studies and is not an adequate basis for ignoring a positive result." (Id. at 17). NRDC suggests that a larger scale study could have resolved this issue. As to forestomach tumors, NRDC disputed EPA's conclusion that these tumors have limited relevance to humans given that humans do not have forestomachs. NRDC notes that all animals have some difference in their organs and tissues and thus the lack of a forestomach in humans does not "automatically mean that the effect is irrelevant to humans." (Id.). According to NRDC, EPA "must provide convincing explanations based on reliable data that their rejection of forestomach tumors is a reasonable certainty and will adequately protect the public health." (Id.).

NRDC also suggests that a study in Denver, Colorado "specifically linked" DDVP pest strips to leukemia in children under 15 (Leiss, J.K., Savitz, D.A. "Home pesticide use and childhood cancer: a case-control study," *American Journal of Public Health* 1995; 85:249-52) and a study of adult men with leukemia in Iowa and Minnesota (Brown, L.M., Blair, A., Gibson, R., *et al.* "Pesticide exposures and other agricultural risk factors for leukemia among men in Iowa and Minnesota," *Cancer Research* 1990;50(20):6585-91) found that these men were twice as likely to have a history of exposure to DDVP.

b. *Amvac's comments.* Disagreeing with NRDC's claims, Amvac argues that NRDC has ignored an extensive DDVP cancer database and the confounding effect that corn oil played in the two positive studies relied upon by NRDC. (Ref. 14 at 27-28). Amvac asserts that 11 cancer studies have been performed with DDVP, involving both oral and inhalation exposure routes, and that the only two positive studies were gavage studies in which the DDVP was administered by gavage in corn oil.

Amvac claims that it is well-recognized that corn oil as a confounding factor in cancer studies and that, in fact, the National Toxicology Program ("NTP") has found corn oil to be carcinogenic. Finally, Amvac cites to a recent review by the European Food Safety Agency, which Amvac asserts concluded, after reviewing all of the evidence, "that the carcinogenic risk from exposure to DDVP is very low." (Ref. 15).

c. *EPA's response.* Initially, EPA responds to NRDC's claims regarding EPA's cancer classification by noting that NRDC's request to amend the cancer classification is not a sufficient ground for seeking revocation of the DDVP tolerances. A cancer classification does not determine whether a pesticide is safe or not; rather, a cancer classification is one step in a multi-stage risk assessment process that ascertains and examines not only the toxicological effects a pesticide causes, but also the potency of the pesticide and the extent of human exposure to the pesticide. A pesticide found to be a "probable" human carcinogen may nonetheless meet the FFDCA section 408 safety standard if it has a low potency and/or low exposure. NRDC's petition contains no arguments or evidence that if DDVP is reclassified as a probable human carcinogen, a cancer risk assessment would show that DDVP is not safe. Accordingly, EPA denies NRDC's petition to revoke DDVP tolerances to the extent that the petition cites EPA's alleged cancer misclassification of DDVP as grounds for such a revocation.

Nonetheless, to clarify the issue, EPA will explain the basis for its revision of the cancer classification of DDVP. EPA's Cancer Assessment Review Committee (CARC) in the Health Effects Division of the Office of Pesticide Programs has held six cancer reviews for DDVP over the past two decades. These multiple reviews have been necessary due to the development of new information on DDVP as well as on carcinogenicity generally. What these reviews show is that EPA has taken a conservative approach to the cancer classification of DDVP, only weakening the classification (i.e., adopting a classification of lower human carcinogenic potential) upon the repeated advice of independent expert scientific panels.

EPA's reviews bridge two versions of its cancer assessment guidelines. These guidelines have slightly different descriptive categories for classifying chemicals as to their carcinogenic potential. In its 1986 Cancer Assessment Guidelines, EPA created the following categories regarding cancer potential: "human carcinogen" (Group A), "probable human carcinogen" (Group B), "possible human carcinogen" (Group C), "not classifiable as to human carcinogenicity" (Group D), and "evidence of non-carcinogenicity for humans" (Group E). (51 FR 33992 (September 24, 1986)). Under the 1986 Guidelines, Group B was further subdivided into Groups B1 and B2 with the former for chemicals categorized on the basis of data from humans and the latter based on data in animals. In an update to these guidelines in 2005, EPA adopted the following classifications: "carcinogenic to humans," "likely to be carcinogenic to humans," "suggestive evidence of carcinogenic potential," "inadequate information to assess carcinogenic potential," and "not likely to be carcinogenic to humans." (70 FR 17765, April 7, 2005). The revised guidelines dropped the alphabetic labeling of the classifications.

In its first review of DDVP in June 1987, the CARC's predecessor, the Carcinogenicity Cancer Peer Review Committee [hereinafter referred to as the CARC for simplicity], classified DDVP as a probable human carcinogen (Group B2), under EPA's 1986 cancer classification system. (Ref. 16). The CARC's classification of DDVP as a probable human carcinogen was based on its conclusion that the evidence showed DDVP satisfied two separate criteria for a "probable human carcinogen:" (1) carcinogenicity seen in multiple species; and (2) carcinogenicity seen in an unusual degree in a single experiment. To show cancer in multiple species, the CARC cited (1) a finding of statistically significant dose-related trend and statistically significant increase in forestomach tumors (combined papillomas and carcinomas) in female mice in a cancer study in the mouse conducted by the National Toxicology Program (NTP); and (2) a finding of a statistically significant dose-related trend and statistically significant increase in mononuclear cell leukemia (MCL) and pancreatic acinar adenomas in male rats in a cancer study in the rat conducted by the NTP. These two findings were supported by a significant positive trend for forestomach tumors in male mice in the NTP mouse study and a finding of statistically significant increased (but overall numbers within the range of historical controls) lung adenomas and combined mammary fibroadenomas and carcinomas in male and female rats, respectively, in the NTP rat study. To satisfy the criterion of cancer in an unusual degree in a single study, the CARC noted that forestomach tumors are a rare tumor in the female mouse. Finally, the CARC relied on positive *in vitro* mutagenicity data in support of the "probable human carcinogen" classification.

In September, 1987, the CARC's classification was evaluated by the FIFRA Scientific Advisory Panel ("SAP"), an independent expert panel created by statute for the purpose of providing EPA advice on scientific matters concerning pesticides. The SAP disagreed with EPA's classification and recommended that DDVP be classified as only a possible human carcinogen (Group C) based on its conclusions that: (1) DDVP only induced benign tumors; (2) the tumors did not show a dose-related trend; and (3) DDVP was not mutagenic in *in vivo* assays. (Ref. 17).

The CARC met for a second time on DDVP in September, 1987, to take the SAP's view into consideration. The CARC refused to alter its Group B2 carcinogen classification. It cited essentially the same reasons from the first review and emphasized the following evidence of malignancy to explain its difference with the SAP: (1) MCL is considered a malignant tumor; (2) both the pancreatic adenomas in rats and forestomach papillomas in mice had the potential to progress to malignancies; and (3) the presence of "some" rare forestomach carcinomas in female mice. (Id.)

A third meeting of the CARC was held in July, 1988 to review a report from the NTP Panel of Experts on the classification of DDVP. (Ref. 18). NTP scientists had reexamined the pancreata of the rats in the NTP rat study and concluded that the statistically significant increase in pancreatic lesions was diminished. For this reason, the NTP recommended that the evidence for carcinogenicity in male rats be downgraded from "clear" evidence to "some" evidence. Nonetheless, the CARC again refused to change DDVP's cancer classification relying on the MCL finding in rats, findings of multiple benign tumors in rat and mouse NTP studies, and DDVP's mutagenic properties. The CARC noted this classification was interim until new cancer and mutagenicity data could be reviewed.

A fourth meeting of the CARC in September, 1989, again reviewed the reanalysis of the pancreatic lesions in the rat, and also examined new cancer studies. (Ref. 19). The CARC noted that, although the NTP reexamination had found pancreatic tumors in treated rats to be statistically increased, albeit to a diminished degree than first thought, a new statistical review by EPA using two common statistical procedures found no statistical significance at all. Further, the CARC examined a DDVP inhalation cancer study in rats and two cancer

studies in which DDVP was administered in drinking water. The inhalation study was negative for cancer effects. The drinking water studies had several deficiencies making quantitative analysis inappropriate but had qualitative evidence that showed some of the tumors seen in previous studies. Taking this information into account, as well as new information questioning the relevance of MCL in rats and forestomach tumors in mice to humans, the CARC downgraded DDVP to a possible human carcinogen (Group C). Nonetheless, the CARC maintained that a quantitative cancer assessment was warranted using the geometric mean of the tumor rates of MCL in rats and forestomach tumors in mice.

The fifth meeting of the CARC, in March 1996, considered new information from Amvac including an evaluation of the severity of the MCL seen in the NTP rat study, studies on the mechanism of forestomach tumors, and *in vivo* mutagenicity testing. (Ref. 20). The evaluation of the severity of the rat MCL in the NTP study showed that there was no statistically significant difference in the severity of the MCL between control and treated animals. (Ref. 21 at 10). Further, the new *in vivo* testing was negative: The CARC, however, rejected Amvac's argument that the studies it submitted demonstrated the mechanism of tumor formation for the mouse forestomach tumors. Weighing all of this information, the CARC retained the possible human carcinogen classification (Group C) and recommendation for quantitative low dose linear cancer assessment. Based on its conclusion that the MCL in rats but not the forestomach papillomas are malignant tumors, however, the CARC concluded that the linear low dose extrapolation should be based on the MCL in rats alone.

The sixth cancer review, finalized in February, 2000, principally focused on the significance of the MCL in the rat NTP study taking into account three new analyses of this cancer. (Ref. 22). The first was a report submitted by Amvac titled "An Evaluation of the Potential Carcinogenicity of Dichlorvos: Final Report of the Expert Panel." (Ref. 23). That report was prepared by various experts in the field, primarily academics, who had been assembled by a consulting firm hired by Amvac. The report describes the steps taken to avoid conflicts of interest and to insure that the substance of the report was not influenced by its sponsor. The report concludes that the "incidence of MCL in the NTP DDVP rat study (1989) . . . does not support a conclusion of carcinogenicity." (Id. at 21). The report summarized the main reasons for this conclusion as follows:

1. The results are species-, strain-, and sex-specific.
2. The endpoint is dramatically affected by administration of corn oil by gavage.
3. There was no significant effect on the relative severity of the disease, time-to-tumor latencies or percentage of rats surviving to study termination.
4. The data do not demonstrate a classic dose-response.
5. The results are not replicated in a very large number of carcinogenicity studies on DDVP and related substances (e.g., Trichlorfon, Metrifonate, Naled).
6. Many other studies are more appropriate to estimate human risks since the routes of administration employed more closely approximated potentially hazardous routes in man (e.g., inhalation, dietary or in drinking water) rather than the gavage method employed in the NTP study.
7. The incidences are similar to normal background rates that are increasing over time.

(Id.). The report further stated that effects seen in the NTP rat study showed "the extremely wide variability that is typically observed with this tumor." (Id.). The finding of a lack of carcinogenicity, the report asserted, is consistent with "similar positions taken by other organizations (e.g., Joint FAO/WHO Panel of Experts on Pesticide Residues, NTP, and OSTP)." (Id.). Additionally, the report concluded that "metabolic considerations and the genotoxic potential of DDVP" do not support a finding of carcinogenicity. Finally, the report concluded that DDVP does cause forestomach tumors in mice but that this "endpoint has no relevance to man and therefore, should not be employed for extrapolation to human risk." (Id.).

The second new analysis was from the SAP review of the CARC's fourth review of the carcinogenicity of DDVP. (Ref. 24). The SAP concluded that "[t]here is compelling evidence to disregard MCL in the Fischer rat." The SAP gave several reasons for this conclusion based both on general information on MCL in Fischer rats and specific information on the NTP rat cancer study with DDVP. In terms of general evidence, the SAP explained that (1) "MCL is one of the most common background tumor types" in the Fischer rat; (2) that there is a high variability in MCL in Fischer rats; and (3) MCL is a strain specific cancer. (Id. at 17). On this last point, the SAP noted that MCL "has been referred to as Fischer rat leukemia . . . [and] [o]ther rat strains and mice do not develop MCL, and there is no human correlate to this disease." (Id.). Turning to the NTP rat study with DDVP, the SAP noted that (1) although MCL was seen at both the low and high doses in the study there was no clear dose-response relationship seen in the study; and (2) chemically-related increases in MCL are marked by advanced severity of the MCL but that the NTP rat study "showed no significant increase in severity of the MCL with increasing dose, indicating that these lesions are background." (Id.).

The SAP also ratified the CARC's earlier position that the forestomach tumors in the NTP mouse study should not be relied upon to estimate risk to humans. The SAP explained that these tumors are "likely due to the chronic irritancy, inflammation, and cytotoxicity during chronic bolus dosing, resulting in extraordinary high local concentration of the chemical." (Id.). Such conditions would not exist outside of the laboratory. Further, such tumors have only limited relevance to humans because "the forestomach in rodents acts as a storage site where irritant chemicals in food have prolonged contact with the sensitive squamous epithelium lining, a situation that does not pertain to humans." (Id.).

The SAP reached an overall conclusion that "the weight of the evidence suggests carcinogenicity in animals treated with DDVP with a non-linear dose-response. However, the compound is considered a weak carcinogen acting via a secondary or indirect mechanism." (Id. at 18.).

The third new analyses was a short memorandum summarizing a conversation with Dr. Gary Boorman of the NTP. (Ref. 25). Dr. Boorman opined that the MCL "tumor type in males[] [Fisher rats] had a high and variable background." (Id.). Further, Dr. Boorman is cited as stating that although "this tumor type can not be dismissed as [ir]relevant to humans, [] it does seem to be found mainly in the Fisher rat and does not appear to be the same type of leukemia as found in [human] adults or children." (Id.).

Relying heavily on the advice of these expert scientific opinions (particularly, the views of the SAP), the CARC in its sixth report softened its view regarding the importance of the MCL seen in the NTP rat study and reaffirmed its view that the forestomach tumors in the NTP mouse study were a localized tumor of limited relevance to humans. Although the CARC maintained that the MCL in the rat study could "not be totally disregarded," it accepted the advice of the expert panel of the SAP and as well

as the report commissioned by Amvac that the evidence on MCL did not warrant use of this cancer to quantitatively estimate cancer risk to humans using a low-dose linear extrapolation. The CARC specifically cited the high background rates and variability of MCL in the Fischer rat, the lack of a dose-response effect in the NTP rat study, and negative results in other cancer studies as justifying its decision to change the cancer classification of DDVP from a "possible human carcinogen" to "suggestive evidence of carcinogenic potential" and to recommend that the data did not support a quantitative cancer risk assessment.

To recap, EPA's initial DDVP cancer classification of "probable human carcinogen" was based on a MCL and pancreatic adenomas in the rat, forestomach papillomas in the mouse, and positive *in vitro* mutagenicity data. EPA only downgraded this classification following: (1) a re-analysis of the rat study showed no statistically significant increase in pancreatic adenomas; (2) presentation of strong evidence concerning the non-relevance of MCL in rats and forestomach tumors in mice to humans; (3) submission of a negative DDVP cancer study in rats by the inhalation route; (4) submission of *in vivo* data showing a lack of mutagenicity for DDVP; and (5) repeated recommendations from independent scientific groups to downgrade the DDVP cancer classification.

A recent review by the European Food Safety Agency ("EFSA") supports EPA's DDVP cancer assessment. (Ref. 15). The EFSA found the only treatment-related tumors from the DDVP studies to be the mouse forestomach tumors: "[The Scientific Panel on Plant health, Plant protection products and their Residues] concludes that with the exception of tumours of the forestomach in the mouse, there was no convincing evidence for a compound-related, relevant tumour response. Tumours observed in other tissues (pancreas, mammary, mononuclear leukaemia) showed no dose-response, were inconsistent between studies and sexes, were reduced in control animals relative to historical control data, or were unique to the experimental conditions of the assay." (Id. at 33). Further, the EFSA found the forestomach tumors to be "a site of contact effect, and a consequence of the very high, sustained concentrations of dichlorvos to the forestomach that would be achieved by gavage dosing in corn oil." (Id.). These tumors, the EFSA concluded, were subject to a threshold dose unlikely to be exceeded in humans due to cholinesterase inhibition effects at a much lower threshold. (Id. at 34).

NRDC is wrong to suggest that variability in MCL occurrence alone drove EPA's decision to change its views regarding the importance of the MCL findings. To the contrary, variability along with several other factors were considered in EPA's weight of the evidence approach. If anything, EPA took a more conservative approach to this cancer than its scientific advisory panel. Further, EPA did not discount the forestomach tumors simply because humans do not have forestomachs. Rather, both EPA and the SAP explained why the unique aspects of the rodent forestomach in connection with the artificial condition of corn oil bolus dosing are likely to produce results of limited relevance to humans.

Further, NRDC's reliance on epidemiological studies by Liess and Brown is misplaced. EPA reviewed the Liess study and identified biases and confounders in the studies that are a more likely explanation for the findings of increased cancer than exposure to pest strips. (Ref. 11 at 142). As to the Brown study, EPA has rejected it as inadequate because the subjects were exposed to other pesticides in addition to DDVP and there was no adjustment made for these other exposures. Other confounders such as multiple statistical comparisons were identified as well. (Ref. 26).

2. *NOAEL/LOAEL*—a. *NRDC's claims.* NRDC notes that a NOAEL for cholinesterase inhibition was not established in a mouse oncogenicity study relied upon by EPA. NRDC claims that failure to identify a NOAEL not only renders the mouse oncogenicity study invalid but "undermines the entire risk assessment and precludes the Agency from finding that the DDVP tolerances are safe . . . ." (Ref. 1 at 47). NRDC argues that if there is no NOAEL identified in a study, the LOAEL from that study is "virtually meaningless information." (Id.). Finally, NRDC argues that EPA cannot legally make the reasonable certainty of no harm finding for DDVP or any other pesticide if EPA is relying on a LOAEL rather than a NOAEL.

b. *EPA's response.* EPA has repeatedly rejected NRDC's legal arguments concerning reliance on LOAELs in making safety findings under FFDCA section 408. (70 FR 46706, 46729; 69 FR 30042, 30066-30067; Ref. 27 at 165-166). EPA incorporates those prior responses herein. Further, EPA disagrees with NRDC's contention that a LOAEL in a study that does not identify a NOAEL provides "virtually meaningless information." Depending on the severity and consistency of the effect at the LOAEL as well as the severity and consistency at higher doses, the LOAEL can provide substantial information bearing on the no adverse effect level. It is for this reason that EPA and FDA, as well as other public health agencies, have long relied on LOAELs, in appropriate circumstances, in making safety findings. (69 FR at 30066; Ref. 28).

EPA relied upon a LOAEL in assessing the risk posed by DDVP for the following exposure scenarios: short-term incidental oral; short-, intermediate-, and long-term dermal; short- and intermediate-term inhalation. The LOAEL was from a single blind, placebo controlled, randomized study to investigate the effects of multiple oral dosing on erythrocyte cholinesterase inhibition in healthy male volunteers and involved a dose of 0.1 milligrams/kilogram of body weight/day ("mg/kg/day"). This value was adjusted with a safety factor of 3X to approximate the value of a NOAEL. The LOAEL provided sufficient information to estimate the NOAEL (using a 3X safety factor) because the study measured the severity of the cholinesterase inhibition response observed. Cholinesterase inhibition is a continuous endpoint where no fixed generic percentage of change from baseline separates potential adverse effects from non-adverse effects. Generally, cholinesterase inhibition of 20 percent from baseline is regarded as showing a potential for adverse effects on the nervous system with lower levels evaluated on a case-by-case basis. (Ref. 9 at 37-38). In the DDVP human study, the cholinesterase inhibition fell at the very low end of the scale (cholinesterase inhibition in individuals varied from baseline within a range from 8 to 23 percent at the end of the study) indicating that the NOAEL was not significantly lower.

NRDC is mistaken to claim that the mouse oncogenicity study was invalid for failure to identify a NOAEL. Oncogenicity (carcinogenicity) studies are not designed to produce NOAELs but rather to examine the cancer responses at high doses. EPA relies on chronic studies in the rodent and non-rodent (generally the rat and dog, respectively) to evaluate and define the level of threshold chronic, non-cancer effects. (40 CFR 158.340(a)). Acceptable chronic rat and dog studies are available for DDVP. (Ref. 11). NRDC also errs in contending that EPA, by examining cholinesterase effects in the mouse oncogenicity study, indicates that it does not have valid and reliable chronic toxicity data. As noted, EPA does not specifically require a chronic toxicity

study in the mouse and it has an acceptable study meeting the requirement for a chronic study in rodents. Nonetheless, where an oncogenicity study in the mouse does shed light on effects seen in chronic studies, EPA certainly will consider that information in its overall weight-of-the-evidence evaluation for the pesticide.

3. *Human studies*—a. *NRDC's claims.* NRDC asserts that none of the DDVP human studies satisfy the standards in EPA's human testing rule because they "violate the Nuremburg Code and fail to satisfy the standards in EPA's human testing rule." (Ref. 1 at 26.). Therefore, NRDC petitions EPA to reject all intentional dosing human studies for DDVP as unethical and unscientific.

NRDC raises various specific concerns as to a particular human study commonly referred to as the Gledhill study (MRID # 44248801). Citing a draft report by EPA's Human Studies Review Board (HSRB), NRDC claims that this study is "statistically meaningless" because it had too few test subjects. Further, NRDC argues that the variability in the cholinesterase inhibition in the study demonstrates that "even greater than the customary numbers of test subjects would be required to permit detection of effects caused by the test substance above background variation." (Ref. 13 at 15). Other scientific defects in the Gledhill study alleged by NRDC include failing to promptly measure red blood cell ("RBC") effects; failing to measure blood plasma effects; not restricting subjects in controlled conditions for living and eating; and failing to properly obtain informed consent. NRDC claims the study was ethically deficient because reference in the consent form to DDVP as a drug made it impossible to obtain informed consent and study conductors failed to monitor the health of subjects after the conclusion of the study. Finally, NRDC argues that if EPA relies on the study, EPA cannot conclude that the DDVP tolerances are safe because the LOAEL for humans in the study (reported by NRDC to be 0.01 mg/kg/day) is well below the lowest LOAEL in animal studies (0.1 mg/kg/day).

NRDC also objects to EPA's reliance on a number of other human studies which NRDC describes as "ethically repugnant" due to involvement of children as test subjects.

b. *Amvac's comments.* In its comments, Amvac argues that "there is a large body of human data from a variety of sources that provide information directly relevant to the DDVP risk assessment process." (Ref. 14 at 32). According to Amvac these human studies show that the most sensitive endpoint for DDVP is inhibition of red blood cell cholinesterase; DDVP operates by a common mechanism in animals and humans; DDVP inhibits RBC cholinesterase at similar levels in animals and humans; and DDVP has similar effects no matter what the route of exposure. (Id. at 33). As to the Gledhill study, Amvac disputes NRDC's criticisms of its scientific value and ethics. (Id. at 37). Amvac claims that "[t]he number of subjects employed, six per dose, is . . . a standard number of test subjects sufficient to provide statistical power in human studies." (Id. at 38). Measuring plasma cholinesterase was not essential, according to Amvac, because RBC cholinesterase "is relevant to assessing the risk of inhibition of the toxicologically important brain cholinesterase enzyme." (Id. at 37).

c. *EPA's response.* In responding to the petition, EPA would first note that the petition simply asks EPA not to rely on any of the DDVP human studies but does not contend that reliance on animal studies instead of the human studies will show the DDVP tolerances to be unsafe. Subsequent to NRDC's petition, EPA did rely on the Gledhill study in assessing the risk posed by DDVP. (Ref. 11 at 133). To clarify the basis for EPA's decision to rely on the Gledhill study, EPA has described its decision-making process below.

EPA decisions regarding the ethics and scientific value of human studies are governed by the Protection for Subjects in Human Research final rule (Human Research Rule), which significantly strengthened and expanded protections for subjects of human research. (71 FR 6138 (February 6, 2006)). The framework of the Research Rule rests on the basic principle that EPA will not, in its actions, rely on data derived from unethical research. The rule divides human studies into two groups: "new" studies—those initiated after April 7, 2006—and "old" studies—those initiated before April 7, 2006. The Human Research Rule forbids EPA from relying on data from any "new" study, unless EPA has adequate information to determine that the research was conducted in substantial compliance with the ethical requirements contained therein. (40 CFR 26.1705). These ethical rules are derived primarily from the "Common Rule," (40 CFR part 26), a rule setting ethical parameters for studies conducted or supported by the federal government. In addition to requiring informed consent and protection of the safety of the subjects, among other things, the Rule specifies that "[r]isks to subjects [must be] reasonable in relation to . . . the importance of the knowledge that may reasonably be expected to result [from the study]." (40 CFR 26.1111(a)(2)). In other words, a study would be judged unethical if it did not have scientific value outweighing any risks to the test subjects.

As to "old" studies, the Human Research Rule forbids EPA from relying on such data if there is clear and convincing evidence that the conduct of the research was fundamentally unethical or significantly deficient with respect to the ethical standards prevailing at the time the research was conducted. (40 CFR 26.1704). EPA has indicated that in evaluating "the ethical standards prevailing at the time the research was conducted" it will consider the Nuremburg Code, various editions of the Declaration of Helsinki, the Belmont Report, and the Common Rule, as among the standards that may be applicable to any particular study. (71 FR at 6161).

Whether the data are "new" or "old," the Human Research Rule forbids EPA to rely on data from any study involving intentional exposure of pregnant women, fetuses, or children. (40 CFR 26.1704).

To aid EPA in making ethical determinations under the Human Research Rule, the rule established an independent Human Studies Review Board (HSRB) to review both proposals for new research and reports of covered human research on which EPA proposes to rely. (40 CFR 26.1603). The HSRB is comprised of non-EPA employees "who have expertise in fields appropriate for the scientific and ethical review of human research, including research ethics, biostatistics, and human toxicology." (40 CFR 26.1603(a)). If EPA intends to rely on the results from "old" human research, EPA must submit the results of its assessment to the HSRB for evaluation of the ethical and scientific merit of the research. (40 CFR 26.1602(b)(2)). EPA has established the HSRB as a Federal advisory committee under the Federal Advisory Committee Act ("FACA") to take advantage of "the benefits of the transparency and opportunities for public participation" that accompany a FACA committee. (71 FR at 6156).

In the risk assessment for DDVP, EPA has relied upon one human study for several exposure scenarios. The study, conducted by A.J. Gledhill, involved a single blind, randomized placebo-controlled oral study in which 6 healthy male volunteers were administered a daily dose of DDVP for 21 days at approximately 0.1/mg/kg/day and 3 volunteers were administered a placebo

(Ref. 11 at 133). Prior to relying on the Gledhill study in the IRED, EPA presented this study as well as 10 other DDVP human studies to the HSRB for review. In its presentation to the HSRB, EPA stated that it had concluded that the Gledhill study "is sufficiently robust for developing a Point of Departure for estimating dermal, incidental oral, and inhalation risk from exposure to DDVP" for the purpose of assessing DDVP by itself but not for conducting a cumulative assessment of DDVP and other organophosphate pesticides. (Ref. 29 at 19). EPA recommended that the other 10 studies should not be used. (Id. at 20).

As part of the public participation procedures that have been adopted by the HSRB, NRDC appeared before the HSRB when DDVP was being considered to make the points it has raised in this petition. (Ref. 30).

The HSRB agreed with EPA on the appropriateness of using the Gledhill study after a detailed evaluation of the scientific merit of the study as well as an evaluation of other ethical considerations. (Ref. 31). In examining scientific merit, the HSRB identified both strengths and weaknesses of the Gledhill study. Identified as strengths were: the repeated dose approach which allowed examination of the sustained nature of RBC cholinesterase inhibition; robust analysis of RBC cholinesterase inhibition both in terms of identifying pre-treatment levels and consistency of response within and between subjects; and the observation of a low, but statistically significant RBC cholinesterase inhibition response. Weaknesses seen included: use of a single dose; preventing establishment of a dose-response relationship; small sample size and use of males subjects only; measurement of RBC cholinesterase inhibition at 24 hours after dosing which may have missed peak inhibition; no analysis of plasma cholinesterase; sampling and analysis of enzyme inhibition ended 3 days before the end of dosing; lack of clarity as to whether steady state inhibition was achieved; and lack of follow-up with subjects following completion of dosing. After carefully considering these factors, the HSRB concluded that despite the "numerous technical difficulties" with the study that it "was sufficiently robust for developing a Point of Departure for estimating dermal, incidental oral, and inhalation risk from exposure to DDVP in a single chemical assessment." (Id. at 41). The HSRB's reasoning was that "[a]lthough a study using a single dose level is not ideal for establishing a LOAEL, there was general consensus that RBC cholinesterase is a well-characterized endpoint for compounds that inhibit acetylcholinesterase activity and therefore, because the decreased activity in RBC cholinesterase activity observed in this study was at or near the limit of what could be distinguished from baseline values, it was unlikely that a lower dose would produce a measurable effect in RBC cholinesterase activity." (Id.).

Turning to other ethical considerations, the HSRB examined whether there was clear and convincing evidence that prevailing ethical standards had been violated. Specifically, the HSRB considered whether informed consent had been compromised by certain references in test subject disclosure forms to DDVP as a "drug," or by deficiencies in the monitoring of subjects both during and after conclusion of the study. Ultimately, the HSRB concluded that although the study "failed to fully meet the specific ethical standards prevalent at the time the research was conducted, . . . [t]here was no clear and convincing evidence that the research was fundamentally unethical—intended to seriously harm participants or that informed consent was not obtained." (Id. at 46). The HSRB reasoned that references to DDVP as a drug did not vitiate informed consent because "the consent materials clearly advised subjects that this was a study involving consuming an insecticide." (Id.). Deficiencies in monitoring of subjects were found not to provide clear and convincing evidence that the study was ethically deficient by subjecting the test subjects to the threat of serious harm because prior studies by this researcher involving higher doses had only invoked minimal responses. (Id.).

The HSRB also agreed with EPA that the technical difficulties identified with the Gledhill study limited its usefulness in the organophosphate cumulative assessment. (Id. at 41). Finally, the HSRB agreed with EPA that there were scientific value or other ethical considerations that precluded reliance by EPA on the other ten DDVP human studies. (Id. at 41–42).

EPA adopts the HSRB's reasoning and finds it persuasive in rejecting NRDC's arguments concerning why the Gledhill study should not be relied upon. In fact, NRDC has not raised in its petition any arguments not considered and rejected by the HSRB.

EPA would add the following further information regarding NRDC's criticisms of the Gledhill study's use of males only, the number of test subjects in the study, the 24-hour period between dosing and measurement of cholinesterase inhibition, the failure to measure plasma cholinesterase, and purported increased sensitivity in humans demonstrated by the study.

As to the use of males only, EPA would note that no sex differences were observed in the comparative cholinesterase studies in animals. (Ref. 32). With regard to statistical significance of the study results due to the number of test subjects, EPA strongly disagrees with the claims of NRDC. The results of the repeated dose study of 9 subjects (6 DDVP and 3 placebo) in the Gledhill study were analyzed statistically for significance in addition to being analyzed for biological significance. Although as a general matter more subjects would provide greater "statistical power," in this case the use of 6 to 9 subjects with the appropriate statistical methodology is acceptable to EPA because a positive response was seen. Indeed, all of the 6 dosed subjects exhibited statistically significant (with respect to their pre-dose levels) RBC cholinesterase depression on one or more days. One of the three placebo controls exhibited statistically significant depression on one day. However, the group means of RBC cholinesterase activity in treated subjects are statistically below the group means of the placebo controls on days 7, 11, 14, 16 and 18 by repeated measures analysis of variance. (Ref. 33). The statistics of the study clearly show the ability to demonstrate a statistically significant response. For the sake of comparison it is worth noting that use of 6 male test subjects exceeds the long-standing EPA recommendation for 4/sex/dose subjects in non-rodent (usually dog) animal studies. (Ref. 34). Nor does EPA agree with NRDC that the variability in cholinesterase inhibition for test subjects shows that more subjects are required to detect effects above background variations. First, the variability seen in the study (cholinesterase inhibition in individuals varied from baseline within a range from 8 to 23 percent at the end of the study) is not large, particularly since the percentage inhibition in all instances was at the marginal end of the range. Second, EPA concluded, and the HSRB agreed, that the study did identify an effect above background. Moreover, an intra-species safety factor of 10X was applied to the study results to address variability in human sensitivity.

As to failure of the study to assess inhibition of plasma cholinesterase, EPA does not believe that this deficiency has much significance. Although the study should have had measurements of both RBC and plasma cholinesterase, the use of RBC cholinesterase findings provides a more

useful regulatory estimate for assessing the effects of DDVP on brain and peripheral cholinesterase depression in humans. In its policy on use of data on cholinesterase inhibition in assessing the risk of organophosphates and carbamates, EPA made clear that "[r]ed blood cell measures of acetylcholinesterase inhibition, if reliable, generally are preferred over plasma data." (Ref. 9 at 29). EPA explained that "[s]ince the red blood cell contains only acetylcholinesterase, the potential for exerting effects on neural or neuroeffector acetylcholinesterase may be better reflected by changes in red blood cell acetylcholinesterase than by changes in plasma cholinesterases which contain both butyrylcholinesterase and acetylcholinesterase in varying ratios depending upon the species." (Id.). Although testing for plasma inhibition may have provided additional information, given that the study identified statistically significant effects on RBC at a marginal level, data on a less preferred endpoint such as plasma cholinesterase adds little meaningful information.

With regard to the study procedure of waiting 24 hours after dosing to measure cholinesterase inhibition, the study was designed to evaluate the cumulative effect of repeat dosing with DDVP. While a shorter interval between dosing and measurement would have provided more information about acute effects of DDVP, this study has not been relied upon to assess acute risks.

Finally, NRDC is mistaken to claim that the Gledhill study showed humans to be more sensitive than test animals. The LOAEL from the Gledhill study is 0.1 mg/kg/day, not 0.01 mg/kg/day, as claimed by NRDC. (Ref. 11 at 133). The correct LOAEL is similar to the LOAEL from animal studies.

4. *Mutagenicity*—a. *NRDC's claim.* NRDC claims that EPA cannot find the DDVP tolerances are safe because EPA has not "reliably establish[ed] the bounds of risk posed by the mutagenic potential of DDVP." (Ref. 1 at 47). NRDC notes that EPA has found DDVP to be mutagenic in *in vitro* assays and asserts EPA has not taken this mutagenic risk into account in assessing the safety of DDVP.

b. *Amvac's Comment.* Amvac claims that NRDC has focused on *in vitro* assays to the exclusion of the more important *in vivo* studies. These later studies, Amvac asserts "provide[] support for the lack of *in vivo* carcinogenic activity seen in the DDVP animal bioassays." (Ref. 14 at 31). According to Amvac, "[p]harmacokinetic data have demonstrated that DDVP is quickly metabolized and this likely accounts for the difference in the *in vitro* and *in vivo* response in the mutagenicity testing." (Id.).

c. *EPA's response.* NRDC's claim that EPA has not taken mutagenic risk into account is mistaken. EPA has fully examined the data on DDVP's potential for mutagenic effects and concluded that these data do not raise a safety concern.

Mutagenicity data on DDVP shows the following: (1) DDVP does produce positive *in vitro* results in the absence of activation by rat derived liver enzymes; (2) these positive results generally disappear in the presence of activation by liver enzymes; (3) there is some evidence that DDVP is a weak mutagen in *in vivo* testing; and (4) an *in vivo* chromosome aberrations study requested to address the *in vivo* mutagenicity study was negative. (Refs. 11, 20 at 13, 35 and 36).

Mutagenicity data are considered by EPA both as evidence bearing on a pesticide's carcinogenic potential and on whether the pesticide can result in heritable mutagenic effects. As described in Unit VII.A.1.c., EPA fully considered the mutagenicity data in its cancer evaluation. As to DDVP's potential to cause heritable mutagenic effects, EPA specifically requested that an *in vivo* chromosome aberrations study be performed in which germ cells as well as somatic cells were examined to address this question. This study was negative resolving any concern with heritable mutagenic effects. (Ref. 20 at 13). One agency reviewer suggested a further mutagenicity study at higher doses addressing heritable effects but EPA has not required such testing because existing testing already tests at the maximum tolerated dose. (Ref. 37).

5. *Endocrine effects*—a. *NRDC's claim.* NRDC asserts that EPA has failed to assess the endocrine disruption effects of DDVP. NRDC notes that the statute requires EPA to consider, in making safety determinations as to tolerances, whether a pesticide has an effect that mimics estrogen or has other endocrine effects, (see 21 U.S.C. 346a(b)(2)(D)(viii)), and to establish an endocrine screening program, (see 21 U.S.C. 346a(p)), but that EPA has not collected any data under this program. NRDC claims that "[i]n light of [EPA's] failure to carry out its mandatory statutory duty to investigate the potential of DDVP to cause endocrine disruption, EPA cannot conclude that . . . the [DDVP] tolerances are safe." (Ref. 1 at 49).

b. *Amvac's Comment.* Amvac, in its comments, notes that EPA has already indicated that it will rely on several studies currently required for pesticides to assess endocrine effects and that EPA has these studies for DDVP. (Ref. 14 at 74-75).

c. *EPA's response.* In a prior order adjudicating a petition to revoke tolerances, EPA has rejected the argument that data gathered under the Endocrine Disruptor Screening Program ("EDSP") is a prerequisite to a safety determination under FFDCA section 408. (71 FR 43906, 43919-43921 (August 2, 2006)). There, EPA noted that the proposed study to be used for chemicals that initial screening suggests may have the potential to interact with the endocrine system (the two generation reproduction study in rats) is a study that is currently required for approval of agricultural or other food use pesticides. (Id. at 43920). Additionally, EPA pointed out that several other toxicological studies required for pesticides provide information relevant to potential endocrine disruption.

EPA has adequate data on DDVP's potential endocrine effects to evaluate DDVP's safety. In the 1989 NTP cancer studies with rats and mice, male and female reproductive organs (prostate, testes, epididymis, ovaries, uterus) were examined and no changes attributable to DDVP were found. The 52-week dog study with DDVP also was without effect in the reproductive organs (testes, prostate, epididymides, cervix, ovaries, uterus, vagina). EPA also has a 1992 two-generation rat reproduction study with DDVP (via drinking water) that is similar to the most recent guidelines (1998) for conduct of such a study with respect to endocrine-related endpoints. Although that study did not include certain evaluations that the 1998 guidelines recommended related to endocrine-related effects (age of vaginal opening and preputial separation), it did incorporate other aspects of the 1998 guidelines such as an examination of estrous cycling in females and sperm number, motility, and morphology in males. The study did identify an adverse effect on estrous cycling in females but only at the high dose (8.3 mg/kg/day). All doses in the study showed significant cholinesterase inhibition. Further, the NOAEL and LOAEL from the estrous cycling endpoint in the reproduction study are nearly two orders of magnitude higher than the NOAEL and LOAEL used as a Point of Departure in setting the chronic RfD/PAD for DDVP.

Finally, based on a comprehensive evaluation of the testicular toxicity of dichlorvos in rats, a recent publication reported that there were no testicular effects, except for slightly decreased

sperm motility, at doses causing significant inhibition of cholinesterase. (Ref. 38). The NOAEL for dichlorvos with respect to reproductive organ weights, sperm counts, sperm morphology, plasma testosterone, and testes histopathology was 4 mg/kg, the highest dose tested.

Given that EPA has (1) data bearing on potential endocrine effects from a two-generation reproduction study as well as other chronic data in which effects on reproductive organs were examined; (2) EPA well understands DDVP's most sensitive mechanism of toxicity (cholinesterase inhibition); and (3) the potential endocrine-related effects seen for DDVP appeared in the presence of significant cholinesterase inhibition and at levels nearly two orders of magnitude above the most sensitive cholinesterase effects, EPA believes it has adequate data to make a safety finding as to DDVP's potential endocrine-related effects.

6. *Neurotoxicity*—a. *NRDC's claim.* NRDC notes that in the 2000 preliminary risk assessment, EPA imposed a 3X uncertainty factor because there was no measurement for cholinesterase inhibition in an acute neurotoxicity rat study. NRDC contends that in light of the failure to measure cholinesterase inhibition, EPA should have required the study to be redone and that in the absence such data, EPA cannot make its FFDCA safety finding. (Ref. 1 at 47–48). NRDC also faults the Agency for failing to explain why, in these circumstances, a 3X uncertainty factor is safe.

b. *EPA's response.* Subsequent to the 2000 preliminary risk assessment, EPA has received additional acute neurotoxicity data in the rat which measured cholinesterase inhibition and thus the deficiency in the prior acute neurotoxicity study has been cured. (Ref. 11 at 130). Accordingly, the Agency has removed the 3X uncertainty factor that had been retained due to the deficiency in the prior study.

7. *Translation of oral study to dermal endpoint*—a. *NRDC's claim.* NRDC asserts that EPA cannot make a safety finding for DDVP because EPA relied on a rabbit oral study to derive a safe level of acute dermal exposure. (Ref. 1 at 48). According to NRDC, this approach is "based on unwarranted and unsubstantiated assumption that the toxicology and pharmacokinetics of oral exposure are the same as for dermal exposure." (Id.) Moreover, NRDC argues that even if it were appropriate to use oral data in place of dermal data, the "inherent" uncertainty requires the imposition of a properly supported uncertainty factor. (Id.). Similarly, NRDC argues that using an oral dog study for an intermediate-term dermal toxicity scenario is legally inappropriate and scientifically unsupportable.

b. *Amvac's comments.* Amvac states that "[i]t is common practice in risk assessments . . . to extrapolate across exposure routes if the characteristics of the chemical being considered, and the available data, support such extrapolation." (Ref. 14 at 40). Amvac argues that extrapolation from the oral route to the dermal route is appropriate for DDVP because the data show that both DDVP's metabolism and types of toxicity it causes are consistent across all routes of exposure. (Id.). Additionally, Amvac asserts that the greater absorption of DDVP in oral studies than in dermal studies makes it more likely that oral studies will show DDVP-related effects than dermal studies.

c. *EPA's response.* Initially, EPA would note that in the IRED EPA relied upon an oral rat and oral human study for assessing dermal risks. Presumably, however, NRDC would have similar objections to reliance on translation of these oral data to the dermal route.

Use of oral studies to assess dermal risks is, and has been, a common practice at EPA for some time. (Ref. 39). Data specific to DDVP confirm that this is a reasonable approach for this pesticide. First, numerous toxicity studies have been performed with DDVP, involving both acute and chronic dosing and dosing by all routes of exposure. These studies consistently show that DDVP is an inhibitor of cholinesterase, if doses are high enough, regardless of the duration or route of exposure. Similar results are consistently found across the class of organophosphate pesticides. (See, e.g., Refs. 40 and 41). Second, oral metabolism studies indicate both that DDVP is well-absorbed from the gastro-intestinal tract and that there are no significant differences in excretion of DDVP doses given orally and intravenously. (Refs. 42 and 43). Accordingly, an orally-administered dose is a reliable prediction of systemic dose. Thus, it is reasonable to use a RfD derived from an oral DDVP study to evaluate the safety of systemic exposures occurring as a result of dermal absorption of DDVP. Moreover, there are two reasons to believe that EPA's use of a dermal absorption factor of 11 percent for DDVP in translating the oral RfD into dermal RfD tends to overstate dermal absorption, exposure, and risk. (Ref. 44). First, dermal absorption studies with volatile chemicals such as DDVP are likely to overstate the degree of absorption because such studies attempt to minimize losses of the chemical through evaporation. Outside of the laboratory, there are usually no such barriers to evaporation. Second, human skin is generally less permeable than the rat skin (largely due to species differences in epidermal anatomy, such as skin thickness, sebaceous secretions, and the density of hair follicles, (Ref. 45), and thus dermal absorption studies with the rat, such as the DDVP dermal absorption study, tend to overstate absorption in humans.

For all of these reasons, EPA concludes that using oral DDVP studies in assessing risk from dermal DDVP exposures is a well-supported scientific assessment technique that would not underestimate risks from dermal DDVP exposure. Consequently, the application of an additional safety factor to account for uncertainty of the route to route extrapolation is not necessary.

8. *Degradates*—a. *NRDC's claim.* NRDC asserts that the Agency has an incomplete database regarding degradates of DDVP. (Ref. 1 at 9). Specifically, NRDC contends that degradates identified by the Agency were never searched for "or even detectable in the various monitoring and metabolism studies relied upon by the Agency." (Id.). Further, NRDC states that "[t]here is no indication whether these degradates were ever separately subjected to toxicological testing." (Id.). Based upon this assumption, NRDC contends that it is impossible for EPA to find that the DDVP tolerances are "safe."

b. *Amvac's comments.* Amvac claims that NRDC has failed to consider whether the DDVP degradates are toxicologically significant. (Ref. 14 at 68). According to Amvac, "[i]t is clear just from the structures of some of these degradates that they are either not toxicologically significant, and/or, based on structure activity relationships and knowledge concerning mechanisms of toxicity, that these degradates have much lower toxicity than the parent compound." (Id.).

c. *EPA's response.* NRDC's concern that EPA has not searched for DDVP's major metabolites in magnitude of the residue studies is misplaced because EPA has determined that these metabolites are rapidly degraded to harmless chemicals in the normal course of plant and mammalian metabolism. The residue of concern is DDVP and that is the chemical identified by DDVP's analytical method.

EPA has a robust understanding of DDVP's metabolites and degradates derived from multiple metabolism studies in several different animal and

plant species. (Refs. 46, 47, 48, 49, 50 and 51). In animals, DDVP's primary metabolites are dichloroacetaldehyde or (minor pathway) des-methyl DDVP. Des-methyl DDVP also breaks down into dichloroacetaldehyde. Dichloroacetaldehyde is rapidly dechlorinated and oxidized and either expelled from the body through respiration as carbon dioxide or through excretion in the urine and feces as urea or hippuric acid or converted into basic carbon compounds which are incorporated in amino acids (e.g., glycine, serine) and proteins. In metabolism studies using radioactive-labeled DDVP, little or no DDVP or its primary metabolites were found in animal tissues and milk.

In plants, DDVP is hydrolyzed to dimethyl phosphate and dichloroacetaldehyde. Dimethyl phosphate is sequentially degraded to monomethyl phosphate and inorganic phosphates. Dichloroacetaldehyde is converted to 2,2-dichloroethanol which is conjugated and/or incorporated into naturally-occurring plant components after additional metabolism.

9. *Inerts*—a. *NRDC's claims.* NRDC asserts that the "apparent absence of data on the risks posed by the inert ingredients and impurities in all DDVP end-use products compels . . . the revocation of all DDVP tolerances." (Ref. 1 at 68).

b. *EPA's response.* If an inert ingredient that is combined with DDVP in an end-use product poses a risk of concern, then there would be grounds for modifying or revoking the tolerance or tolerance exemption pertaining to the inert ingredient. It would not be grounds for revoking the DDVP tolerance, which is evaluated based on the safety of DDVP. All impurities in technical active ingredient DDVP, which would be included at lower levels in DDVP end use products, were tested as part of the technical active ingredient when the toxicology tests on the technical active ingredient DDVP were conducted.

10. *Other allegedly missing toxicity data*—a. *NRDC's claims.* NRDC contends that the Agency cannot make its statutory determination of safety for DDVP dependent upon the submission of data. Specifically, NRDC asserts that in the absence of a dermal sensitization study and a developmental neurotoxicity test (DNT) study, EPA cannot make a safety finding for DDVP under the FFDCA.

b. *EPA's response.* EPA has received and reviewed a DNT study for DDVP. (Ref. 11 at 127). Additionally, NRDC is incorrect in asserting that EPA does not have any dermal sensitization data for DDVP. On the contrary, the Agency has four dermal sensitization studies for DDVP. (Refs. 52, 53, 54 and 55). The DDVP dermal sensitization studies were conducted with formulations, containing varying levels of technical DDVP. All four of the studies were negative for sensitization in guinea pigs. Although none of the studies tested DDVP in isolation, sufficient information was obtained from the four studies to define the dermal sensitization toxicity of DDVP.

B. Dietary Exposure Issues

1. *Revised dietary exposure and risk assessment.* NRDC's petition challenges numerous aspects of EPA's 2000 proposed dietary exposure and risk assessment of DDVP. This exposure and risk assessment was incorporated into the 2006 DDVP IRED without major changes. In responding to NRDC's petition, EPA has updated the DDVP dietary exposure and risk assessment. The main changes in the revised assessment include: (1) use of EPA's current dietary assessment program, DEEM-FCID, instead of DEEM; (2) incorporation of residue estimates for drinking water directly into the DEEM-FCID program; (3) updated monitoring data (principally from the USDA-Pesticide Data Program ("PDP")) and percent crop treated data; and (4) incorporation of estimated exposure from use of naled as a wide area treatment for mosquitoes. A summary of the revised dietary risk assessment is presented in this unit and NRDC's specific comments are responded to individually below. (Ref. 56).

The estimated risk levels, presented in Table 1, are largely unchanged from the 2006 IRED when both food and water are considered. Although this risk assessment is highly refined as to some commodities it still contains numerous conservatisms. More details concerning the revised risk assessment are provided in responding to NRDC's specific objections.

TABLE 1.—DIETARY (FOOD AND WATER) EXPOSURE AND RISK FOR DDVP

Population Subgroup	Acute Dietary (99.9 Percentile)		Chronic Dietary	
	Dietary Exposure (mg/kg/day)	% aPAD	Dietary Exposure (mg/kg/day)	% cPAD
General U.S. Population	0.001313	16	0.000060	*COM041*12
All Infants (< 1 year old)	0.003735	47	0.000116	23
Children 1-2 years old	0.001523	19	0.000111	22
Children 3-5 years old	0.001312	16	0.000103	21
Children 6-12 years old	0.000911	11	0.000069	14
Youth 13-19 years old	0.000967	12	0.000048	10
Adults 20-49 years old	0.001475	18	0.000057	11
Adults 50+ years old	0.000929	12	0.000051	10
Females 13-49 years old	0.001000	13	0.000050	10

2. *Drinking water models*—a. *NRDC's claims.* NRDC argues that the DDVP tolerances are unsafe because EPA has inadequate data on DDVP levels in drinking water. (Ref. 1 at 40). NRDC notes that EPA has limited groundwater monitoring data and no surface water monitoring data for DDVP, naled, and trichlorfon. In the absence of DDVP

water monitoring data, NRDC claims EPA cannot find the DDVP tolerances to be safe. Further, NRDC claims that the surface water exposure model used by EPA in the preliminary risk assessment (PRA), GENEEC, has not been properly validated, and that "EPA has failed to demonstrate that the surrogate data [in the model] are properly matched to DDVP and that the model's assumptions and parameters are justified." (Id. at 54). NRDC makes similar claims regarding the matching of surrogate groundwater data to DDVP through the operation of the SCI-GROW ground water model. (Id. at 55). According to NRDC, "if the SCI-GROW model employed surrogate data [on DDVP], it cannot be assumed to be reliable unless full disclosure of its construction and inputs is made and this information demonstrates its reliability." (Id.).

In its comments on the DDVP IRED, NRDC raised similar issues. (Ref. 13 at 9). Citing a number of alleged uncertainties pertaining to the SCI-GROW model, NRDC argues that because "[n]one of these uncertainties is quantitatively bounded ... the Agency has not or cannot determine with reasonable certainty that the risks from groundwater contamination by DDVP will not harm people." (Id.). Additionally, NRDC claims the assessment for groundwater is incomplete, because EPA has not aggregated DDVP in groundwater resulting from uses of DDVP, naled, and trichlorfon. (Id.).

Finally, in its petition, NRDC asserts that EPA's conclusion that DDVP will not be persistent in surface waters is mere speculation. (Ref. 1 at 44).

b. *Amvac's comments.* Amvac disputes NRDC's criticism of EPA's drinking water models stating "NRDC appears to not understand the underlying assumption and highly conservative nature of these models." (Ref. 14 at 63). Further, Amvac argues that, because of the highly conservative nature of the models, the targeted monitoring data NRDC calls for would show that DDVP exposure in drinking water is lower than projected. (Id. at 70-71). Amvac further notes that targeted monitoring data has limited applicability and would be unlikely "to be representative of potential exposure on a wider geographical scale." (Id. at 71).

c. *EPA's response.* NRDC's general claims regarding EPA's drinking water models are addressed for the most part in a prior EPA order denying NRDC objections to use of these models in making a safety finding for a pesticide tolerance. (69 FR 30042, 30058-30065 (May 24, 2006). In that order, EPA explained in detail as to each of the models: (1) the basic principles on which the model is based; (2) the data underlying the models; (3) the numerous conservatisms built in to each of the models; (4) the extensive independent peer review used in the development of the models; and (5) the external and internal testing of the accuracy of the models. After this extensive analysis, EPA concluded the models "are based on reliable data and have produced estimates that EPA can reliably conclude will not underestimate exposure to pesticides in drinking water." (Id. at 30065). Not only does this order provide a detailed description of the models and data underlying the models but it referenced the many SAP reviews and Agency policy documents that further explained the models. Additionally, it should be noted that detailed information concerning the models is available on EPA's website. EPA has recently updated this information to insure that the website provides not only the ability to run the models but also a description of the how the models work and the underlying codes included in the structure of the model. (Ref. 57)

NRDC's more specific allegations are also without merit. First, EPA took the characteristics of DDVP, naled, and trichlorfon into account in modeling DDVP levels in drinking water. Specific information concerning these pesticides' mobility and persistence was combined with information pertaining to application amounts in use of PRZM-EXAMS to model surface water DDVP levels and SCI-GROW to model groundwater DDVP levels. In addition, information on soil properties, cropping characteristics, and weather appropriate to use of these pesticides was incorporated in the PRZM-EXAMS model run. (Ref. 58). Second, EPA has adequately addressed uncertainties in the PRZM-EXAMS model through peer review and validation. NRDC claims that EPA has not quantified the uncertainties in the SCI-GROW model and thus cannot rely on it; however, NRDC's listing of uncertainties (e.g., small drinking water reservoir, runoff prone soils) applies to considerations relative to the surface water model PRZM-EXAMS not SCI-GROW. These apparent criticisms of the PRZM-EXAMS model are without merit. As noted above, while EPA has not specifically quantified each individual uncertainty associated with the model, the overall model has been extensively peer-reviewed and validated, and has proved very conservative in practice. Third, EPA's estimation of surface water DDVP levels is not flawed for failure to combine exposures from DDVP, naled, and trichlorfon. The highest estimated surface water DDVP levels are from the naled use on brassica and the trichlorfon use on turf ((33 parts per billion ("ppb") and 60 ppb, respectively, for acute exposure and 1.83 ppb and 1.56 ppb, respectively, for chronic exposure). These estimates are based on the conservative assumption that 87 percent of the area of the watershed is cropped to either brassica or turf and all of the brassica or turf is treated with naled or trichlorfon, respectively. The figure of 87 percent is based on the fact that "87 percent cropped was the largest cropped area in any 8-digit hydrologic unit in the continental United States." (69 FR 30042, 30060 (May 26, 2004)). Thus, there is no reason to combine these estimates. A watershed may be 87 percent turf or 87 percent brassica but not both. Moreover, the available data indicate that both trichlorfon and naled are used relatively infrequently on turf and brassica, respectively; thus, the water level estimate is overstated to begin with. (Refs. 56 and 59). In theory, the DDVP use producing the highest estimated surface water levels (wide area treatment for mosquitoes) could overlap somewhat with these uses but not only is estimated water concentration from the DDVP use insignificant compared to the levels used to assess acute and chronic drinking water exposure (10X and 20X lower, respectively) but relevant survey data show no report of DDVP for this use. (Ref. 60).

EPA has chosen to rely on modeling estimates of DDVP in drinking water because the drinking water modeling data it has were not necessarily collected in areas of DDVP, naled, or trichlorfon usage and there is inadequate data on drinking water from shallow, groundwater wells. Nonetheless, the sampling data give some indication of the conservativeness of the modeling estimates. USDA's Pesticide Data Program ("PDP") collected finished drinking water samples from California and New York in 2001 (214 samples) and from California, Colorado, Kansas, New York, and Texas in 2002 and 2003 (371 and 699 samples, respectively). In 2004, PDP sampled raw and finished water from 171 community water systems from Michigan, North Carolina, Ohio, Oregon, Pennsylvania, and Washington (234 samples). Although the samples were analyzed for DDVP, no detectable residues of DDVP were found in any sample. The limits of detection for these

monitoring data were between 0.4 and 22.5 parts per trillion (ppt). By comparison, the estimates from EPA's drinking water models that EPA is using in the DDVP risk assessment are 60 ppb for acute risk and 1.83 ppb for chronic risk. (Ref. 11). In parts per trillion, these values would be 60,000 ppt and 1,830 ppt.

As to NRDC's claims that EPA is simply speculating in stating that DDVP is unlikely to persist in surface water, NRDC is mistaken. The conclusion that DDVP will not be persistent in surface water is based on the physical and chemical properties of DDVP and the results of the suite of environmental fate and transport studies on the compound. As EPA noted in the DDVP IRED, "dichlorvos should not be persistent in any surface waters due to its susceptibility to rapid hydrolysis and volatilization." (Ref. 11 at 152).

2. *Dietary exposure models*—a. *NRDC's claims.* NRDC contends that the Dietary Exposure Model (DEEM) cannot be used to demonstrate the safety of the DDVP tolerances because "[t]he model is secret in that the codes, internal structure and assumptions have not been made available to the public for scrutiny and comment." (Ref 1 at 44). Additionally, NRDC argues that the model cannot be relied upon because it has never been validated. (Id.).

b. *Amvac's comments.* Amvac notes that EPA has used DEEM for many years and claims that the DEEM "software and its use have received many peer reviews ...." (Ref. 14 at 57). Further, Amvac asserts that "[t]his model and the other models that EPA uses to assess dietary risk (i.e., LifelineTM and CARES) have all been made available to the public and their computer codes are available for public review and comment." (Id. at 57-58).

c. *EPA's response.* DEEM and its successor, DEEM-FCID, are not secret models. As explained in Unit III.B.3.b.i.(B)., these dietary assessment models use relatively simple formulas to combine consumption information with residue levels in food to estimate exposure and risk. In 2000, the company that developed DEEM made a detailed explanation of the model public so that the model could be reviewed by the FIFRA SAP. (Ref. 7). That explanatory paper documented the data included in DEEM and the algorithms DEEM uses to manipulate that data to estimate exposure and risk. In addition to the algorithms, the paper contained a full delineation of underlying computer segment codes that comprise the DEEM program. In response to the SAP's concern that the DEEM paper did not make public the "recipes" used to translate the CSFII consumption data back to the precursor agricultural commodities (e.g. translating pizza into tomatoes, wheat, cheese, etc.), EPA contracted to have a new set of translations produced that would not be subject to proprietary restrictions. Those new translations have been completed and incorporated into DEEM-FCID, DEEM's successor, and are fully available to the public. (Ref.61).

Thus, NRDC is wrong in its assertion that DEEM is a "secret" model. The fundamental logic of this model is available to the public (including both the algorithms and computer codes) and data on food recipes is available on DEEM's successor DEEM-FCID, the model used to run EPA's latest dietary risk assessment for DDVP. NRDC's concerns regarding validation are misplaced as well in that DEEM and DEEM-FCID have been reviewed by the SAP and produce similar results to other publicly-available dietary exposure models. (See, e.g., 70 FR 77363 (December 30, 2005); 70 FR 40202 (July 13, 2005)). Accordingly, NRDC's request that the DDVP tolerances be revoked because of reliance on DEEM is denied.

3. *Percent crop treated data*—a. *NRDC's claims.* NRDC asserts that EPA has used percent crop treated data in calculating aggregate exposure for DDVP without making the findings required by section 408(b)(2)(F). (Ref. 1 at 39). That section imposes certain conditions upon EPA's use of percent crop treated data when assessing chronic dietary risk. Among the specified conditions are the requirements that EPA find (1) "the data are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide chemical residue;" (2) "the exposure estimate does not understate exposure for any significant subpopulation group;" and (3) "if data are available on pesticide use and consumption of food in a particular area, the population in such area is not dietarily exposed to residues above those estimated by [EPA]." (21 U.S.C. 346a(b)(2)(F)). Finally, if EPA does rely on percent crop treated data EPA must provide for the periodic reevaluation of the estimate of anticipated dietary exposure. (Id.). NRDC claims that EPA, having failed to make the foregoing findings cannot rely on percent crop treated in making a safety finding for the DDVP tolerances.

b. *Amvac's comments.* Amvac asserts that adequate data are available on percent crop treated referring to an EPA memorandum (Hummel, 2000). (Ref. 14 at 47-48). According to Amvac, "[t]hat memorandum describes the source of the data and states that the upper end of the range was assumed for acute dietary exposure analysis and that the typical or average was used for the chronic dietary exposure analysis, as is typical EPA practice." (Id.).

c. *EPA's response.* EPA conducted a comprehensive evaluation of the usage of DDVP, naled, and trichlorfon for the DDVP IRED. That evaluation was described in the memorandum cited by Amvac and the memorandum was included in the docket and on EPA's website page for DDVP. In response to NRDC's petition EPA has updated its analysis of percent crop treated information. Specifically, in its revised analysis EPA used percent crop treated data in estimating exposure from use of: (1) DDVP on livestock; (2) trichlorfon on turf; (3) DDVP and naled as a mosquito (wide area) treatment; and (4) naled on agricultural crops.

Based on the findings below, EPA concludes that its consideration of usage or percent crop treated data to estimate percent crop treated conforms to the requirements in section 408(b)(2)(F).

i. *Reliable data.* The primary source of data for estimating the percent of a commodity treated with a pesticide is the United States Department of Agriculture's National Agricultural Statistics Service ("NASS"). NASS collects data on a wide variety of agricultural topics including pesticide usage. NASS uses the Agricultural Resources Management Survey ("ARMS") as well as other surveys to collect data on pesticide usage and other agricultural topics. These surveys are designed to produce statistically representative estimates of pesticide usage on targeted crops in the surveyed States using a probabilistically-based sampling procedure. (See *http://www.usda.gov/nass/nassinfo/surveyprograms/index.htm* and https://arms.ers.usda.gov/GlobalDocumentation.htm).

ARMS is a multi-phase, multi-frame, stratified, probability-weighted sampling design. There are three phases to the annual survey: a screening phase to update data and help target sampling for phases two and three; a second phase that collects information on agricultural practices and chemical usage; and a third phase that collects costs and financial information. ARMS consists of two "frames" collecting farms and ranches. The main frame is the "list frame" that is intended to contain the names and addresses of all farms and ranches in the continental United States along with the acreage of the farms/ranches and the crops grown or livestock raised. The list frame is compiled based on the Census of Agriculture as well as numerous other

surveys and governmental and non-governmental sources. The list frame is back-stopped by the "area frame" which is constructed from satellite images of the continental United States broken down into segments based upon degree and type of cultivation. Both frames are divided into different strata such as crop type. Due to the complexity of the sample design, ARMS uses a weighting system to adjust data gathered in reports from sampling of the frames.

Data is gathered by a statistically-designed sampling of the list and area frames. The sampling is done on a state basis with the focus for any particular crop on the major production states. Generally, samples are conducted in states representing 90 percent or better of the production acreage. Reports are usually prepared based on face-to-face interviews with the identified growers. Surveys for field crops are conducted annually with the crops varying each year. (See *http://usda.mannlib.cornell.edu/MannUsda/viewDocumentInfo.do?documentID=1560)* Surveys for fruits and surveys for vegetables are conducted in alternating years with fruits surveyed in odd years and vegetables in even years. (See *http://usda.mannlib.cornell.edu/MannUsda/viewDocumentInfo.do?documentID=1567* and *http://usda.mannlib.cornell.edu/MannUsda/viewDocumentInfo.do?documentID=1572).* There is some variation in the crops sampled in each survey. NASS data on pesticide use on livestock are published periodically by USDA (1999 (summary of 1997 livestock and general farm survey), 2000 (summary of 1999 swine and swine facilities survey), 2001 (summary of 2000 sheep and sheep facilities survey), 2002 (summary of 2001 dairy cattle and dairy cattle facilities survey), and 2006 (summary of 2005 swine and swine facilities survey), see *http://usda.mannlib.cornell.edu/MannUsda/viewDocumentInfo.do?documentID=1569).*

To estimate percent crop treated for pre-harvest pesticide uses, EPA has created a database containing NASS data from the years 1999-2005. Also included in this database is data from a private service, Doane Marketing Research, Inc., now known as dmrkynetec. This database was used for making the majority of the percent crop treated estimates for the DDVP assessment, namely, the estimates pertaining to the use of naled as an agricultural pesticide. The 2007 estimates show that naled is generally used on a very small percentage of crop acreage. This is consistent with the estimates made for the 2000 dietary risk assessment. Most estimates from the two assessments were similar with a few crops showing declining use over time and one crop (strawberries) showing increased use. (Refs. 62 at 27-30; 56 at 29).

Dmrkynetec is a market research company. Originally, it focused on providing market and tracking data to agribusiness but has expanded its services to a wide range of industry sectors. In the agriculture area, dmrkynetec gathers information by survey research on, among other things, crop acres grown, pesticide active ingredients used, total acres treated with pesticides, pesticide application rates and timing, number of pesticide applications, and pesticide prices. For over 30 years, EPA has purchased dmrkynetec's proprietary database, which provides pesticide usage information for over 50 crops. As part of EPA's contract with dmrkynetec, EPA requires both a quality management plan and a quality assurance project plan to insure that dmrkynetec's survey practices and data compilation are well-designed and reliably executed. Data from dmrkynetec is relied upon not only by EPA but by other Federal agencies and private industry. (Ref.63).

For one commodity, poultry, for which sufficient NASS and dmrkynetec data were not available, EPA followed a different approach in estimating percent crop treated. EPA interviewed agricultural extension agents and professors in agricultural colleges in major poultry-producing states and reviewed crop profiles compiled by USDA and other literature from the extension services to obtain rough estimates of usage. Because this information was not based on statistically-designed surveys, EPA used it in a very conservative manner to estimate worst case percent crop treated estimates. Information gathered on broilers indicated that, DDVP was rarely, if ever used in broiler production in most of the major producing states. The one exception is Georgia, the largest broiler producing state, where approximately 1/3 of the broiler flock is treated with a product containing DDVP. As to layers (egg producers), DDVP is also not used in significant amounts in most of the major producing states. However, an expert in California (fourth in egg production among states) indicated that a product containing DDVP was used on approximately 75 percent of the state's layers. As a very conservative estimate, EPA assumed that 75 percent of the broilers and layers nationwide are treated with DDVP. (Ref. 64).

Estimates of the percent of crops that receive incidental treatment with naled or DDVP as a result of these pesticides' usage as a wide area treatment for the control of mosquitoes was based on a combination of data from NASS and Kline and Company, Inc., a private market research firm. Data from NASS' Census of Agriculture was used to determine the total farm acreage in the United States. Data from Kline provided information on the poundage of naled and dichlorvos used for mosquito treatment. This information was combined in a very conservative fashion with the data on total crop acreage in the United States. EPA calculated what percentage of the total crop acreage could have been treated with the naled and DDVP used for mosquito control and assumed that every crop in the United States was treated to that extent (3 percent). Although some treatment of agricultural crops will occur from the mosquito usage, a significant part, if not most, of the treatment area will be in wetlands, forest, urban and suburban land, and other non-crop areas. Even where agriculture land is treated, such treatment may occur when no crop is present or, even if a crop is present, at such a time that all residues would be expected to degrade prior to harvest. Estimates of percent crop treated for turf uses was also based on data from Kline. This information was not used to quantitatively estimate exposure but simply to qualitatively characterize the conservativeness of the drinking water concentration estimates from turf usage produced by EPA's drinking water model.

NASS's Census of Agriculture is as the name would suggest a complete count of United States farms and ranches. Additionally, the Census collects information on land use and ownership, agricultural practices, and farm income and costs. The Census is conducted every 5 years by law and involves individual contact with all farmers and ranchers in the United States. (See *http://www.agcensus.usda.gov*).

Kline, like dmrkynetec, conducts market research through surveys on a wide range of products. EPA has been purchasing data on non-agricultural pesticide usage from Kline for over 20 years. As with the dmrkynetec contract, EPA has required both a quality management plan and a quality assurance project plan to insure that Kline's survey practices and data compilation are well-designed and reliably executed. Data from Kline is relied upon not only by EPA but by other federal agencies and private industry. (Ref. 63).

EPA concludes these data sources provided reliable data for the percent crop treated estimates that were used by EPA.

ii. *Significant subpopulation group.* EPA considered DDVP exposure to the general population as well as 32 subpopulation groups based on regional location, ethnicity, and age. Reliance on the estimates of percent crop treated discussed above will not underestimate exposure for any of these population subgroups.

iii. *Data on pesticide use and consumption.* EPA takes information on regional consumption patterns into account in estimating exposure to significant subpopulation groups. EPA's information on percent crop treated is primarily national in scope and does not indicate that regional groups have greater exposures to DDVP than estimated by EPA.

iv. *Periodic evaluation.* The statute provides that EPA shall periodically reevaluate the estimate of anticipated dietary exposure. This is a prospective requirement. Although it may do so sooner, EPA expects that the exposure estimates will be reevaluated periodically through the registration review process. (21 U.S.C. 346a(b)(2)(F); Ref. 65).

To evaluate the sensitivity of dietary risk assessment to EPA's percent crop treated findings, EPA conducted an alternate dietary assessment assuming 100 percent crop treated for all commodities. (Ref. 56). As Table 2 shows, even using this very conservative assumption, dietary exposure is well below the RfD/PAD for DDVP.

TABLE 2.—DIETARY (FOOD AND WATER) EXPOSURE AND RISK FOR DDVP INCORPORATING 100 PERCENT CT FOR ALL COMMODITIES

Population Subgroup	Acute Dietary(99.9 Percentile)		Chronic Dietary	
	Dietary Exposure (mg/kg/day)	% aPAD	Dietary Exposure (mg/kg/day)	% cPAD
General U.S. Population	0.002274	28	0.000112	22
All Infants (<1 year old)	0.004152	52	0.000154	31
Children 1-2 years old	0.004663	58	0.000252	50
Children 3-5 years old	0.003533	44	0.000214	.....
Children 6-12 years old	0.002677	33	0.000138	28
Youth 13-19 years old	0.001660	21	0.000092	18
Adults 20-49 years old	0.001850	23	0.000102	20
Adults 50+ years old	0.001437	18	0.000088	18
Females 13-49 years old	0.001603	20	0.000097	19

4. *Anticipated residues*— a. *NRDC's claims.* NRDC asserts that because EPA relied upon anticipated residue data, EPA must issue a data call-in to demonstrate that actual residues are not higher than the anticipated residues relied upon by the Agency. (21 U.S.C. 346a(b)(2)(E)(ii)).

b. *EPA's response.* This is a prospective requirement. To the extent that NRDC is claiming that EPA must revoke all DDVP tolerances because the FFDCA provides that EPA must require the registrant to submit data in the next 5 years pursuant to section 408(f), that claim is rejected.

5. *Trichlorfon and naled*—a. *NRDC's claims.* Based solely upon EPA's statement in the prelimanry risk assessment that "[n]on-detectable Dichlorvos residues in livestock commodities are expected as a result of Trichlorfon use[,]" NRDC speculates that the method for detecting DDVP in beef may not be sensitive enough to detect toxicologically significant residues. (Ref. 1 at 40). Based on this speculation, NRDC claims that the DDVP tolerances do not comply with the requirement in section 408(b)(3) that "a tolerance ... shall not be established at ... a level lower than the limit of detection of the method for detecting and measuring the pesticide chemical residue ... ." (21 U.S.C. 346a(b)(3)(B)). Further, NRDC claims that EPA has not explained its conclusion that residues from trichlorfon use are estimated not to increase residues from the use of DDVP. (Ref. 1 at 51). In addition, NRDC contends that the Agency's analysis of DDVP residues from the use of naled (which also degrades into DDVP) for mosquito control is inadequate.

b. *EPA's response*— i. *Trichlorfon.* Trichlorfon degrades in plants and livestock and one of the products (metabolites) that forms is dichlorvos. Trichlorfon livestock feeding studies did not detect residues of dichlorvos using a level of detection ("LOD") of 0.05 ppm. The trichlorfon RED concluded that dichlorvos was not a significant residue in the cattle based on the feeding study and a metabolism study. The metabolism study found DDVP in subcutaneous fat at 4 percent of the total radioactive residue (TRR), and less than 1 percent of the TRR in loin muscle (0.006 ppm). (Ref. 66). Subcutaneous fat is not used for human consumption, and often has residues higher than that in fat more distal from the site of application. Thus, it is highly unlikely that livestock will contain residues of dichlorvos from the use of trichlorfon. In any event, the residue monitoring data on DDVP includes DDVP as a degradate of trichlorfon and thus any DDVP in beef from use of trichlorfon would be captured by the monitoring data.

The Agency has substantial data showing that residues of dichlorvos as a result of trichlorfon use will be non-detectable in beef. USDA-FSIS has sampled for trichlorfon and dichlorvos in the past. Although there is no U.S. registration for trichlorfon on cattle, there are tolerances so that foreign cattle can be treated and imported to the United States. From 1993 through 1997, FSIS monitored over 12,000 samples of beef. (Ref. 67). No residues of dichlorvos

or trichlorfon were detected at a LOD of 0.2 ppm. However, detectable residues of other organophosphates were found.

In addition, monitoring data from PDP were available for milk at the time the last anticipated residues were determined for the 2000 IRED, and were used in the dietary exposure assessment for the IRED. One detectable residue was reported at 0.003 ppm out of 1,881 samples, with an LOD of 0.001 - 0.002 ppm (avg. 0.0014 ppm). (Ref. 62 at 12). Since that time, PDP collected over 300 samples of beef fat, liver, and muscle from 2001 to 2002 and found no detectable dichlorvos at a LOD of 1.0 ppb; over 300 samples of pork in 2005 and found no detectable dichlorvos residues at an LOD of 0.9 ppb in fat; and LOD of 0.45 ppb in pork muscle; and over 600 samples of poultry commodities in 2000-2001 with no detectable residues of dichlorvos at an LOD of 6.3 ppb. PDP also analyzed over 100 samples of heavy cream, and found no detectable residues of dichlorvos at a LOD of 1-2 ppb. Finally, no detects of DDVP were found 1,485 samples of milk analyzed in 2004-2005, at an LOD of 0.06 ppb. (Refs. 56 at 13; and 68).

NRDC is mistaken to claim that the detection method for DDVP in meat is not adequately sensitive. Generally, the Agency accounts for non-detectable residues by using ½ the LOD or LOQ in its calculations. (Ref. 69). If this calculation shows a potential risk problem, then the limits of detection must be lowered. In the case of dichlorvos, no risks of concern were identified for livestock commodities when they were assessed at ½ the LOD. In fact, total dietary risk from DDVP in food is just a small fraction of the RfD. Thus, the LODs are low enough to be below the level of risk concern and to ensure detection of toxicologically significant metabolites.

ii. *Naled.* DDVP exposure from use of naled to control mosquitoes through wide area treatment is likely to be very low to non-existent for two reasons: (1) The treatment rate is very low—0.25 lb ai naled/Acre, compared to the usual application rate for field crops of 1.8 lb ai naled/Acre; (2) residues from treatment degrade rapidly; and (3) the usage rate indicates few crops will be impacted by the mosquito use. Residue data from field trials showed most samples to be 0.03 ppm or less. One DDVP residue from the wide area treatment with naled was as high as 0.27 ppm, with the duplicate of this sample having a residue of 0.08 ppm (average residue 0.18 ppm DDVP). (Ref. 70). Additional data show that residues of DDVP are formed 1-3 days after field treatment with naled, and decline to non-detectable within 7 days of treatment with naled. (Ref. 71). Further, PDP data showed no detectable levels of DDVP in crops not registered to be treated with naled out of roughly 10,000 samples. (Ref. 56 at 19-20).

Despite these data suggesting there will be little to no exposure in the diet from use of naled to control mosquitoes, EPA took a very conservative approach to estimating exposure from the naled mosquito use in its revised risk assessment. (Ref. 56). First, EPA examined usage data to determine a rough estimate of the acreage treated with naled for mosquito control. (Ref. 72). EPA assumed that all acres treated were cropped farmland and not wetlands, woodlands, urban or suburban areas, or other non-cropped areas. This acreage was then expressed as a percentage of the overall farm acreage in the United States. That percentage (3 percent) was the value used in estimating the percent crop treated for all crops grown in the United States. If DDVP or naled is not registered for use on a crop, EPA assumed that three percent of that crop was treated. If DDVP or naled are registered on a crop and EPA has data on the percent of that crop treated as an agricultural use with DDVP or naled, EPA summed the percentages from the agricultural use and the mosquito use in estimating percent crop treated. Finally, if DDVP or naled are registered on a crop and EPA does not have data on the percent of that crop treated as an agricultural use with DDVP or naled, EPA assumed 100 percent of the crop was treated with DDVP or naled. In the latter circumstance, EPA considered but rejected somehow incorporating the mosquito use as an overlapping use because, for among other reasons, exposure from crops was based not on data from field trials but from monitoring data.

6. *Translation of reside levels*—a. *NRDC's claims.* NRDC contends that EPA cannot make the safety finding for DDVP because EPA has translated data from grain dust to soybean aspirated grain fractions and data from cattle to swine based on speculation and not validated data. Indeed, NRDC argues that every translation of data from one plant or species to another is a major data gap that cannot be addressed through worst case or default assumptions because plant or animal metabolism can produce metabolites that are more toxic than the parent compound.

b. *EPA's response.* EPA's translation of other residue data to soybean aspirated grain fractions is reasonable. EPA translated magnitude of the residue data from wheat and corn aspirated grain fractions to soybean aspirated grain fraction. Another name for "aspirated grain fractions" is "grain dust." This is the dust that is removed from the grain by the rubbing of the grains together during storage. Residues in grain dust are generally surface residues and thus grain crops that have otherwise similar residues tend to have similar residue levels in grain dust. This is especially the case for DDVP given that it is applied in equal amounts to all grains post-harvest. Post-harvest application generally results in surface residues, and there would be no reason to expect different levels of residues across grains. For similar reasons, metabolism of the pesticide in the crop, which can play a role in residue levels, is unlikely to be a factor with DDVP grain dust residues because metabolism occurs primarily when a plant incorporates a pesticide through uptake and not when the pesticide is applied to the crop surface post-harvest. Thus, EPA's analysis is not based upon mere speculation, but rather a reasoned analysis of the similarity between commodities and how DDVP is used.

EPA's treatment of potential residue levels in swine is also reasonable. EPA requires radio-labeled metabolism studies in a few plant and animal commodities to identify all potential metabolites. (Ref. 73). Then magnitude of the residue studies are generally required for each treated plant and animal commodity for the purpose of selecting tolerance values and, in the absence of monitoring data, assessing risk.

EPA has all required animal metabolism studies for DDVP. EPA has required an additional study on the magnitude of DDVP residues in swine. These data are needed to verify that a proper tolerance value has been identified for pork commodities. In the absence of those data, EPA has relied on data on cattle and poultry products because it is likely that the residues will be similar to those in cattle and poultry commodities. These additional magnitude of the residue data are not needed for risk assessment because EPA has monitoring data on swine commodities. These data show no detectable residues.

7. *Food monitoring data*—a. *NRDC's claims.* NRDC asserts that the FDA and USDA monitoring programs are inadequate because the number of samples examined in these programs is too small to be representative of the total quantity of food potentially having DDVP residues. (Ref. 1 at 49, 61-62). In addition, NRDC claims that the monitoring data are old and, therefore,

do not represent current use patterns. NRDC also asserts that the consumption data are insufficient because they have a limited number of individuals in the age group of infants less than one year old. NRDC further notes that samples collected from the FDA Total Diet Study were collected in supermarkets in only four cities per year and residues in other locations may be different and very little monitoring data are available for fumigated commodities, requiring extensive translation from one fumigated commodity to another. Moreover, NRDC raises the concern that some of the FDA data were generated with an analytical methodology that is not capable of detecting "early eluters" such as DDVP and EPA has not taken this fact into account. Finally, NRDC contends that residues potentially present at roadside produce stands or farmer's markets are not represented and, additionally, that EPA failed to consider such consumers major identifiable subgroup of consumers. NRDC therefore concludes that EPA does not have reliable food monitoring data and argues that EPA should use the default assumption of 100 percent crop treated for all foods which may be treated with DDVP as well as the default assumption of tolerance level DDVP residues in all treated commodities.

In a related comment on the IRED, NRDC takes issue with EPA's decision not to sum potential residues resulting from multiple treatments of a food with DDVP at different stages of the food production process. (Ref. 13 at 8). NRDC claims EPA's conclusion that sufficient time would pass between such treatments that only the last treatment needs to be considered in estimating exposure is arbitrary and capricious.

b. *EPA's response.* In general, EPA disagrees that the monitoring data are unreliable. To the contrary, EPA believes that the monitoring data provide for an appropriately conservative risk assessment.

i. *Adequacy of data – Age and number of samples and sample location.* Contrary to NRDC's characterization, FDA and USDA each analyze thousands of samples per year. FDA analyzed several hundred samples per year for DDVP, but now analyzes less than 100. USDA analyzes most of their samples for DDVP, generally 350 to 700 samples per commodity per year, although sometimes only about 175 samples per commodity per year. FDA targets their monitoring toward commodities which have historically had residue problems. USDA-PDP uses a more random sampling plan, which is statistically designed to be representative of the U. S. food supply.

In response to NRDC's concerns regarding the age of the monitoring samples, EPA has updated its dietary risk assessment based almost exclusively on USDA PDP data from the years 2000 to 2005. In the updated assessment, FDA monitoring data was used for only one commodity, berries (not including strawberries). The updated assessment confirms what the earlier assessment found: DDVP residues are rarely found in food commodities. Not including strawberries, PDP data showed only 20 samples with detectable residues of DDVP out of more than 43,000 samples from 34 commodities which could potentially bear DDVP residues. Even focusing on foods covered by registered agricultural uses for DDVP or naled, there were only 20 samples with DDVP residues out of approximately 33,000 samples (not including strawberries). In the PDP data, strawberries were the only commodity with more than a marginal number of detections – with 104 samples showing DDVP out of 1,986 samples. (Ref. 56 at 19-20).

ii. *Infant consumption.* NRDC objects to EPA's reliance on an alleged lack of infant consumption data. In response, EPA notes that there is no more comprehensive a consumption survey in the United States than the CSFII surveys. Moreover, the revised dietary assessment relies upon more recent and updated CSFII data. Specifically, the FQPA required additional sampling of infant and children for information on their consumption has been completed. The results of the additional sampling were incorporated into DEEM and DEEM-FCID. These surveys are available to the public. (Ref. 6).

iii. *Fumigant monitoring data.* EPA believes it has adequate data on the fumigant use of DDVP. EPA has data from residue studies conducted in warehouses with packaged and bagged commodities for the following foods: flour, cocoa beans, coffee, dry beans, walnuts, and soybeans. (Ref. 74). These studies were conducted by fumigating pallets containing these commodities at a maximum rate and then sampling both the outside layer and interior of the foods on the pallet. These data were translated to other packaged and bagged commodities based on starch and moisture content. Although translating these data to other commodities creates some uncertainty as to the residue estimate, this uncertainty is more than offset by other factors. First, the studies used maximum treatment rates and sampled the commodities 6 hours after treatment. Not only does this approach overstate residues that would occur from lower treatment rates but it does not take into account the rapid disappearance of DDVP that occurs due to its volatile nature. Second, EPA assumed 100 percent of bagged and packaged commodities were treated.

iv. *Early eluter.* Because DDVP is an early eluter (i.e., DDVP will avoid detection unless samples are analyzed under low temperature chromatographic conditions), fewer samples are analyzed by FDA for DDVP than are typically analyzed by the Luke multiresidue method. In its prior dietary DDVP assessment EPA relied heavily on FDA monitoring but only used monitoring that used early eluter conditions which are known to detect DDVP. This issue has limited relevance given EPA's revised dietary risk assessment which relies almost entirely on PDP monitoring data which uses analytical methods which are known to detect DDVP.

v. *Farmers' markets and roadside produce stands.* In an order responding to NRDC objections to tolerances for different pesticides, EPA has addressed NRDC's claims regarding pesticide exposure to persons who purchase food at roadside stands or farmers' markets. (70 FR 46733). As EPA explained there, whether EPA relies on data from crop field trials or monitoring data in estimating pesticide exposure, given the sampling methods in field trials and food monitoring, residue levels identified from these sources are unlikely to understate residue levels at farm stands.

EPA also rejects NRDC's challenge to EPA's decision not to sum residues from treatments of a commodity at different stages of the production process. Multiple treatments are a possibility for commodities such as grains which may be treated as a bulk commodity and later as a bagged and packaged commodity. EPA has estimated DDVP exposure based on the treatment of bagged and packaged commodities. EPA's decision was based on a number of inter-related considerations. First, there are data showing that DDVP is a volatile compound that rapidly degrades. Second, general monitoring data consistently show very low to non-existent residues in food with the exception of one commodity (strawberries) that are marketed very promptly. Third, EPA has assumed that 100 percent of all bagged and packaged foods are treated with DDVP and EPA's estimate of residue values in these commodities is based on a conservative value from sampling of bagged and packaged commodities 6 hours after treatment. Finally, the latest data from FDA's Total Diet Study, a study measuring pesticide residues and other

contaminants in food as consumed, has shown zero detections of DDVP in the time period from the survey conducted in 1991 up until the latest survey in 2003. (Ref. 75). The Total Diet Study examines 280 foods, including many bagged and packaged foods, that are collected from different regions in the United States. DDVP is one of many pesticides analyzed for in the study.

8. *Cooking factors*—a. *NRDC's claims.* NRDC takes issue with the Agency's practice of using cooking factors to reduce estimates of residues for particular commodities as well as the Agency's practice of translating these factors to other commodities based upon similarity of cooking time and temperature. In particular, NRDC asserts that in the absence of empirical data demonstrating that each commodity will be affected identically by cooking, EPA cannot use cooking factors in its assessment of DDVP residues. In addition, NRDC contends that "EPA apparently failed to take into account vastly different cooking practices for different commodities, including consumption of some commodities raw." (Ref. 1 at 50). As such, NRDC asserts that EPA should not assume cooking will result in any reduction in observed residue levels.

b. *EPA's response.* EPA's use of cooking factors is reasonable. Amvac submitted a cooking study which examined residue decline due to cooking in the following commodities: cocoa beans, dry pinto beans, tomato juice, coffee beans, hamburger meat, eggs, and raw whole milk. (Ref. 76 at 34-37). The study showed that DDVP residue reduction was time and temperature dependent with dramatic reductions occurring when items were cooked at high temperatures for more than a few minutes. For example, eggs cooked for 3 minutes at greater than 100 degrees C resulted in a residue decline of 38 percent, hamburger cooked at a similar temperature for six minutes showed a 70 percent decline in DDVP residues, and cocoa beans cooked for 10 minutes at 135 degrees C resulted in a residue decline of 99.7 percent. Residue decline factors (i.e., cooking factors) were translated from tested items only to similar commodities which are cooked in a similar manner. For example, data on dry pinto beans was translated to other dried beans and peas and to boiled peanuts; data on hamburger was translated to other meats; and data on tomato juice was translated to celery juice. EPA believes these cooking times and temperatures are reasonable, conservative estimates. Although certain of these commodities may occasionally be cooked for shorter times or at lower temperatures, EPA expects those instances to be infrequent. Moreover, given the conservative assumptions on cooking times any variations are very unlikely to be "vastly different." As to consumption of some of these foods uncooked, NRDC's concern about use of cooking factors is unwarranted because EPA's consumption database differentiates between amounts of foods consumed cooked and uncooked and only applies cooking factors as to the former. Further, EPA concludes that its choice of translation commodities is also reasonable given the similarity between the cooking methods for the tested commodity and the translated commodity and the strong relationship shown in the data between cooking time and temperature and residue decline.

In any event, EPA disagrees that it cannot rely on cooking data unless it has data on all varieties of cooking practices within the United States and its cooking data take that full range of cooking practices into account. Implicit in this argument, is the view that EPA must adopt a cooking factor that reflects the shortest possible cooking time, no matter how infrequently such practice is used. Section 408, however, does not take such an extreme approach to assessing exposure. Rather, section 408, directs EPA to focus on major, identifiable subgroups of consumers not worst case scenarios or maximally-exposed individuals. EPA believes that use of reasonable, conservative exposure assumptions are consistent with this statutory mandate.

Additionally, it is important for EPA to adapt the assumptions underlying any exposure assessment to the complexity of the assessment. For simple assessments – a single pesticide to which a human is exposed by a single route (e.g., oral) from a single source (e.g., apples) – a more conservative approach to assumptions such as cooking factors may be necessary to assure high end exposures are captured because high end exposure may be defined by consumption of a single food. This is not the case with complex assessments like for DDVP that involve multiple pesticides, multiple routes of exposure, and multiple sources of exposure within routes. In evaluating exposure to DDVP in food alone, EPA's exposure assessment takes into account residues in hundreds of food commodities. If EPA were to assume worst case residue values for each of these commodities (worst case pesticide usage, worst case potential residues on the raw crop, worst case processing values, worst case cooking factors, etc.) and then combine that information with the assumption of worst case consumption for each commodity, the exposure assessment would not reflect reality. Just as no one person, and certainly no major subgroup of consumers, is a worst-case consumer of every commodity, no one person, or major subgroup of consumers, is likely to be consumers of every commodity at its worst-case residue amount. To make such assumptions when multiple commodities are involved compounds multiple conservatisms and would produce an assessment that overstates exposure probably by several orders of magnitude. For this reason, EPA's exposure assessment guidance advises using a mixture of high end and central tendency assumptions to produce a high end exposure assessment. (Ref. 77). Accordingly, EPA's use of conservative, but not worst case, cooking factors in the DDVP exposure assessment is reasonable.

9. *Missing data*—a. *NRDC's claims.* NRDC claims that various data are missing: storage stability data for meat, milk, poultry, and egg residue studies; crop field trials on tomatoes; and tomato processing studies. (Ref. 1 at 43).

b. *EPA's response.* The tomato use has been canceled so no data are needed on tomatoes. Although the IRED stated that data are needed on storage stability, that statement was in error. (Ref. 11 at 189). In fact, storage stability requirements have been met. The IRED noted that storage stability data were needed in connection with some of the residue data used in the 1987 Registration Standard for DDVP. Subsequent to 1987, the registrant submitted new residue data on the commodities in question and that residue data met the requirements for storage stability data. (See, e.g., Ref. 74 at 10).

10. *Uncertainties in estimating residues in foods*—a. *NRDC's claims.* NRDC argues that EPA has identified uncertainties in its dietary assessment but fails to take these uncertainties into account. Uncertainties cited by NRDC include lack of data on residue values in foods sold at farm stands, use of cooking data, the limited sampling sites in the FDA Total Diet Study, the reliance on residue trial instead of monitoring data for warehouse uses of DDVP, the extensive translation between commodities in estimating residues from DDVP warehouse uses, and the reliance on field trial data for some commodities. (Refs. 1 at 52; and 13 at 8-9).

b. *EPA's response.* EPA does take into account any uncertainties in its food exposure analysis in determining whether it has estimated risk in a manner that is protective of the general

population and all major identifiable consumer subgroups. For DDVP there were a number of factors that might have led to an underestimation of exposure levels but these factors are dwarfed by considerations indicating that EPA has overestimated exposure. Each of the factors highlighted by NRDC as well as others are discussed below:

i. *Food from farm stands.* As discussed above, EPA does not believe that farm stands are likely to sell food containing a significantly different residue profile than found in PDP monitoring data. This factor introduces little to no uncertainty concerning the possibility of underestimation of residues into EPA's analysis.

ii. *Use of cooking factors.* As discussed above, EPA used cooking factors in a conservative fashion in estimating exposure. For several reasons, EPA believes its use of cooking factors did not fully take into account the degree of reduction of DDVP residues that occurs with cooking. First, cooking factors were only applied to a relatively small number of commodities that may contain DDVP residues. Cooking of other commodities containing DDVP residues (e.g., grains and vegetables) will undoubtedly decrease residues in those commodities substantially. Second, the manner in which EPA translated the residue reduction data will tend to exaggerate residue levels in many commodities. For example, data on the residue reduction that occurs from cooking hamburger for six minutes was translated to all cooked meats. Given that most meats are cooked substantially longer than six minutes, this use of the cooking data will understate exposure. This factor will overestimate exposure to DDVP.

iii. *FDA Total Diet Study.* In the updated risk assessment the FDA Total Diet Study data was not relied upon to quantitatively estimate residues in food. This factor has no bearing on the DDVP exposure assessment.

iv. *Residues from warehouse use.* EPA did do extensive translation of data between commodities for the warehouse use. There was a reasonable basis for these translations; nonetheless, some uncertainty attends any such translation. However, EPA's estimation of exposure from the warehouse use will clearly overstate DDVP exposure for two reasons. First, EPA is not relying on monitoring data from warehouses but data from residue trials in the warehouse. Invariably, residue trials result in findings of higher residue values than monitoring data because residue trials involve prompt sampling after treatment whereas monitoring can occur days or weeks later. Thus, residue trials do not take into account the normal degradation that occurs over time. With DDVP, this decline in residues is likely to be exaggerated given the data showing both DDVP's volatility and rapid degradation. Monitoring data that is available on other commodities confirms the rapid decline of residues. Second, EPA assumed that all food in warehouses is treated with DDVP. This is a very conservative estimate. Accordingly, this factor will tend to significantly overstate exposure to DDVP.

v. *Reliance on field trial data.* For many commodities that may be legally treated with naled, EPA relied upon field trial data or assumed tolerance level residues rather than monitoring data. For the reasons noted immediately above, this assumption will significantly overstate residues on those commodities.

vi. *Percent crop treated.* For many commodities that may be legally treated with DDVP or naled (other than in warehouses), EPA assumed that 100 percent of the commodity is treated. Again, this is a very conservative estimate and will significantly overstate DDVP exposure from those commodities.

vii. *Default processing factors.* For several processed commodities, EPA relied on default processing factors in estimating DDVP residues in the processed food. EPA's default processing factors project worst case levels of pesticides in processed food. (70 FR at 46733-46734). Thus, use of default processing factors instead of specific processing data for DDVP will overestimate residues in food.

Considering all of this information, EPA's conclusion is that its assessment of exposure to DDVP from food will not under-estimate but rather over-estimate, and in all likelihood substantially over-estimate, DDVP exposure.

In any event, EPA's latest dietary assessment shows that, by a large margin, the biggest driver in the DDVP dietary risk assessment are DDVP residues in water not food. (Ref. 56). To the extent food is a driver, that food is food with residue estimates from its treatment as a bagged and packaged food. As explained above, estimates of residues in bagged and packaged foods are likely to be a significant overestimate due to the assumption of 100 percent treatment and use of magnitude of the residue study rather than actual monitoring data.

C. Residential Exposure

1. *Aggregating Exposures.* The safety standard in FFDCA section 408 for tolerances requires that there be a reasonable certainty of no harm from "aggregate exposure to the pesticide chemical residue, including all dietary exposures and all other exposure for which there is reliable information." (21 U.S.C. 346a(b)(2)(A)(ii)). Further, EPA in evaluating the safety of tolerances is directed to "consider ... available information concerning the aggregate exposures of consumers ... to the pesticide chemical residue ... including dietary exposure under [all] tolerance[s] ... in effect for the pesticide chemical residue and exposure from other non-occupational sources." (21 U.S.C. 346a(b)(2)(D)(vi)).

Unit VII.B. discusses EPA's assessment of aggregate dietary exposure to DDVP from residues in food and water. That assessment showed that these aggregate exposure levels were well below the acute and chronic RfD/PADs. Although refined, these exposure estimates still are likely to overstate exposure and risk. This is particularly apparent when it is considered that the commodities that drove the risk numbers were those commodities (drinking water and bagged and packaged goods) for which the most conservative assumptions were made. (Ref. 56).

Pesticide residues to which humans are exposed from residential uses of pesticides must be considered as part of section 408's aggregate exposure calculus. The concern, of course, is that pesticide tolerances should not be established or left in effect if dietary exposures, when combined with other sources of exposure, exceed safe levels. As the analysis in Unit VII.D.2. shows, however, dietary exposures are insignificant compared to residential exposures and thus the safety determination turns on an evaluation of the exposure and risk from the residential uses of DDVP.

2. *Revised residential exposure – pest strips.* In light of the numerous issues raised by NRDC concerning EPA's assessment of the risk posed by DDVP pest strips, EPA has substantially revised its assessment of exposure and risk from this use. EPA first discusses that revised assessment before turning to NRDC's specific claims. The changes in the assessment come in three areas: (1) analysis of exposure data and exposure assumptions used; (2) the types of durational scenarios assessed; and (3) the endpoint used for chronic exposure. (Ref. 78).

Currently, there are four sizes of DDVP pest strips that are registered. The largest strip (65-80 grams) may only be used in unoccupied areas in and around the house (garage, attic, crawl space,

shed) where humans are present for no greater than four hours per day. There are three smaller strips (16, 10.5, and 5.25 grams) that may be used in the home in closets, wardrobes, or cupboards. The IRED recommended, and Amvac has accepted, label restrictions for these smaller strips which bars use in closets of rooms where infants or children or sick or elderly people will be confined for an extended period or generally in closets of rooms for which any person will be present for extended periods. (Refs. 11 at 161; and 79). EPA's risk assessments examined each of these pest strips.

a. *Exposure data and assumptions.* In assessing exposure from pest strips, EPA has relied on a study (Collins and DeVries) measuring air concentrations in 15 houses treated with multiple large DDVP pest strips hung directly in the living areas of the houses. (Id.). In its prior assessment, EPA averaged air concentrations measured in the study across houses. To insure its assessment is conservative, EPA, in its most recent assessment, estimated risk based on the air concentrations in the individual houses. (Id.). Additionally, for chronic risk assessment, rather than project exposure from the 91 days of the Collins and DeVries study over a period of 120 days (the period for which a pest strip is generally designed to be effective), EPA used the air concentration measured over the 91 days in the study. This approach increases exposure estimates as the data show that DDVP air concentrations are higher in the first weeks. Finally, rather than calculate MOEs for different time periods in the home for strips used in occupied portions of the home, EPA calculated MOEs assuming that people are exposed in their homes 24 hours per day and spend 24 hours per day in a room with a pest strip. For strips used in unoccupied portions of the home, EPA assessed the risk based on 4 hours of exposure per day.

b. *Durational scenarios.* Previously, EPA focused only on chronic exposure to DDVP from pest strips and compared that chronic exposure to the chronic RfD/PAD. In its revised risk assessment, EPA assessed risks for acute, short/intermediate-term, and chronic exposures. (Id.). The acute assessment examined risk based on the air concentrations in the 15 houses in the Collins and DeVries studies for the first 24 hours after the pest strip is installed. The short/intermediate-term assessment examined risk based on the air concentrations for the first two weeks after installation of a pest strip. Appropriate acute and short/intermediate-term endpoints were used.

c. *Chronic endpoint.* EPA's prior risk assessment used the benchmark dose level of 10 percent ($BMDL_{10}$) for RBC cholinesterase from a chronic inhalation study in rats to assess chronic risk from exposure to pest strips. EPA reexamined this choice in light of its policy on the use of cholinesterase inhibition in risk assessments. Consistent with that policy, EPA determined that it would be more appropriate to use the $BMDL_{20}$ for RBC cholinesterase from that study in assessing chronic risk (but not for acute risk). That decision was based on the consistent and large difference in doses between indications of RBC cholinesterase inhibition at both the $BMDL_{10}$ and the $BMDL_{20}$ and inhibition of brain cholinesterase and clinical signs in numerous studies when exposure was for 90 days or greater. (Id.).

d. *Revised risk assessments.* EPA's revised assessment shows that (1) for the large strips permitted only in unoccupied portions of a home, the target MOE is exceeded (i.e., there is not a risk of concern) for all homes for four hours of exposure for acute, short/intermediate-term, and chronic scenarios (Table 3, Table 5, and Table 7); (2) for the largest closet strip the target MOE is exceeded for all homes for 24 hours of exposure for the acute scenario (Table 4); (3) for the largest closet strip the target MOE is exceeded for most homes for 24 hours of exposure for the short/intermediate-term and chronic scenarios (Table 6 and Table 8); (4) for the smaller closet strip and the cupboard strip the target MOE is all but met or exceeded for all homes for acute, short/intermediate-term, and chronic scenarios (Table 9 and Table 10); and (5) dietary exposure is insignificant compared to pest strip exposure for all scenarios. (Id.). The MOEs for all of these scenarios for the large pest strip and the large closet strip are presented in the tables below.

The acute risk assessments for large pest strips (Table 3) and closet, wardrobe, and cupboard pest strips (Table 4) use a hazard value of 0.800 mg/kg which is the $BMDL_{10}$ for RBC cholinesterase from a rat study. Exposure is based on Day 1 air concentrations in the Collins and DeVries study. Four hours of exposure is assumed for the large strip and 24 hours of exposure is assumed for the closet, wardrobe, and cupboard strips. The MOE of concern is 30, as opposed to 100, because when exposure is expressed in units of air concentration such as part per million ("ppm") or milligrams/meter^3 ("mg/m^3") (as it is in the Collins and Devries data), then the pharmacokinetic component of the interspecies factor is decreased from 10X to 3X to account for the different breathing rates between species. (Id.).

TABLE 3.—ACUTE RISK FROM EXPOSURE TO LARGE (65 G) STRIPS FOR 4 HOURS

Collins and DeVries Home ID	Day 1 Concentration (mg/m^3)	MOE
6N	0.11	45
7W	0.11	45
2C	0.08	61
14W	0.08	61
10C	0.07	70
13W	0.07	70
5N	0.05	98
11C	0.05	98
12N	0.05	98
3C	0.04	123
15N	0.04	123
1W	0.02	245
4N	0.02	245
8W	0.02	245
9C	0.01	490

TABLE 4.— ACUTE RISK FROM EXPOSURE TO LARGE CLOSET (16 G) PEST STRIPS FOR 24 HOURS

Collins and DeVries Home ID	Day 1 Concentration (mg/m^3)	MOE
6N	0.028	30
7W	0.028	30
2C	0.020	41
14W	0.020	41
10C	0.018	47
13W	0.018	47
5N	0.013	66
11C	0.013	66
12N	0.013	66
3C	0.010	82
15N	0.010	82
1W	0.005	165

TABLE 4.— ACUTE RISK FROM EXPOSURE TO LARGE CLOSET (16 G) PEST STRIPS FOR 24 HOURS—Continued

Collins and DeVries Home ID	Day 1 Concentration (mg/m³)	MOE
4N	0.005	165
8W	0.005	165
9C	0.003	329

The smaller closet strip and cupboard strip will have higher MOEs. Background dietary DDVP exposure when expressed in mg/m³ is 0.00026 and this value is insignificant compared to the air concentration levels in higher concentration houses.

The short/intermediate-term risk assessments for large pest strips (Table 5) and for closet, wardrobe, and cupboard pest strips (Table 6) use a hazard value of 0.1 mg/kg/day which is the LOAEL for the human repeat dose oral study. Exposure is based on the average air concentration of the first 2 weeks of exposure in the Collins and DeVries study. Four hours of exposure is assumed for the large strip and 24 hours of exposure is assumed for the closet, wardrobe, and cupboard strips. The MOE of concern is 30 based on an intraspecies safety factor of 10X and an additional safety factor of 3X for reliance on a LOAEL.

TABLE 5.—SHORT/INTERMEDIATE-TERM RISK FROM EXPOSURE TO LARGE (65 G) STRIPS FOR 4 HOURS/DAY

Collins and DeVries Home ID	2-Week Average Concentration (mg/m³)	MOE
7W	0.074	29
2C	0.073	29
10C	0.072	29

TABLE 5.—SHORT/INTERMEDIATE-TERM RISK FROM EXPOSURE TO LARGE (65 G) STRIPS FOR 4 HOURS/DAY—Continued

Collins and DeVries Home ID	2-Week Average Concentration (mg/m³)	MOE
6N	0.066	32
13W	0.065	32
14W	0.059	36
12N	0.048	43
11C	0.038	55
3C	0.032	65
5N	0.030	69
15N	0.028	74
8W	0.019	109
1W	0.019	112
4N	0.017	126
9C	0.012	177

TABLE 6.—SHORT/INTERMEDIATE-TERM RISK FROM EXPOSURE TO LARGE CLOSET (16 G) PEST STRIPS FOR 24 HOURS/DAY

Collins and DeVries Home ID	2-Week Average Concentration (mg/m³)	MOE
7W	0.018	19
2C	0.018	19
10C	0.018	20
6N	0.016	21
13W	0.016	22
14W	0.015	24

TABLE 6.—SHORT/INTERMEDIATE-TERM RISK FROM EXPOSURE TO LARGE CLOSET (16 G) PEST STRIPS FOR 24 HOURS/DAY—Continued

Collins and DeVries Home ID	2-Week Average Concentration (mg/m³)	MOE
12N	0.012	29
11C	0.010	37
3C	0.008	43
5N	0.008	46
15N	0.007	50
8W	0.005	73
1W	0.005	75
4N	0.004	84
9C	0.003	118

The smaller closet strip and cupboard strip will have MOEs of 29 or higher. Background dietary DDVP exposure when expressed in mg/m³ is 0.00026 and this value is insignificant compared to the air concentration levels in higher concentration houses.

For the chronic risk assessments for large pest strips (Table 7) and closet, wardrobe, and cupboard pest strips (Table 8, Table 9, and Table 10), EPA calculated MOEs for a range of hazard values: the $BMDL_{10}$ and $BMDL_{20}$ for RBC cholinesterase from a 2–year chronic rat study, $BMDL_{10}$ for brain cholinesterase from a 90–day rat study, and the NOAEL for clinical signs from a 7–day rat study. Exposure is based on the average air concentration for the 91 days of the Collins and DeVries study. Four hours of exposure is assumed for the large strip and 24 hours of exposure is assumed for the closet, wardrobe, and cupboard strips. The MOE of concern is 30 for the same reason as with the acute exposure assessment.

TABLE 7.—CHRONIC RISK FROM EXPOSURE TO LARGE (65 G) STRIPS FOR 4 HOURS/DAY

Study		Rat 2-Year Inhalation			Rate 90 Day oral	Rate 7 Day oral
POD Type		$BMDL_{10}$		$BMDL_{20}$	$BMDL_{10}$	LOAEL
POD (mg/m³)		0.078	0.41	0.196	0.4	7.3
Home ID	CD avg ÷ 6	RBC	Brain	RBC	RBC	Clincal signs
10C	0.00607	13	67	32	66	1200
2C	0.00575	14	70	34	70	1300

TABLE 7.—CHRONIC RISK FROM EXPOSURE TO LARGE (65 G) STRIPS FOR 4 HOURS/DAY—Continued

Study		Rat 2-Year Inhalation			Rate 90 Day oral	Rate 7 Day oral
POD Type		$BMDL_{10}$		$BMDL_{20}$	$BMDL_{10}$	LOAEL
POD (mg/m^3)		0.078	0.41	0.196	0.4	7.3
Home ID	CD avg + 6	RBC	Brain	RBC	RBC	Clincal signs
13W	0.00483	16	84	41	83	1500
7W	0.00337	23	120	58	119	2200
12N	0.00330	24	123	59	121	2200
14W	0.00330	24	123	59	121	2200
6N	0.00212	37	191	93	189	3400
3C	0.00212	37	191	93	189	3400
11C	0.00207	38	196	95	194	3500
15N	0.00192	41	211	102	208	3800
8W	0.00161	48	251	122	248	4500
1W	0.00137	57	295	143	291	5300
9C	0.00127	61	318	154	314	5700
5N	0.00109	71	370	179	366	6700
4N	0.00099	79	409	198	404	7400

TABLE 8.—CHRONIC RISK FROM EXPOSURE TO LARGE (16 G) CLOSET STRIPS FOR 24 HOURS/DAY

Study		Rat 2-Year Inhalation			Rate 90 Day oral	Rate 7 Day oral
POD Type		$BMDL_{10}$		$BMDL_{20}$	$BMDL_{10}$*	LOAEL
POD (mg/m^3)		0.078	0.41	0.196	0.4	7.3
Home ID	CD avg + 4	RBC	Brain	RBC	RBC	Clinical signs
10C	0.00910	9	45	22	44	780
2C	0.00862	9	47	23	46	830
13W	0.00725	11	56	27	55	980
7W	0.00506	15	80	39	79	1400
12N	0.00495	16	82	40	81	1400
14W	0.00495	16	82	40	81	1400
6N	0.00318	25	127	62	126	2100
3C	0.00318	25	127	62	126	2200
11C	0.00310	25	131	63	129	2300
15N	0.00288	27	141	68	139	2500
8W	0.00242	32	168	81	166	3000
1W	0.00206	38	196	95	194	3400
9C	0.00191	41	212	103	209	3800
5N	0.00164	48	247	119	244	4100
4N	0.00148	53	273	132	270	4700

TABLE 9.—CHRONIC RISK FROM EXPOSURE TO SMALL CLOSET (10.5 G) STRIPS FOR 24 HOURS/DAY

Study		Rat 2-Year Inhalation		
POD Type		$BMDL_{10}$		$BMDL_{20}$
POD (mg/m^3)		0.078	0.41	0.196
Home ID	CD avg + 6	RBC	Brain	RBC
10C	0.00607	13	67	32
2C	0.00575	14	70	34
13W	0.00483	16	84	41
7W	0.00337	23	120	58
12N	0.00330	24	123	59
14W	0.00330	24	123	59
6N	0.00212	37	191	93
3C	0.00212	37	191	93
11C	0.00207	38	196	95
15N	0.00192	41	211	102
8W	0.00161	48	251	122
1W	0.00137	57	295	143
9C	0.00127	61	318	154
5N	0.00109	71	370	179
4N	0.00099	79	409	198

TABLE 10.—CHRONIC RISK FROM EXPOSURE TO CUPBOARD (5.25 G) STRIPS FOR 24 HOURS/DAY

Study		Rat 2-Year Inhalation		
POD Type		$BMDL_{10}$		$BMDL_{20}$
POD (mg/m^3)		0.078	0.41	0.196
Home ID	CD avg + 12	RBC	brain	RBC
10C	0.00303	26	134	65
2C	0.00287	27	141	68
13W	0.00242	32	168	81
7W	0.00169	46	240	116
12N	0.00165	47	245	119
14W	0.00165	47	245	119
6N	0.00106	74	382	185
3C	0.00106	74	382	185
11C	0.00103	75	392	190
15N	0.00096	81	422	204
8W	0.00081	97	503	243
1W	0.00069	113	589	285
9C	0.00064	123	636	308

TABLE 10.—CHRONIC RISK FROM EXPOSURE TO CUPBOARD (5.25 G) STRIPS FOR 24 HOURS/DAY—Continued

Study		Rat 2-Year Inhalation		
POD Type		$BMDL_{10}$		$BMDL_{20}$
POD (mg/m^3)		0.078	0.41	0.196
Home ID	CD avg + 12	RBC	brain	RBC
5N	0.00055	143	740	358
4N	0.00049	158	819	396

Background dietary DDVP exposure when expressed in mg/m^3 is 0.00026 and this value is insignificant compared to the air concentration levels in higher concentration houses.

Despite the fact that some homes from the Collins and DeVries study do not have acceptable MOEs for the short/intermediate-term and chronic scenarios for the large closet strip, EPA concludes that the pest strips do not pose a risk of concern for the following reasons. First, use of $BMDL_{20}$ for RBC cholinesterase is a conservative endpoint based on the DDVP database. As Table 7 indicates, target MOEs are well exceeded for all homes for chronic risk if the $BMDL_{10}$ for brain cholinesterase or the NOAEL for clinical signs are used as the Point of Departure. Second, for short/intermediate-term risk, EPA has used the results of the human oral study in a conservative fashion. The maximum inhibition of RBC cholinesterase from the 0.1 mg/kg/day dose used in that study was 16 percent (group mean) after 18 days of exposure. As discussed above, however, 20 percent inhibition is a more appropriate line of demarcation for DDVP given, among other things, the wide margin between RBC cholinesterase inhibition and clinical effects. If that approach is followed the one dose from that study, then 0.1 mg/kg/day would be a NOAEL not a LOAEL and the additional 3X safety factor would be unnecessary. Without that 3X safety factor, the MOE of concern would drop to 10. The conservativeness of the 3X safety factor is also supported by the HSRB's conclusion that a dose lower than 0.1 mg/kg/day would not be expected to show a significant inhibition response.

Finally, EPA made numerous conservative assumptions regarding interpretation of the Collins and DeVries data in using it to estimate exposure, including that: (1) the large strips used in the Collins and DeVries study emitted the same amount of DDVP as the largest strip currently registered even though the current large strip (65 – 80 grams) is smaller than the strip used in the Collins and DeVries study (100 grams); (2) placement of a strip in a closet is the same as hanging it in the adjacent living area; (3) for closet, wardrobe, and cupboard strips, exposure is 24 hours per day (despite label restrictions barring use in rooms where people would be exposed for extended periods); (4) during the 24 hours per day a person is in a home that person is continually in a room with a pest strip; and (5) strips are replaced every 90 days.

3. *Issues raised by NRDC concerning pest strips*—a. *NRDC's claims.* NRDC argues that EPA's exposure assessment for pest strips "is based on unsupported assumptions and inadequate data" and therefore EPA cannot conclude that aggregate exposure to DDVP is safe. NRDC's specific allegations are described below.

i. *Reliance on an inadequate exposure study.* NRDC notes that EPA relied on a single study (Collins and DeVries) monitoring 15 homes in one geographic area to estimate residential exposure to DDVP from pest strips. NRDC claims this study is inadequate because (1) the number of homes monitored is too small to be representative of the housing stock in the United States; (2) the study was conducted in only one geographic area and at one time of year and thus would not be representative of weather conditions (including humidity and temperature) in other regions of the United States; (3) sampling in the homes was done in only one location and thus the study "provides no information about the movement of residues from room-to-room and [] exposure in other rooms in the homes;" (4) homes were only treated with three or four pest strips but homeowners with severe pest problems may "place pest strips in every room or most rooms in the house;" and (5) the study contained insufficient information to estimate exposure levels for pest strips of different sizes. (Ref. 1 at 19, 58-59).

ii. *Unsupported assumption that users will not replace pest strips more frequently than every 120 days.* NRDC claims that EPA's assumption that homeowners will not replace pest strips until the strip has been in use for at least 120 days is unreasonable because the label does not prohibit more frequent replacement and EPA has no empirical data to support this assumption. (Id. at 59). NRDC argues that "[i]n the absence of reliable empirical data demonstrating that consumers do not ... replace the strips more often than is assumed by EPA, at a minimum, the labels of these products should be amended to place restrictions on use consistent with the assumptions made in the risk assessment." (Ref. 13 at 10).

iii. *Only considered average exposure over 120 days.* NRDC argues that EPA erred by averaging exposure levels over a 120–day period. According to NRDC, EPA should have considered "the higher, more dangerous exposures that occur when a strip is first hung ...." (Ref. 1 at 59). Instead, NRDC asserts, EPA "should have presented the range of risks displayed over time." (Id.).

iv. *Failure to consider exposure from use in unoccupied spaces.* NRDC claims that EPA has not taken into account that DDVP residues could migrate from use of the full-size pest strips in attics, crawl spaces, and garages to the main living areas of a home. (Ref. 13 at 10). NRDC notes that EPA has found that use of chlorpyrifos in crawl spaces leads to residues in living areas. (Id.). NRDC further contends that attics can be part of the air exchange for the living areas in a house.

v. *Estimates of exposure durations in homes are too low.* While NRDC concedes that an estimate of 16 hours/day in a home would be a high end estimate for most people, NRDC argues that this estimate ignores "several significant population groups" such as "[p]eople who work or stay at home, retired and elderly people, and pre-school children." (Id.). Further, NRDC asserts that EPA's low end estimate of 2 hours/day in the home is "absurd on its face." (Id.).

vi. *No consideration of incidental oral and dermal exposure.* NRDC claims that

EPA had insufficient data to conclude that incidental oral and dermal exposure resulting from DDVP residues that settle on home surfaces would be minimal. (Id. at 19.). According to NRDC, the only information EPA relied upon was data on residues that settle on foodstuffs and such data would not be representative of other home surfaces.

vii. *Failure to collect data on consumer use practices with pest strips.* Echoing comments from the SAP that "better knowledge of real world use practices would serve to improve residential exposure analyses," NRDC argues that the failure of EPA to collect such data "undermines the risk analysis for pest strips." (Ref. 1 at 62).

viii. *Failure to consider aggregation of pest strip exposure with other residential exposures.* NRDC claims that EPA does not support its statement that pest strip exposures would not co-occur with high dietary exposures. NRDC also argues that EPA should consider co-occurrence of exposure between pest strips and other DDVP residential products. (Ref. 13 at 12-13).

b. *Amvac's comments.* Amvac contends that the Collins and DeVries study is adequate for assessing exposure from pest strips citing several other studies which it states contain similar results. (Ref. 14 at 45). Further, Amvac argues that "the estimated time-weighted average concentration used by EPA (0.015mg/m^3) is higher than found in many other studies." (Id.). Amvac also defends EPA's use of a time-weighted average in estimating risk noting that "EPA is assessing chronic exposure and thus it is appropriate to average over the entire period to compare to a chronic endpoint." (Id.). Finally, Amvac argues that, if EPA assessed acute risk from pest strips, it would be appropriate for EPA to use the highest concentration from the Collins and DeVries study (0.11 mg/m^3) but that this exposure level does not show an acute risk concern. (Id.).

c. *EPA's response—adequacy of the Collins and DeVries Study.* EPA believes this study is sufficiently representative to estimate exposure and EPA disagrees with each of NRDC's contentions. First, EPA does not believe the study is inadequate due to being performed in a single location on 15 houses during a single season of the year. As noted by Amvac, there are a number of studies other than Collins and Devries that test DDVP pest strips in houses. Specifically, data on DDVP air concentrations from the use of pest strips are available for over 100 homes in the United States, United Kingdom, and France. (Ref. 80). There was no major difference in the DDVP air concentration in the 100 houses and the DDVP air concentration in the study of the 15 houses that were used for exposure estimates.

Second, EPA does not view the study as flawed because it only sampled DDVP concentrations in one location in each home. Importantly, the sample location in each instance was in a room with a pest strip, pest strips were used in other rooms of the house, and EPA assumed, for its calculation of the MOE, that the air concentration for all areas of a house is the same as at the sampled location. Thus, EPA has assessed MOEs in an appropriately conservative fashion given the sampling location in the Collins and DeVries study.

Third, NRDC's suggestion that some homeowners may put a pest strip in every room fails to take into account that (1) the label now bars use of full-size pest strips except in infrequently-occupied spaces (attics, crawl spaces, sheds, and garages); (2) in-home pest strips must contain significantly less DDVP than full-size strips and are limited to use in closets, wardrobes, and cupboards; and (3) EPA's risk assessment assumes a person spends all of their time in a room with a closet or cupboard that contains a pest strip. Relevantly, the largest closet strip is only labeled as effective in a 200 cubic foot area. Areas beyond that efficacious zone of treatment are likely to contain significantly lower air concentrations.

Fourth, the Collins and DeVries study does provide sufficient information to estimate exposure from different size strips. The Collins and Devries study used a pest strip that was larger than the largest size available today and EPA made the conservative assumption that the currently-registered large strip would have similar exposure to the older, larger version and extrapolated exposure levels for smaller strips proportionately based on that conservative assumption.

Finally, to insure that EPA has the most accurate information possible on exposure for pest strips, EPA plans to require as part of the data call-in to be issued in connection with reregistration that an additional study be conducted that measures DDVP air concentrations in houses from use of pest strips.

i. *Replacement of strips.* EPA's risk assessment has a built-in margin of error in the event strips are replaced more frequently than every 120 days because it is based on an average of the first 91 days of exposure which was the period of time air concentrations were measured in the Collins and DeVries study.

ii. *Use of time-weighted average exposure.* EPA believes that use of a time-weighted average of the DDVP concentration levels is appropriate for chronic risk and does not understand NRDC to be contesting this approach to assessing chronic risk. As to acute exposures that occur during the first day after a strip is hung, EPA has now expanded its risk assessment to address both this scenario and a short/intermediate-term exposure scenario (exposure for the two weeks after a strip is installed).

iii. *Exposure from use in unoccupied spaces.* EPA believes it unlikely that DDVP residues will migrate from attics, crawl spaces, garages, and sheds to living areas within a house because it would be unusual for these spaces to be connected to the air exchange for a house. On the other hand, basements may be included in a home's air exchange system and, for that reason, the large pest strips may not be used in a basement. This is likely part of the explanation for the result in the cited chlorpyrifos study. In that study, the chlorpyrifos was injected into the foundation and migrated to the basement of the house. From there, it is likely that chlorpyrifos moved to other rooms in the house through air exchange. Further, the chlorpyrifos study cited by NRDC has little relevance to pest strips given the vastly different amounts of active ingredient involved. (Ref. 81). In the chlorpyrifos study, approximately 100 gallons of a solution containing 1 percent of pesticide product (Dursban TC) was injected into basement walls. According to the label, Dursban TC contains 4 pounds per gallon of chlorpyrifos. Thus, that study used approximately 4 pounds of chlorpyrifos. A large pest strip contains, at most, 80 grams of pesticide product, of which 18.6 percent is DDVP. Accordingly, the pest strip exposure in unoccupied areas would contain roughly 15 grams of DDVP compared to approximately 1,800 grams of chlorpyrifos in the study cited.

iv. *Exposure durations in homes.* First, EPA believes it is unlikely that a person would spend four hours per day, day in and day out for an extended period in an attic, crawl space, garage, or shed. In any event, the label forbids use of the large pest strips in such locations should they be occupied that regularly. Second, as to the closet, wardrobe, and cupboard strips, EPA has assumed 24 hours per day exposure in calculating margins of exposure. Amvac has agreed to modify labels on these products so that they bar use of these strips in closets in rooms where infants or children, or sick or elderly people are confined for extended periods. Additionally, the label prohibits use of

the strip in any area of the house where people are present for extended periods.

v. *Incidental oral and dermal exposure.* NRDC is incorrect in its assertion that EPA's risk assessment does not take into account incidental oral and dermal exposure. Although dermal and incidental oral exposure from contact with DDVP adsorbed on solid surfaces was not assessed directly, the inhalation study used for assessing inhalation risk includes dermal and oral exposure components because the study involved continuous whole-body exposure resulting in adsorption of DDVP vapors to the animal's fur and food. In other words, the inhalation study is actually a total exposure study accounting for exposure by all routes when DDVP is delivered as a vapor. Further, the pest strip use is unlikely to leave significant DDVP residues on residential surfaces leading to dermal or incidental oral exposures. DDVP is highly volatile and degrades rapidly. Thus, even if a person repeatedly uses pest strips in the home, significant long-term dermal exposure is unlikely. The Collins and DeVries study showed very low concentrations of DDVP in the air and almost all food sampled in the home had no detectable residues. EPA reasonably concluded that any dermal exposures from deposit of air residues on surfaces would be negligible compared to residues inhaled directly.

vi. *Data on real world use practices.* Data on "real world" use practices of pest strips might make it possible for EPA to determine the extent to which EPA is likely overestimating exposure. EPA believes its conservative projection of exposure, given the clarity and reasonableness of the label directions, as amended, preclude the need to require additional data on use practices.

vii. *Aggregating pest strip exposure with other residential exposures.* In assessing aggregate risks, EPA believes it is unrealistic to add high-end exposures from intermittent and unconnected pesticide exposures which are likely to affect relatively small population groups. Thus, in aggregating dietary exposures to pest strip exposures, EPA has compared chronic (rather than acute) dietary exposure levels of DDVP as a background exposure to the various pest strip durational scenarios (acute, short/intermediate-term, chronic). It should also be noted that the dietary exposure estimates for DDVP are driven by high-end model estimates of residues in drinking water which is an additional conservatism.

For similar reasons, EPA does not believe it is realistic to add high-end acute or short-term exposures for the residential use of trichlorfon on turf and DDVP as a spot insect treatment by aerosol spray. Although dietary exposure to DDVP, and possibly exposure from a DDVP pest strip, may be appropriately aggregated as a background exposure to the turf or spot treatment uses, assuming that the windows for high-end acute exposures from the turf use and the spot treatment overlap is overly conservative. In any event, however, even if exposures from turf and spot treatment uses are aggregated with each other and with background exposures from food and water and pest strips, the aggregate exposure still does not show a risk of concern. Aggregating the MOEs of 100 for both the turf and spot treatment uses, (Ref. 11 at 160, 165), with MOEs for background exposure for dietary (900) and pest strips (93) gives an aggregate short-term MOE of 31 for the child who simultaneously experiences outdoor exposures from the trichlorfon turf use with indoor exposures from DDVP spot treatments and pest strips. The target MOE here is 30. This aggregation relies upon average dietary exposure for the most highly exposed subgroup which may have turf post-application exposures (children aged 1-2) compared to the short-term oral Point of Departure and average pest strip exposure over 91 days compared to the short-term inhalation Point of Departure. (Refs. 11 at 138, 162; 56 at 18).

D. Risk Characterization

1. *99.9th percentile*—a. *NRDC's claims.* NRDC asserts that EPA has failed to provide a rationale for using the 99.9th percentile in the DDVP risk assessment for acute population effects. (Ref. 1 at 51). NRDC further contends that some 300,000—0.1 percent of the U.S. population—will not be considered because they "fall below the level of sensitivity of the calculation method." (Id.). NRDC therefore argues that EPA cannot make its FFDCA safety finding.

b. *EPA's response.* Contrary to NRDC's assertion, EPA has not ignored 300,000 of the U.S. population in estimating acute DDVP risks through reliance on the 99.9th exposure percentile in the DDVP risk assessment. As EPA has repeatedly explained in the past – in science policy documents and in responses to NRDC's objections to tolerances – "the use of a particular percentile of exposure is a tool to estimate exposures for the entire population and population subgroups and not a means to eliminate protection for a certain segment of a subgroup." (69 FR 30070 and 70 FR 46733).

In examining pesticide exposure, EPA does not have the capability of measuring actual exposure to individuals across the population. Rather, EPA uses data on factors bearing on exposure such as residue levels in food and drinking water, food consumption patterns, and air concentration levels and transferable surface residues to estimate exposure to hypothetical individuals across major identifiable subgroups in the population. These data on exposure factors can range from highly conservative values (e.g., assumption that 100 percent of a crop is treated with a pesticide) to highly realistic values (e.g., market basket monitoring data on pesticide residue levels). In interpreting exposure estimates based on such factors, EPA makes judgments regarding what exposure level (expressed as a percentile) is protective of the relevant population subgroups taking into account the relative conservativeness of the factors which are the basis of the assessment.

Generally, EPA uses the 95th percentile exposure as a starting point for evaluating the safety of pesticide in circumstances where EPA has employed very conservative assumptions on residue values and risk assessment techniques. In EPA's judgment, the 95th percentile exposure, when calculated using such conservative assumptions, will not underestimate exposure for any major identifiable subgroups. However, when EPA uses more realistic residue values and refined risk assessment techniques, it starts its evaluation of safety at the 99.9th percentile of exposure to be sure that it is protecting the entire population and all major, identifiable subgroups. EPA uses the 99.9th percentile as the starting point for refined assessments rather than the 100th percentile because generally its exposure assumptions, even when refined, contain residual conservatisms. Thus, whether EPA is relying on the 95th percentile, the 99.9th percentile, or some other value, the population exposure percentile is a means to an end and not a designation of those people worthy of protection. As EPA noted in a science policy document on this issue: "just as when OPP uses the 95th percentile with non-probabilistic exposure assessments OPP is not suggesting that OPP is leaving 5 percent of the population unprotected, OPP is not by choosing the 99.9th percentile for probabilistic exposure assessments concluding that only 99.9 percent of the population deserves protection." (Ref. 8 at 31). Perhaps the best evidence that use of population percentiles is not identifying those worthy of protection but simply a tool in estimating exposure

is that refined assessments using the 99.9th percentile invariably estimate exposure to be lower for a pesticide than an unrefined assessment for that same pesticide using the 95th percentile. (69 FR 30071). Yet, under NRDC's logic the use of the 95th percentile, by itself, would signal that fewer people are being protected than if the 99.9th percentile was used, and thus an exposure estimate based on the 95th percentile should necessarily be lower than one based on the 99.9th percentile.

2. *Inappropriate use of 100% of the RfD/PAD as a "Bright Line" Rule*—a. *NRDC's claims.* NRDC contends that EPA is unlawfully disregarding significant risks by relying on a "bright line rule" that risks below 100 percent of the acute population adjusted does (aPAD) are not of concern and risks above 100 percent are of concern. (Ref. 1 at 51-52). Specifically, NRDC argues that (i) EPA treats the 100 percent threshold as a rule that has not been subject to notice and comment rulemakings; (ii) use of a 100 percent threshold is arbitrary and capricious; (iii) use of 100 percent threshold improperly excludes acute risks unless they exceed 100 percent of the aPAD; and (iv) EPA cannot reasonably explain how children aged 1 to 6, the sub-population with the highest percentage exposure, will not be harmed.

b. *EPA's response.* NRDC appears to be suggesting that EPA's approach of comparing estimated DDVP exposure to an EPA-derived safe dose for DDVP is unlawful because (1) EPA cannot adopt an analytical approach of comparing exposure to the safe dose without a regulation that permits such an approach; and (2) EPA has not adequately justified that its chosen safe dose is actually safe. Such claims are baseless.

In assessing risks posed by a pesticide, EPA first examines toxicological studies with the pesticide and calculates a safe dose in humans (RfD/PAD) based on the results of those studies and incorporating appropriate safety factors. This analysis, based on well-established risk assessment principles used both across the federal government and internationally, is designed to establish a dose without appreciable risk to humans. EPA then compares estimated aggregate exposure to humans to the safe dose to make a determination on the safety of the pesticide. EPA believes this type of case-by-case assessment of the risk from exposure to a pesticide is precisely what section 408 demands. Other than the statutory mandates in FFDCA section 408, EPA does not follow "bright line" rules in making safety determinations but rather is guided by what the data show on a particular pesticide. Of course, at the end of its pesticide-specific analysis EPA must make a safety determination. EPA does not believe it needs a rule saying so to conclude that, where it has confidence that exposure is below the safe dose, a tolerance is safe. Further, there is no merit to NRDC's bald claim that EPA's safe dose determination for DDVP is arbitrary and capricious because EPA has failed to explain the basis for its safe dose determination. EPA's safe dose determination is supported and explained by extensive documentation including the IRED and numerous EPA-produced data evaluation and other analytical memoranda addressing DDVP as well as long-established and commonly-employed risk assessment principles. (See, e.g., Ref. 11).

3. *FQPA Safety Factor*—a. *NRDC's claims.* NRDC asserts that the Agency has no basis upon which to apply anything lower than a 10X FQPA safety factor in the DDVP risk assessment. According to NRDC, "[t]he admitted potential for pre- and post-natal toxicity from exposure to DDVP, combined with incomplete data regarding toxicity and exposure to infants and children, compel EPA to retain the default FQPA tenfold safety factor for DDVP." (Ref. 1 at 15). As to pre- and post-natal toxicity, NRDC called particular attention to a study in the open literature (Mehl *et al* (1993), which reported brain effects in guinea pig pups. (Id. at 15-16). As to missing data, NRDC placed particular evidence on the absence of a DNT study. NRDC also criticizes EPA's choice of an additional safety factor of 3X arguing that "[t]he Agency did not explain why it chose 3X as opposed to 4X or any other factor." (Id. at 14).

b. *EPA's response.* As discussed above, under the FQPA, EPA presumptively applies an additional tenfold margin of safety (i.e., safety factor) when assessing the risk of pesticide exposure to infants and children to take into account potential pre-and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. FQPA, however, authorizes the Agency to use a different margin of safety for pesticide residues if, on the basis of reliable data, such a margin will be safe for infants and children. When EPA issued its preliminary risk assessment for DDVP, it employed an FQPA safety factor of 3X because the Agency lacked an acceptable DNT study as well as an FQPA safety factor of 3X for various residential risk assessments.

Since the preliminary risk assessment was issued for public comment in 2000, the Agency received two Developmental Neurotoxicity Test (DNT) studies. The NOAEL/LOAEL for the two combined DNT studies is 1.0/7.5 mg/kg/day based on increased auditory startle amplitude in male offspring in both studies. The NOAEL is much higher than the points of departure used for regulation of dichlorvos: 0.05 mg/kg/day from a dog study used to assess long-term effects, and 0.1 mg/kg/day from a human study used for short- and intermediate-term scenarios. Now that the DNT studies have been submitted, EPA believes it has reliable data showing it is safe for infants and children to remove the additional safety factor for all risk assessments other than the residential assessments. This conclusion is based on:

(1) The toxicity database is complete.

(2) There are no residual concerns for pre- and/or postnatal toxicity resulting from exposure to dichlorvos. There was no evidence for increased susceptibility of the rat and rabbit offspring to prenatal or postnatal exposure to dichlorvos. In both rat and rabbit developmental studies, no developmental effects were observed. In the reproduction study, the parental/systemic NOAEL/LOAEL was 2.3/8.3 mg/kg/day which was identical to the reproductive/offspring NOAEL/LOAEL. The DNT showed evidence of susceptibility in one parameter, auditory startle amplitude. However, there are no residual concerns for susceptibility from this because the affects in pups were seen at a dose well above the points of departure upon which EPA is regulating and a clear NOAEL for the effect (again, well above the points of departure) was identified. In addition, using a Benchmark Dose Methods (BMD) analysis of studies with pup and adult cholinesterase depression results did not demonstrate any substantial numerical differences in BMDL values for either RBC or brain cholinesterase between young and adult animals.

(3) Although the exposure estimate for DDVP in food is highly refined as to some commodities, EPA is confident that its DDVP exposure estimate from food, if anything overstates DDVP exposure, given the many conservatisms retained in the exposure assessment and DDVP's documented volatility and rapid degradation. Additionally, the very conservative estimate on DDVP exposure through drinking water based on the use of trichlorfon on turf and naled on brassica is likely to significantly overstate DDVP exposure. Finally, EPA believes its residential exposure estimates will also not underestimate exposure given the conservative assumptions used in the

assessment and in EPA's residential exposure models and the data on residential exposure.

With respect to the Mehl study, NRDC has mischaracterized the issue. Although the Mehl study raised an initial concern for potential developmental neurotoxicity, this concern was resolved by the subsequent DNT studies.

EPA has retained a FQPA safety factor of 3X for various residential risk assessments. This additional safety factor is due to these assessments' reliance on a LOAEL rather than a NOAEL. EPA chose a safety factor other than 10X based on its evaluation of the study in question. EPA determined that a 3X safety factor would be more than adequate to identify a NOAEL based upon the slight adverse effect (marginal RBC cholinesterase inhibition in a human study) observed at the LOAEL. The HSRB confirmed EPA's interpretation of this study in its review of the scientific merit of the study. Specifically, the HSRB concluded that "because the decreased activity in RBC cholinesterase activity observed in this study was at or near the limit of what could be distinguished from baseline values, it was unlikely that a lower dose would produce a measurable effect in RBC cholinesterase activity." (Ref. 31 at 41).

In choosing a safety factor in circumstances where the data does not warrant a full 10X, EPA generally does not attempt to mathematically derive a precise replacement safety factor because regulatory agencies' traditional use of 10X safety factors (upon which the FQPA safety factor was modeled) was based on rough estimates rather than detailed calculations. Instead, where a 10X factor would clearly overstate the uncertainty, EPA simply applies a factor valued at half of 10X. In determining half of a 10X factor, EPA assumes that the distribution of effects within the range of a safety factor is distributed lognormally (which is generally the case for biological effects), and reduction of a lognormal distribution by half is equal to half a log ($10^{.5}$) or approximately 3X. (Ref. 82). A lognormal distribution is a distribution which if plotted based on the logarithm of each of its values would yield a bell-shaped (normal) distribution but if plotted according to actual values would be skewed having a clumping of values along the vertical axis of the plot.

Without in any way implying that there is anything improper with agency decisionmakers making a FQPA safety factor determination, NRDC's comments about who made the decision on the FQPA safety factor for DDVP can be dismissed because NRDC is referring a prior decision on the FQPA safety factor pre-dating the submission of the DNT.

E. Conclusion

NRDC's petition to revoke all DDVP tolerances is denied. NRDC's arguments have not convinced EPA that the DDVP tolerances are unsafe; to the contrary, EPA finds that its risk assessments show that the DDVP tolerances pose a reasonable certainty of no harm. EPA specifically rejects NRDC's claims that (1) EPA has mischaracterized the hazard posed by DDVP; (2) dietary and residential exposure to DDVP pose a risk of concern; and (3) EPA failed to justify removal of the additional 10X safety factor for the protection of infants and children.

VIII. Regulatory Assessment Requirements

As indicated previously, this action announces the Agency's order denying a petition filed, in part, under section 408(d) of FFDCA. As such, this action is an adjudication and not a rule. The regulatory assessment requirements imposed on rulemaking do not, therefore, apply to this action.

IX. Submission to Congress and the Comptroller General

The Congressional Review Act, (5 U.S.C. 801 *et seq.*), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, does not apply because this action is not a rule for purposes of 5 U.S.C. 804(3).

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List of Subjects

Environmental protection, pesticides and pest.

Dated: November 16, 2007

Debra Edwards,

Director, Office of Pesticide Programs.

[FR Doc. E7–23571 Filed 12–4–07; 8:45 a.m.]

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Federal Register

Wednesday,
December 5, 2007

Part V

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 422 and 423

Medicare Program; Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 422 and 423

[CMS–4124–FC]

RIN 0938–AO78

Medicare Program; Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals, and Intermediate Sanctions Processes

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule with comment period.

SUMMARY: This rule with comment period finalizes the Medicare program provisions relating to contract determinations involving Medicare Advantage (MA) organizations and Medicare Part D prescription drug plan sponsors, including eliminating the reconsideration process for review of contract determinations, revising the provisions related to appeals of contract determinations, and clarifying the process for MA organizations and Part D plan sponsors to complete corrective action plans. In this final rule with comment period, we also clarify the intermediate sanction and civil money penalty (CMP) provisions that apply to MA organizations and Medicare Part D prescription drug plan sponsors, modify elements of their compliance plans, retain voluntary self-reporting for Part D sponsors and implement a voluntary self-reporting recommendation for MA organizations, and revise provisions to ensure HHS has access to the books and records of MA organizations and Part D plan sponsors' first tier, downstream, and related entities. Although we have decided not to finalize the mandatory self-reporting provisions that we proposed, CMS remains committed to adopting a mandatory self-reporting requirement. To that end, we are requesting comments that will assist CMS in crafting a future proposed regulation for a mandatory self-reporting requirement.

DATES: *Effective date:* These regulations are effective on January 4, 2008, except for the amendments to §§ 422.503, 422.504, 423.504, and 423.505, which are effective January 1, 2009.

Comment Period: We will consider comments on the mandatory self-reporting provisions discussed in section II of this final rule with comment period at the appropriate address, as provided below, no later than February 4, 2008.

ADDRESSES: In commenting, please refer to file code CMS–4124–FC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/eRulemaking.* Click on the link "Submit electronic comments on CMS regulations with an open comment period." (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–4124–FC, P.O. Box 8020, Baltimore, MD 21244–8020.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–4124–FC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or

7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Christine Reinhard, (410) 786–2987.

Kevin Stansbury, (410) 786–2570.

Stephanie Kaisler, (410) 786–0957, for issues regarding voluntary self-reporting, access to records, and compliance.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on mandatory self-reporting to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–4124–FC and "self-reporting."

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.cms.hhs.gov/eRulemaking.* Click on the link "Electronic Comments on CMS Regulations" on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

Abbreviations

Because of the many terms to which we refer by abbreviation in this final rule with comment period, we are listing these abbreviations and their corresponding terms in alphabetical order below:

ALJ Administrative Law Judge
BBA Balanced Budget Act of 1997
CAP Corrective Action Plan
CMP Civil Money Penalty
CMS Centers for Medicare & Medicaid Services
DAB Departmental Appeals Board
FWA Fraud, Waste, and Abuse
HHS U.S. Department of Health and Human Services
MA Medicare Advantage
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003
M+C Medicare + Choice
OIG Office of the Inspector General

PBM Pharmaceutical Benefit Manager
PDE Prescription Drug Event

I. Background

On May 25, 2007, we published a proposed rule in the **Federal Register** (72 FR 29368, hereafter referred to as the proposed rule), setting forth the proposed provisions relating to contract determinations involving Medicare Advantage (MA) organizations and Medicare Part D prescription drug plan sponsors, intermediate sanction and civil money penalty (CMP) provisions, compliance plans, mandatory self-reporting, and provisions to ensure the Department of Health and Human Services (HHS) has access to the books and records of MA organizations and Part D plan sponsors' first tier, downstream, and related entities. In this final rule with comment period we are finalizing the majority of the provisions of the proposed rule, with some clarifications in response to public comments. At this time, we are not finalizing the proposed provision for mandatory self-reporting of potential fraud and abuse, but we intend to issue future rulemaking on this topic, as discussed below in section II.

A. Overview of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)

The President signed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) into law on December 8, 2003. The MMA established the Medicare prescription drug benefit program and renamed the Medicare+Choice (M+C) program the Medicare Advantage (MA) program. In accordance with the MMA, we revised the existing Medicare regulations applicable to the MA program at 42 CFR part 422 and published regulations governing the prescription drug benefit program at 42 CFR part 423.

As we have gained more experience with MA organizations and Part D prescription drug plan sponsors, we proposed clarifications to the Medicare program provisions relating to contract determinations involving MA organizations and Medicare Part D prescription drug plan sponsors, including eliminating the reconsideration process for review of contract determinations; revising the provisions related to appeals of contract determinations and clarifying the process for MA organizations and Part D plan sponsors to complete corrective action plans. We proposed clarifications to the intermediate sanction and civil money penalty (CMP) provisions that apply to MA organizations and Medicare Part D prescription drug plan sponsors. We also proposed changes in both programs to clarify elements of the compliance plan requirements, such as training and education, and changes to clarify our access to the books and records of a MA organization or Part D sponsor's first tier, downstream, and related entities. Finally, we proposed a self-reporting requirement as part of both MA organization and Part D sponsor's compliance plans. We have decided at this time not to finalize the provision requiring mandatory self-reporting of potential fraud and misconduct. Until such time as such a provision is finalized, we have chosen to retain voluntary self-reporting for Part D sponsors and implement a recommendation for voluntary self-reporting for MA Organizations.

B. Relevant Legislative History and Overview

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) established the M+C program. Under section 1851(a)(1) of the Social Security Act (the Act), every individual with Medicare Parts A and B, except for individuals with end-stage renal disease (ESRD), could elect to receive benefits either through the original Medicare program or an M+C plan, if one was offered where the beneficiary lived. The primary goal of the M+C program was to provide Medicare beneficiaries with a wider range of health plan choices.

The Medicare, Medicaid, and State Children's Health Insurance Program (SCHIP) Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), amended the M+C provisions of the BBA. Further amendments were made to the M+C program by the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554), enacted December 21, 2000.

The President signed the MMA into law on December 8, 2003. Title I of the MMA added new sections 1860D–1 through 1860D–42 to the Act creating the Medicare Prescription Drug Benefit program, a landmark change to the Medicare program since its inception in 1965.

Sections 201 through 241 of Title II of the MMA made significant changes to the M+C program. As directed by Title II of the MMA, we renamed the M+C program the MA program. We also revised our regulations to include new payment and bidding provisions based largely on risk, to recognize the addition of regional Preferred Provider Organization (PPO) plans, to address the provision of prescription drug benefits under the Medicare Part D regulations, and to make other changes.

The MMA, at section 1860D–12(b)(3) of the Act, directed that specific aspects of the MA contracting requirements apply to the prescription drug plan benefit program. Consequently, the processes for contract determinations and the administrative appeal rights in the two programs are virtually identical.

We published the regulations implementing the MA and prescription drug benefit regulations separately, though their development and publication were closely coordinated. On August 3, 2004, we published proposed rules for the MA program (69 FR 46866) and prescription drug benefit program (69 FR 46632). The final regulations implementing both the MA and prescription drug programs were published on January 28, 2005 (70 FR 4588 and 70 FR 4194, respectively). We revised some of our proposed provisions in the final rules in response to public comments. For further discussion of the revisions we made to our proposed rules, see the final rules cited above. We have not issued previous guidance, other than regulatory requirements regarding contract determinations, corrective action plans, contract determination appeals, intermediate sanctions, or CMPs. However, we have published guidance on how to develop an effective fraud, waste and abuse (FWA) prevention program. This guidance is found in Chapter 9 of the Prescription Drug Benefit Manual entitled "Part D Program to Control Fraud, Waste and Abuse." This rule makes further revisions to the MA and prescription drug regulations.

II. Summary of the Provisions of the Proposed Rule and Analysis of and Response to Public Comments

In response to the publication of the May 25, 2007 proposed rule, we received 58 timely items of correspondence from the public. We received numerous comments from various trade associations and health insurance providers. Comments also originated from other providers, suppliers, and practitioners, health care consulting firms, and private citizens.

Brief summaries of each proposed provision, a summary of the public comments we received (with the exception of specific comments on the paperwork burden or the impact analysis), and our responses to the comments are set forth below. Comments related to the paperwork burden and the impact analysis are addressed in the Collection of Information and Impact Analysis Sections in this preamble.

A. General Comments on the Proposed Rule

Comment: We received a question related to the applicability of the Part 423 provisions to Medicare cost contractors who offer Part D plans.

Response: Cost plans, per 42 CFR 417.440(b)(2)(ii), which offer a Part D prescription drug program as an optional supplemental benefit, must offer the benefits "in accordance with applicable requirements under Part 423." The current proposed revisions do not change the existing regulations. Therefore, the Part 423 regulations would continue to apply to cost plans just as they have prior to the publication of this rule.

B. Proposed Changes to the Medicare Advantage Program and the Prescription Drug Benefit Program

Our experience involving contract determinations, appeals, intermediate sanctions, and CMPs since the enactment of the BBA of 1997 led us to propose changes to our regulations. In the proposed rule, we proposed to simplify the procedures for contract determinations; to clarify the procedures regarding submission and review of corrective action plans; to clarify the procedures for imposition of intermediate sanctions and CMPs; and to clarify the procedures to appeal CMPs imposed under the MA and Part D programs.

In addition, we proposed revisions to the appeal procedures for all types of contract determinations, which would make these procedures identical for decisions not to contract, nonrenewals, and terminations. We proposed to provide for enhanced beneficiary protections when we decide to terminate a plan on an expedited basis.

In the proposed rule, we also proposed changes and clarifications to Subpart K, contract requirements under the MA and Part D programs. We proposed changes to clarify HHS' access to the books and records of a MA organization or Part D sponsor's first tier, downstream, and related entities. We also proposed changes to clarify that certain elements of the compliance plan apply to first tier, downstream, and related entities. We also proposed mandatory self-reporting in both the MA and Part D programs, but we are not finalizing the provision at this time.

Below, we set forth the final regulatory changes, and corresponding final implementation dates:

Regulation change	Implementation date
Incorporation of Fraud, Waste, and Abuse Prevention Measures into Compliance Plan	1/1/2009
Requirement to apply Compliance Plan's training and communication requirements to first tier, downstream, and related entities	1/1/2009
Voluntary procedures for MA organizations for self-reporting potential fraud and misconduct	1/1/2009
Requirement to obtain access to Part D sponsor's first tier, downstream, and related entity's books and records through contractual arrangements	1/1/2009
Elimination of CMS' requirement to inform organization of renewal	1/4/2008
Change date of CMS' notification of non-renewal from May 1 to August 1	1/4/2008
Provide for same administrative appeal rights (including Corrective Action Plans (CAPs)) for all contract determinations (non-renewal, expedited termination, termination)	1/4/2008
Change regarding CAP process may be provided prior to notification of termination, and the imposition of time limits on Corrective Action Plans	1/4/2008
Change immediate termination to expedited termination with CMS setting the effective date of termination	1/4/2008
Elimination of Reconsideration Step for contract determination appeals	1/4/2008
Implementation of Burden of Proof for contract determinations	1/4/2008
Ability for a hearing officer to issue summary judgment	1/4/2008
Request for Administrator review, submission of information, and timeframe associated with Administrator review	1/4/2008
Settlement of Civil Money Penalties	1/4/2008
Appeal procedures for Civil Money Penalties	1/4/2008

We did not receive any comments on the implementation dates we proposed and are generally finalizing the implementation dates as we proposed, with minor modification to reflect that certain provisions will be effective on January 4, 2008. However, since we are not implementing the proposed mandatory self-reporting requirement at this time, we have only included a reference to an implementation date for the voluntary self-reporting recommendation for MA organizations in the above chart. We are retaining the existing voluntary self-reporting recommendation for Part D sponsors so that recommendation is currently in effect and will remain in effect in the future.

C. Distribution Table

The following crosswalk table references the changes we are making to the prescription drug and the MA programs. We proposed making the same changes to 42 CFR parts 422 and 423 with minimal differences. The crosswalk lists the section headings, for parts 422 and 423, and indicates if the section is being deleted.

TABLE 1.—CROSSWALK OF PART 422 AND PART 423 CFR SECTIONS

Section heading	Section references in part 422	Section references in part 423
Definitions	422.2	423.4
Compliance Plan	422.503(b)(4)(vi)	423.504(b)(4)(vi)
Access to Facilities and Records	422.504(e) and 422.503(d)(2)(iii).	423.505(e)
Contract Provisions	422.504(i)	423.505(i)
Effective Date and Term of Contract	422.505	423.506
Non-renewal of contract	422.506	423.507

TABLE 1.—CROSSWALK OF PART 422 AND PART 423 CFR SECTIONS—Continued

Section heading	Section references in part 422	Section references in part 423
Termination of contract by CMS	422.510	423.509
Notice of contract determination	422.644	423.642
Effect of contract determination	422.646	423.643
Reconsideration: applicability	422.648 (delete)	423.644 (delete)
Request for reconsideration	422.650 (delete)	423.645 (delete)
Opportunity to submit evidence	422.652 (delete)	423.646 (delete)
Reconsidered determination	422.654 (delete)	423.647 (delete)
Notice of reconsidered determination	422.656 (delete)	423.648 (delete)
Effect of reconsidered determination	422.658 (delete)	423.649 (delete)
Right to a hearing and burden of proof	422.660	423.650
Request for hearing	422.662	423.651
Postponement of effective date of a contract determination when a request for a hearing with respect to a contract determination is filed timely.	422.664	423.652
Time and Place of Hearing	422.670	423.655
Discovery	422.682	423.661
Prehearing and Summary Judgment	422.684	423.662
Review by the Administrator	422.692	423.666
Reopening of initial contract determination or intermediate sanction or decision of a hearing officer or the Administrator.	422.696	423.668
Effect of revised determination	422.698 (delete)	423.669 (delete)
Types of intermediate sanctions and civil money penalties	422.750	423.750
Basis for imposing intermediate sanctions and civil money penalties	422.752	423.752
Procedures for imposing intermediate sanctions and civil money penalties	422.756	423.756
Collection of civil money penalty imposed by CMS	422.758	423.758
Determinations regarding the amount of civil money penalties and assessment imposed by CMS.	422.760	423.760
Settlement of penalties	422.762	423.762
Other applicable provisions	422.764	423.764
Basis and scope	422.1000	423.1000
Definitions	422.1002	423.1002
Scope and applicability	422.1004	423.1004
Appeal rights	422.1006	423.1006
Appointment of representatives	422.1008	423.1008
Authority of representatives	422.1010	423.1010
Fees for services of representatives	422.1012	423.1012
Charge for transcripts	422.1014	423.1014
Filing of briefs with the Administrative Law Judge or Departmental Appeals Board, and opportunity for rebuttal.	422.1016	423.1016
Notice and effect of initial determinations	422.1018	423.1018
Request for hearing	422.1020	423.1020
Parties to the hearing	422.1022	423.1022
Designation of hearing official	422.1024	423.1024
Disqualification of Administrative Law Judge	422.1026	423.1026
Prehearing conference	422.1028	423.1028
Notice of prehearing conference	422.1030	423.1030
Conduct of prehearing conference	422.1032	423.1032
Record, order, and effect of prehearing conference	422.1034	423.1034
Time and place of hearing	422.1036	423.1036
Change in time and place of hearing	422.1038	423.1038
Joint hearing	422.1040	423.1040
Hearing on new issues	422.1042	423.1042
Subpoenas	422.1044	423.1044
Conduct of hearing	422.1046	423.1046
Evidence	422.1048	423.1048
Witnesses	422.1050	423.1050
Oral and written summation	422.1052	423.1052
Record of hearing	422.1054	423.1054
Waiver of right to appear and present evidence	422.1056	423.1056
Dismissal of request for hearing	422.1058	423.1058
Dismissal for abandonment	422.1060	423.1060
Dismissal for cause	422.1062	423.1062
Notice and effect of dismissal and right to request review	422.1064	423.1064
Vacating a dismissal of request for hearing	422.1066	423.1066
Administrative Law Judge's decision	422.1068	423.1068
Removal of hearing to Departmental Appeals Board	422.1070	423.1070
Remand by the Administrative Law Judge	422.1072	423.1072
Right to request Departmental Appeals Board review of Administrative Law Judge's decision or dismissal.	422.1074	423.1074
Request for Departmental Appeals Board review	422.1076	423.1076
Departmental Appeals Board action on request for review	422.1078	423.1078
Procedures before Departmental Appeals Board on review	422.1080	423.1080

TABLE 1.—CROSSWALK OF PART 422 AND PART 423 CFR SECTIONS—Continued

Section heading	Section references in part 422	Section references in part 423
Evidence admissible on review	422.1082	423.1082
Decision or remand by the Departmental Appeals Board	422.1084	423.1084
Effect of Departmental Appeals Board decision	422.1086	423.1086
Extension of time for seeking judicial review	422.1088	423.1088
Basis, timing, and authority for reopening an Administrative Law Judge or Board decision	422.1090	423.1090
Revision of reopened decision	422.1092	423.1092
Notice and effect of revised decision	422.1094	423.1094

We did not receive any comments on the crosswalk distribution table and have made no substantial changes to it. We are finalizing the table as proposed.

D. Proposed Changes to Part 422—Medicare Advantage Program and Part 423—Medicare Prescription Drug Benefit Program

Sections 422.2 and 423.4—Definitions

We proposed to correct a technical oversight in both regulations by including the definitions of "downstream entity," "first tier entity," and "related entity," in the overall definitions sections of both the MA and Part D regulations at § 422.2 and § 423.4 to ensure that these terms are used consistently throughout both programs. Since these three terms are only defined in Subpart K of parts 422 and 423, we proposed to add them to Subpart A, General Provisions at § 422.2 and § 423.4.

Please see page 29372 of the proposed rule for a flow chart that provides examples of, and describes the relationships between, Part D sponsors, and first tier, downstream, and related entities.

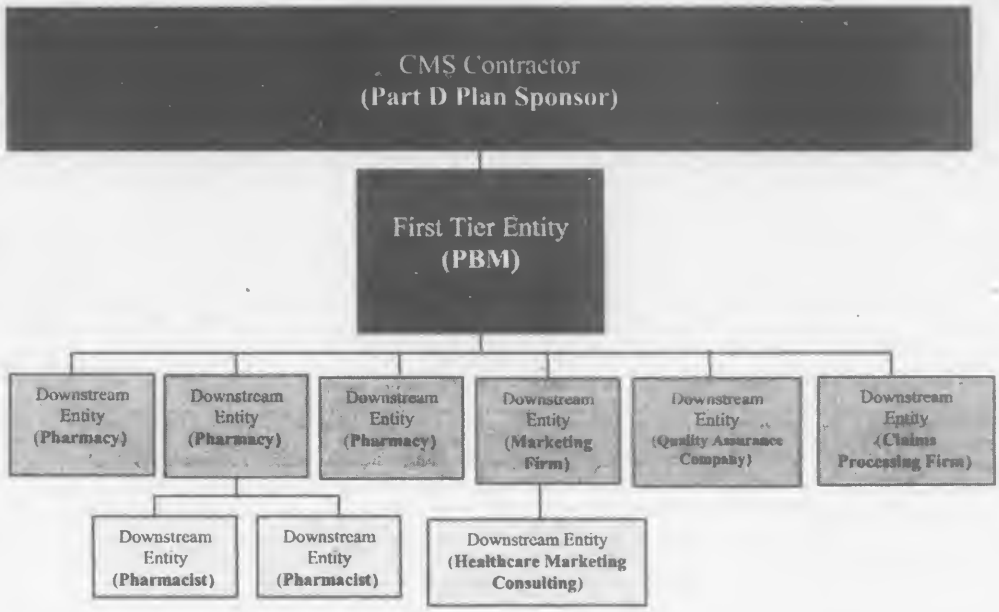
Comment: A few commenters requested more explicit definitions of first tier, downstream, and related entities. They asked us to provide clarification for the terms record retention, administrative services, written arrangements, acceptable to CMS, CMS instructions, and directors. We also received a request that we clarify the phrase "a written agreement, acceptable to CMS," found in the definition of "downstream entity," and a request that we clarify which entities are involved in such an arrangement.

Response: The terms "first tier entity," "downstream entity," and "related entity" are already defined in Subpart K of parts 422 and 423, and we are only including them in Subpart A, General Provisions at § 422.2 and § 423.4 for clarity, since these terms were originally defined in only Subpart K. Examples of downstream entities include, but are not limited to, pharmacy benefit managers, mail order pharmacies, retail pharmacies, firms providing agent/broker services, agents, brokers, marketing firms, and call center firms. We are neither providing definitions nor clarifications for the terms "record retention," "administrative services," "written arrangements," "acceptable to CMS," "CMS instructions," or "directors," since these terms are longstanding terms used by us and the industry. We are finalizing the definitions of "first tier entity" and "related entity" as proposed.

Based upon an unintentional oversight in the proposed regulation, we are revising the definition of "downstream entity" for improved clarity, as described below. The definition of a Part D "downstream entity" at § 423.4 states that a "[d]ownstream entity means any party that enters into a written arrangement acceptable to CMS, below the level of the arrangement between a Part D plan sponsor (or applicant) and a first tier entity." In response to this comment, we are modifying the proposed definition to address with whom the entity is entering into a written arrangement. The definition is revised to read: "Downstream entity means any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the Part D benefit, below the level of the arrangement between a Part D plan sponsor (or applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services." We are making similar changes to the definition of "downstream entity" in the MA regulation at § 422.2.

Comment: One commenter questioned whether a pharmacist is a downstream entity.

Response: As illustrated in the sample flowchart provided on p. 29372 of the proposed rule, and below, a pharmacist would be considered a downstream entity as defined in the regulation.



Sections 422.503 and 423.504—General Provisions

The current regulations at § 423.504 include a requirement that a Part D sponsor's compliance plan consist of training and education, and effective lines of communication between the compliance officer, and the organization's employees, contractors, agents, directors, and managers. The terms "contractor" and "agent" are not defined in the current regulations, and it has been unclear to the industry which entities are subject to the training and education, and the effective lines of communication requirements. In response to industry concerns and to eliminate the confusion associated with using the term "contractor", currently used in those sections, we proposed to revise paragraphs (b)(4)(vi)(C) and (b)(4)(vi)(D) of § 423.504. The proposed revision clarified that a compliance plan must consist of training and education, and effective lines of communication between the compliance officer and the Part D sponsor's employees, managers, and directors, as well as the Part D sponsor's "first tier, downstream, and related entities" which are defined at 422.500 and 423.501. This change clarifies that Part D plan sponsors need to apply these training and communication requirements to all entities they are partnering with to provide benefits or services in the Part D program, not just to their direct employees within their organizations.

Pursuant to our authority under § 1856(b)(1) of the Act to establish MA standards by regulation, we also proposed to make the same changes in the MA program. We similarly proposed to require MA organizations to apply their training and education and effective lines of communication requirements to their first tier, downstream, and related entities, in an effort to make the compliance plan requirements uniform across MA organizations, Medicare Advantage Prescription Drug Plans (MA–PDs), and other Part D sponsors. Additionally, we proposed clarifying paragraph (b)(4)(vi) in § 422.503 and § 423.504 by removing what we believe to be a duplicative and confusing "final element" of the compliance plan—a comprehensive "fraud, waste, and abuse plan to detect, correct, and prevent fraud, waste, and abuse," at paragraph (b)(4)(vi)(H) of both regulations. We proposed to remove this element because since the Part D program's inception, we received feedback from many Part D sponsors indicating that it was not clear whether we were requiring a fraud, waste, and abuse (FWA) plan separate and distinct from a compliance plan.

In April 2006, we issued Chapter 9 of the Prescription Drug Benefit Manual ("Part D Program to Control Fraud, Waste and Abuse," hereafter referred to as "Chapter 9") as best practices guidance for Part D sponsors to develop an FWA plan. We intend for Chapter 9 to be similar to the type of best practices guidance issued by the Office of the Inspector General (OIG) in its Compliance Program Guidance for drug manufacturers and health care providers. While we clarified in Chapter 9 that Part D sponsors could choose whether to incorporate FWA measures in a compliance plan, we believe the final element continues to cause potential confusion to the industry, and therefore, proposed to remove this element from (b)(4)(vi) of § 422.503 (for MA–PDs) and § 423.504 (for Part D sponsors).

We continue to believe an effective compliance plan includes procedures and policies for preventing fraud, waste, and abuse, and so proposed changes to the introductory clause of § 423.504(b)(4)(vi) that reflect our policy stance. Congress mandated that Part D sponsors have a "program to control fraud, waste, and abuse." See § 1860D–4(c)(1)(D) of the Act. Therefore, we are also clarifying that if Part D plan sponsors develop an effective compliance plan that incorporates measures to detect, prevent, and correct fraud, waste, and abuse, this compliance plan would also satisfy the statutory requirement that sponsors have a FWA plan in place. Part D sponsors should continue to look to Chapter 9 as recommended guidance for the types of measures we recommend in detecting and preventing fraud, waste, and abuse. Chapter 9 can be viewed at: *http://www.cms.gov/PrescriptionDrugCovContra/Downloads/PDBManual_Chapter9_FWA.pdf.*

We recognize that Chapter 9 was specifically developed for Part D sponsors and is not applicable for MA organizations that do not offer a prescription drug benefit. In the interim,

MA organizations should refer to Chapter 9 as a reference regarding how to incorporate fraud, waste, and abuse detection and prevention into their compliance plans. We plan to develop separate guidelines for MA organizations for implementation by January 1, 2009.

Pursuant to our authority under section 1856(b)(1) of the Act, we also proposed to make the same change to the introductory clause of § 422.503(b)(4)(vi), so that the compliance plan requirements for MA organizations will be identical to those for Part D sponsors. We proposed that MA organizations must include "measures to detect, correct, and prevent fraud, waste, and abuse" throughout the 7 elements of the compliance plan requirement. Before this proposed change, only MA-PDs were explicitly required to include detection and prevention of fraud, waste, and abuse into their compliance plans. However, it has always been our expectation that fraud, waste, and abuse would be addressed through the implementation of all 7 elements in a MA organization's compliance plan, enumerated at paragraphs (A) through (G) of § 422.504(b)(4)(vi). It has been our longstanding policy that an effective MA compliance plan addresses the detection, correction, and prevention of fraud, waste, and abuse in the MA program, and we believe that our proposed change makes this policy explicit in our regulations. As previously stated in this final rule with comment period, MA organizations may refer to Chapter 9 in the interim, and further guidance on the types of measures we recommend in detecting and preventing fraud, waste, and abuse will be developed specifically for MA organizations.

Comment: A number of respondents requested further clarification regarding who must provide training and education under the compliance plan and who must be trained and educated.

Response: We did not intend to imply that MA organizations and Part D sponsors are required to directly provide Part D compliance training and education to all of their first tier, downstream, and related entities. Instead, we seek to reaffirm the role and responsibilities of the MA organization and Part D sponsor in this area. To the extent that aspects of the compliance plan are delegated, it is important to remember that the MA organization's or Part D sponsor's compliance officer must maintain appropriate oversight of those delegated activities. The Part D sponsor and the MA organization maintain ultimate responsibility regardless of whether training has been delegated to the first tier, downstream, or related entities. In accordance with the Part D and MA applications, the Part D sponsor or MA organization must attest it will implement a compliance plan that includes effective training and education between the compliance officer, organization employees, contractors, agents and directors. In addition, as part of plan audits, CMS will verify that all necessary training has been provided. Therefore, CMS would expect that a Part D sponsor and MA organization would have training logs and copies of attestations from the first tier, downstream or related entities to comply with this requirement. As previously stated in this final rule with comment period, MA organizations may refer to Chapter 9 in the interim, and further guidance will be developed for MA organizations.

Comment: A few commenters questioned "who would be responsible" for implementing the compliance program's fraud, waste, and abuse detection and prevention efforts related to Part D.

Response: The MA organization or Part D sponsor is ultimately responsible for meeting the compliance plan requirement to implement measures for detecting and preventing fraud, waste, and abuse. However, we realize that each MA organization and Part D sponsor has a unique business model and structure, and that some will choose to perform certain functions themselves while some MA organizations and Part D sponsors will subcontract certain functions and rely on the expertise and operations that first tier, downstream, and related entities offer. The job of the compliance officer cannot be delegated. But MA organizations and Part D sponsors have the flexibility to determine how, and to what extent, they will delegate their compliance activities, which may include training and education to control fraud, waste, and abuse. MA organizations and Part D sponsors have the flexibility to determine how and to what extent they will delegate other aspects of their contractual requirements. To the extent that any compliance activities are delegated to first tier, downstream, and related entities, MA organizations and Part D sponsors are ultimately responsible for compliance plan oversight, including monitoring training and education, and complying with all statutory and regulatory requirements, as well as any additional guidance identified by us. One option MA organizations and Part D sponsors may choose is to contractually require their first tier, downstream, and related entities to train their own workforce on delegated activities and establish lines of communication to the appropriate managers in those entities. We recommend that Part D sponsors review chapter 9 of the Prescription Drug Benefit Manual for further guidance regarding accountability and oversight of first tier, downstream, and related entities. As previously stated in this final rule with comment period, MA organizations may refer to Chapter 9 in the interim, and further guidance will be developed specifically for MA organizations.

MA organizations and Part D sponsors should consider requiring that any first tier, downstream, and related entities performing activities on behalf of the MA organization or Part D sponsor, provide their own training in accordance with § 422.504(b)(4)(vi)(C) or § 423.504(b)(4)(vi)(C) respectively, or where there are sufficient organizational similarities, the MA organization or sponsor may choose to make its training programs available to these entities. This will allow the first tier, downstream, and related entities the choice of accessing the MA organization or Part D sponsor's training and education materials, or providing proof to them of their compliance with the training and education requirement. For further guidance, please refer to chapter 9 of the Prescription Drug Benefit Manual.

Employees with specific responsibilities in Medicare Part D business areas should receive specialized training on issues posing compliance risks based on their job function (for example, pharmacist, statistician, and so on), upon initial hire, when requirements change, or when an employee works in an area previously found to be noncompliant with program requirements or associated with past misconduct. Such training should also be required at least annually thereafter as a condition of employment. Specialized training content may be developed by the sponsor or employees may attend professional education courses that help meet this objective. Further discussion related to this subject may be found in Chapter 9.

In Chapter 9, we discuss how delegation of training would be applicable, if deemed appropriate by the sponsor, for General Compliance Training and Specialized Compliance Training. We did not make any changes to our proposed provisions as a result of this comment.

Comment: We received some comments suggesting that we should work with the industry to develop a

standardized training and communication plan applicable to all stakeholders, and make it available on the internet. This way, stakeholders would receive one comprehensive training and communication package.

Response: We believe this to be a valuable suggestion, and we will take it under consideration.

Comment: Some commenters requested that we conduct certifications to verify that training and education had been completed for Part D plans and their first tier, downstream, and related entities.

Response: At this time, we do not require a certification process but rather, through our audit and review process, will determine whether or not the training and education requirements were fulfilled. We hold the Part D sponsor or MA organization responsible for fulfilling this requirement regardless of whether first tier, downstream, and related entities certify to that effect. We may revisit the idea of certification in the future.

Comment: One respondent questioned who downstream entities should contact with "compliance concerns."

Response: We have contracted with program integrity contractors who will use innovative techniques to monitor and analyze data to help identify and prevent fraud, waste, and abuse. Any person or entity at a first tier, downstream, or related entity level that wishes to report potential fraud or misconduct may contact a program integrity contractor and/or the MA organization or the Part D sponsor, depending on the type of violation.

Comment: Another respondent questioned who would be responsible for reporting potential prescription drug fraud.

Response: The Part D sponsor or MA organization maintains ultimate responsibility regardless of whether oversight duties have been delegated. To the extent that any of the compliance activities for Parts C or D are delegated, it is important that the MA or Part D compliance officer maintain appropriate oversight of those duties that have been delegated. The compliance officer is responsible for determining whether voluntary self-reporting of any potential fraud or misconduct related to the MA or Part D program is appropriate. In addition. first tier, downstream, and related entities are encouraged to report fraud, waste, or abuse to the program integrity contractor and/or the MA organization or the Part D sponsor.

Sections 422.503(b)(4)(vi)(G)(*3*) and 423.504(b)(4)(vi)(G)(*3*)—Mandatory Self-Reporting

At § 422.503(b)(4)(vi)(G)(*3*) and § 423.504(b)(4)(vi)(G)(*3*), we proposed mandatory self-reporting of potential fraud or misconduct in both the MA and Part D programs. We believe that it is important for the government to have information on potential fraud or misconduct as soon as possible. The comments we received on the May 25, 2007, proposed rule highlighted the challenges in establishing the parameters of a mandatory self-reporting process in the context of MA and PDP plans. Commenters expressed several concerns during the public comment period, including the need for us to better define what constitutes "potential" fraud and misconduct, the process for reporting, and the need to be consistent with other agencies' guidance regarding self-reporting. After reviewing these comments, we determined that additional analysis needs to be undertaken and additional information sought before implementing a mandatory self-reporting requirement.

In the meantime, we believe that self-reporting is a valuable component of an MA organization's or Part D sponsor's compliance plan. Therefore, in an effort to make the compliance plan requirements uniform across MA organizations, Medicare Advantage Prescription Drug Plans (MA-PDs), and other Part D sponsors, we will amend proposed paragraph (b)(4)(vi)(G)(*3*) of both §§ 422.503 and 423.504 to read: A MA organization or Part D sponsor "should have procedures for voluntary self-reporting of potential fraud or misconduct * * *." We are essentially retaining the voluntary self-reporting recommendation for Part D sponsors, but merely moving it within the regulatory text to accommodate other regulatory changes we are making, and implementing a voluntary self-reporting recommendation for MA organizations. We are strongly recommending that, if after conducting a reasonable inquiry, it is determined that potential fraud or misconduct has occurred, the conduct should be promptly referred to the program integrity contractor for further investigation. While we are not requiring mandatory self-reporting in this final rule with comment period, there may be instances under federal criminal and fraud and abuse statutes where MA organizations and Part D sponsors are potentially subject to prosecution if certain issues are not properly addressed. We further note that our decision not to amend the existing MA and PDP requirements further at this time does not mean that organizations may not be liable under other Federal laws or regulations if they fail to disclose a violation they have discovered.

We wish to call attention to the existing guidance we provide on self-reporting. Key documents include Chapter 9 of the Prescription Drug Benefit Manual, concerning fraud, waste, and abuse (at *http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBManual_Chapter9_FWA.pdf*) and the Medicare Part D Reporting Requirements for Contract Year 2007 (at *http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PartDReportingRequirements_CurrentYear.pdf*). While these documents are not codified rules, the guidance they contain provides clear direction to plans as to our expectations. We will periodically revise these guidelines to reflect additional guidance on ways to improve reporting of fraud, waste, and abuse.

We are committed to implementing mandatory self-reporting and we intend to issue a proposed rule. Finally, we believe that it would be valuable to obtain additional input at this time, in order to inform our evaluative, analytic, and guidance efforts. Accordingly, we are asking for additional public comments on this issue. Specifically, we ask for comments regarding the following:

- We proposed requiring MA organizations and Part D sponsors to report potential "fraud or misconduct." We seek guidance as to how to define what kinds of offenses would constitute fraud and misconduct for purposes of this reporting requirement. We seek specific examples of what constitutes potential fraud and misconduct.
- Alternatively, we seek input as to whether there is an alternate formulation, rather than "fraud or misconduct" that would better describe the categories of offenses that should be reported to CMS (for example violations of administrative, civil and/or criminal authorities).
- Who are the entities that would be responsible for reporting to CMS (sponsor, first tier, downstream entities)?
- At what point would CMS require that a MA or Part D plan report a potential issue that could fall into the category of offenses that would require self-reporting (for example, upon initial discovery or after an opportunity for reasonable inquiry or due diligence)?
- How should this information be reported to CMS (through the MEDICs, disclosure to the CMS plan manager, or

CMS central office)? Please provide a discussion of the advantages or disadvantages of any of these or other reporting mechanisms.

• In addition to the specific questions raised above, please provide us with any other comments or constructive feedback that might assist us in crafting a mandatory self-reporting requirement.

Sections 422.504 and 423.505—General Provisions

We proposed to clarify which entities under contract to MA organizations and Part D sponsors are subject to the contract provisions in the MA and Part D programs. Currently, the contract provisions at 422.504 and 423.505 refer to such entities as the MA organization or Part D sponsor's "contractors" and "subcontractors," which as we described in the proposed rule, are undefined terms in the statute and regulations. We proposed, where applicable, to delete the term "contractor," because of potential confusion and redundancy, and replace the term "subcontractor" with the terms "first tier entity" and "downstream entity" in 422.504(e) and (i), to clarify which entities are subject to the contract provisions at 422.504.

We also proposed, where applicable, to delete the term "contractor," and replace the term "subcontractor" with the terms "first tier entity" and "downstream entity" in the Part D contract provisions at 423.505(e) and (i) for the same reasons. We believed using "first tier and downstream, entities" instead of "subcontractor" would lessen the potential for confusion in the Part D program. Please see page 29372 of the proposed rule for examples of first tier, downstream, and related entities.

Comment: We received a number of technical comments concerning the definitions of "contractor" and "subcontractor."

Response: Based on these comments, we are correcting a few typographical errors in § 423.505(i)(3)(v) by replacing the phrase "related entity, contractor or subcontractor" with the phrase "first tier, downstream, and related entities" to be consistent with the other parts of the regulation. In §§ 423.505(i)(3), and §§ 423.505(i)(3)(ii), (i)(4), and (i)(4)(v), we are deleting the term "pharmacy" as it was included in error and is redundant. Section 423.505(i)(4) will now read: "If any of the Part D plan sponsor's activities or responsibilities under its contract with CMS is delegated to other parties, the following requirements apply to any first tier, downstream, and related entity," and § 423.505(i)(4)(v) will read: "All contracts or written arrangements must specify that the first tier, downstream, or related entity must comply with all applicable Federal laws, regulations, and CMS instructions." We also are making similar corrections to § 422.504(i)(3), (i)(3)(ii), and (i)(4) where the term "provider" was left in the regulations unintentionally. All references to "provider" have been deleted in the final regulations.

We proposed to add a provision to the contracts and written arrangements between sponsors and their first tier, downstream, and related entities at § 423.505(i)(3)(iv) to clarify that this information can be provided to either the Part D sponsor to give to CMS, or can be provided directly to CMS or its designees. We discussed in the proposed rule at page 29373 our existing authority under section 1860D–12(b)(3)(c) of the Act and § 422.504(e) and § 423.505(e) to inspect and audit any books, contracts, requests, and records of a Part D sponsor or MA organization relating to the Part D program. Because of the proposed contract provision, we also proposed to redesignate § 423.505(i)(3)(iv) as § 423.505(i)(3)(v). We are finalizing these changes as proposed.

Comment: A few commenters questioned our authority to access the books and records of first tier, downstream and related entities. One commenter suggested a need for more formal rulemaking on this topic.

Response: We have existing authority under section 1860D–12(b)(3)(c) of the Act and § 422.504(e)(2) and § 423.505(e)(2) to inspect and audit any books, contracts, and records of a Part D sponsor or MA organization and its first tier, downstream, and related entities that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of accounts payable under the contract or as the Secretary may deem necessary to enforce the contract. Therefore, it is not necessary, as the commenters suggested, to propose a more formal regulation and offer another public comment period. These third party disclosure requirements were finalized in the final MA and Part D rules and were approved under the Paperwork Reduction Act approval under OMB #0938–1004 (Part C) and OMB #0938–1000 (Part D). Additionally, in the preamble to the Part D proposed rule, published on January 28, 2005 (70 FR 4194), we clearly stated our inspection and audit rights with respect to a Part D sponsor and its contractors, subcontractors, and related entities under the section entitled "Access to Facilities and Records" (69 FR 46632–46712). In this regulation, we have further clarified that our access rights apply to "first tier, downstream, and related entities," and not "contractors, subcontractors, and related entities."

The limited rebate and other price concession information provided to the Part D sponsor by its contracting entities may provide some payment information to us, but it may not be enough for us to determine in all cases whether appropriate payments have been made to the sponsor. Therefore, it may be necessary for us to rely on our authority to access books and records to obtain more detailed rebate and other price concession information in order to verify proper payments were made to the Part D sponsor.

Comment: We received a number of comments questioning whether books and records must be made available to us directly or through the Part D sponsor.

Response: We have chosen not to be prescriptive regarding whether first tier, downstream, and related entities must make their books and records available to us directly or through the Part D Sponsor. It is our opinion that this is considered to be part of the negotiation process between the Part D sponsor and its first tier, downstream, and related entities. The provision must be clear as to whether or not the requested documentation is to be submitted through the Part D sponsor to us (or our designee(s)), or submitted directly to us (or our designee(s)). The parties could also decide to have such books and records made directly available to us, or our designee(s), through onsite access. The Part D sponsor must be prepared to submit evidence of this agreed upon provision in its executed contracts to us. To clarify, the "designee" either refers to entities under a program integrity contract with us, or entities, such as law enforcement, working in collaboration with us to fight fraud, waste and abuse in the Medicare Part D program.

HHS, the Comptroller General, or its designees have the authority to collect any information from the first tier, downstream, or related entities that is related to the Medicare Part D prescription drug transaction. Examples of the type of information collected are provided at § 423.505(e)(2).

In addition to proposing a new contract provision at § 423.505(i)(4)(iv), we also proposed minor regulatory changes which clarify the Part D sponsor's CMS contractual requirements. While we continue to believe our regulations clearly state our authority to access the books and records of a Part D sponsor's first tier, downstream, and related entities, we proposed to add language about these

partnering entities to § 423.505(b)(10), and proposed to consolidate § 423.505(e)(2) and (3) into one provision at (e)(2). We proposed these revisions to make explicit the Part D plan sponsor's contractual obligation to ensure HHS, the Comptroller General, or their designees have access to any books and records related to the Part D program, including those of a sponsor's first tier, downstream, and related entities. These revisions do not impose any new requirements on Part D sponsors or its partnering entities. We are finalizing these proposed provisions without change.

Comment: A few commenters noted that the proposed revision to § 422.504 and § 423.505 has not prescribed "typical" data sets to be reported within the context of our request for books and records of first tier, downstream, and related entities. Another commenter indicated that the information that could be collected is too broad.

Response: We want to clarify that the "books and records" we are entitled to access do not make up a typical data set included in the Medicare Part D Reporting Requirements. There is no report form to be defined, as the format will be dependent upon the information being requested and the unique circumstances upon which the request is based. The scope of the information collected will be based on the type of audit being performed. If upon review of the information submitted we, or our designee(s), determine that additional information or clarification is warranted, the scope of the review may be expanded.

Comment: A commenter suggested that we should rely on subpoena authority, regulation, provider contracts, or some other method to collect books and records in connection with investigations.

Response: We do not have subpoena authority; however, our law enforcement partners such as OIG and DOJ do. The government may use a variety of methods to obtain records and books from entities under contract with MA organizations and/or Part D sponsors. There may be instances where we may need to see books and records without involving law enforcement. These provisions at § 422.504 and § 423.505 only clarify one method we may employ to do so.

We clarified in the preamble to the proposed rule that HHS, the Comptroller General, or their designees have the authority under the statute to request records from MA organizations and Part D sponsors or their first tier, downstream, or related entities. MA organizations and Part D plan sponsors must maintain, as required by § 423.505(d), "books, records, documents and other evidence of accounting procedures and practices," pertaining to determinations of amounts payable under the contract, agreements, contracts, and subcontracts. Since Part D sponsors have delegated many Part D functions to their first tier entities, we are aware that many of these records reside with first tier and downstream entities, such as pharmaceutical benefits managers (PBMs). We are taking the opportunity again, in this final rule with comment period, to make explicit that we have the authority to request for verification of payment purposes, any records relating to rebates and any other price concessions between PBMs and manufacturers that may impact payments made to sponsors in the Part D program.

Comment: We received a comment addressing the 10-year record retention requirement.

Response: This requirement was implemented in a prior regulation and is outside the scope of this final rule with comment period.

Comment: A number of commenters expressed concern that information submitted by first tier, downstream, and related entities, especially proprietary information, would not be kept confidential by us.

Response: As an agency, we are subject to various Federal disclosure laws, such as the Trade Secrets Act, the Privacy Act, and the Freedom of Information Act (FOIA) (5 U.S.C. 552). We are also subject to confidentiality and disclosure regulations at 42 CFR Part 401 Subpart B. In addition, sections 1860D–15(d)(2)(B) and (f)(2) of the Act place restrictions on the Secretary's disclosure of certain payment data collected in the Part D program to anyone outside of HHS. Therefore, we believe there are sufficient legal restrictions to protect the disclosure of such proprietary data outside of the agency.

Comment: One commenter questioned our need to gather information about rebate agreements between potential first tier and downstream entity contracted partners.

Response: Our proposal to obtain rebate and price-concession related records is supported by statute. Sections 1860D–15(d)(2) and 1860D–15(f)(1)(A) of the Act authorize us to request any information "necessary" to carry out the payment provisions in section 1860D–15 of the Act, which include payments of direct subsidies, reinsurance, and risk corridor costs to sponsors. While the rebate and other price concession information reported by the sponsors may provide some payment information, it may not be enough for us to determine in all cases whether appropriate payments have been made to the sponsor. It may be "necessary" for us to obtain more detailed rebate and other price concession information from first tier, downstream, and related entities in order to verify proper payments made to the sponsor. For example, we must receive accurate and complete rebate and other price concession information in order to determine what was "actually paid" and to clearly reflect what was a gross prescription drug covered cost, which excludes administrative costs.

As stated in the CMS 2007 Prescription Drug Sponsor Call Letter, "CMS must assume that if a PBM retains a portion of the manufacturer rebates it negotiates on behalf of the Part D sponsors then the direct payment the sponsor pays the PBM for its services will be less, that is, the sponsor receives a price concession from the PBM." If the rebates are passed completely through to the Plan then the charge from the PBM to the Plan would be an administrative cost that will need to be deducted from the "gross covered prescription drug costs" which along with the "actually paid costs" are a basis for CMS payment to the plans.

In addition, such rebate and other price concession information is critical to our oversight efforts in curbing fraud, waste, and abuse in the Part D program. Under section 1860D–2(d)(3) of the MMA, Congress granted us the right to conduct periodic audits of a sponsor's financial statements, books, and records "to protect against fraud and abuse and to ensure proper disclosure and accounting" in the Part D program.

Given the history of rebate reporting problems the government has encountered with PBMs in administering the Medicaid Drug Rebate Act, we believe we must have the ability to evaluate and inspect records relating to Part D rebates and other price concessions in order to fulfill our statutory duty of protecting beneficiaries from fraud and abuse and to ensure the financial integrity of the Part D program. Therefore, we are restating in this final rule with comment period that we reserve the right to request records relating to Part D rebates and price concessions from the sponsor's first tier entities, downstream, and related entities when appropriate.

Comment: A commenter questioned whether certain contracted partners are considered to be downstream entities.

Response: In Exhibit 1 of the proposed rule, on p. 29372, and in this final rule with comment period, we

provided examples of first tier and downstream entities. We encourage you to contact the CMS staff listed at the beginning of this final rule with comment period if you have any questions as to whether a contracted partner is a downstream entity.

Sections 422.505 and 423.506—Effective Date and Term of Contract

We proposed removing § 422.505(c)(1) and § 423.506(c)(1), which state that contracts with MA organizations or Part D plan sponsors are only renewed if CMS informs the MA organization or Part D sponsor that it has authorized a renewal. Section 1857(c)(1) of the Act provides that the contract renews automatically, unless CMS or the organization notifies the other party of its intent to terminate the contract at the end of the existing contract term. Therefore, we proposed to revise § 422.505(c) and § 423.506(c) to state that in accordance with § 422.506 and § 423.507, contracts are renewed annually only if the MA organization or Part D plan sponsor has not provided us with a notice of intent not to renew and we have not provided the MA organization or Part D plan sponsor with a notice of intent not to renew. This change better aligns the regulations with the statute and we are finalizing the provision as proposed.

Comment: One commenter asked whether contracts needing amendment as a result of this final rule with comment period could be made at the time of contract renewal.

Response: As indicated in the proposed rule and finalized here, the implementation date of this provision is January 1, 2009. Therefore, all revised contracts need to be in place by that date. We did not make any changes based on this comment and are finalizing the provision as proposed.

Sections 422.506 and § 423.507 Nonrenewal of a Contract

We proposed revising the introductory text for § 422.506(b)(2) and § 423.507(b)(2). In addition, we proposed revising § 422.506(b)(2)(i) and § 423.507(b)(2)(i). The existing provisions require us to provide plans with notice of both renewal and nonrenewal decisions by May 1. We proposed that a notice only be provided if we decide not to renew an MA organization or a Part D plan sponsor's contract with us. As discussed in the proposed rule, Section 1857(c)(1) of the Act provides for an automatically renewable contract and does not require us to provide notice when we decide to renew a plan or sponsor's contract with us.

We proposed revising the § 422.506(b)(2) introductory text and the § 423.507(b)(2) introductory text to clarify that we must provide notice of our decision not to authorize renewal of a contract. In addition, we proposed to revise § 422.506(b)(2)(i) and § 423.507 (b)(2)(i) to require that we provide such notice by September 1 of the contract year, rather than May 1. If an MA organization or Part D sponsor receives a nonrenewal notice from CMS, we will not provide information regarding the MA or Part D plans that the organization or sponsor offers in certain hard copy materials, such as the "Medicare & You" handbook. Information regarding the plans would continue to be available on the CMS Web site. For purposes of this final rule with comment period, a nonrenewal would take effect on January 1 of the following contract year (unless a nonrenewal is being appealed through the administrative appeals process and the appeals process is ongoing, or additional time is required to comply with our requirements with respect to providing notice to beneficiaries of the nonrenewal, in which case the nonrenewal may become effective during the following calendar year), whereas a termination may take effect at any time during the contract year. Our proposed provisions make contract renewal automatic, without notice, unless we notify the MA organization or Medicare Part D plan sponsor of our intent to nonrenew the contract by September 1 of the current contract year. Please see the proposed rule for our rational for changing the nonrenewal notification date to a date later than May 1.

Comment: We received several comments concerning the proposed September 1 nonrenewal notification date. Several commenters believed that plans will have to incur significant expenditures prior to September 1 to prepare for the following calendar year, and that a September 1 date would require plans to incur expenditures that would not have been incurred before the existing May 1 nonrenewal notification date, in the event that we take action to nonrenew a plan.

Response: We understand that MA organizations and Part D sponsors expend effort in preparing for the following contract year. Therefore, while we will not retain the existing May 1 nonrenewal notification date, we are revising our proposal and finalizing a notification date of August 1, instead of our proposed September 1 notification date.

We understand that MA organizations and Part D sponsors expend effort in preparing for the following contract year. Therefore, while we will not retain the existing May 1 nonrenewal notification date, we are responding to commenters' concerns and revising our proposal and finalizing a notification date of August 1, instead of our proposed September 1 notification date. We believe that this is an appropriate compromise. While we appreciate commenters' concerns, we believe we have a significant countervailing interest in moving the current May 1 nonrenewal notification date to later in the calendar year. As we explained in the preamble to the proposed rule, these additional months will allow us to have access to significantly more information about plan performance, which will allow for more informed and educated decisions about MA organizations and Part D sponsors that have serious compliance problems and may be the subject of a nonrenewal determination. We believe that allowing for the opportunity to access this data will benefit both CMS and the MA organizations and Part D sponsors.

Comment: Another commenter said that the September 1 date would not provide for enough time for beneficiary notification.

Response: As explained above, we are finalizing a nonrenewal notification date of August 1, rather than September 1 as we proposed. We believe this change is more likely to result in administrative appeals of CMS nonrenewal actions being completed in time to allow for 90 days notice of the nonrenewal to be provided to members and the general public prior to the end of the calendar year.

Comment: One commenter requested clarification as to whether deficiencies could be cured after receiving the notice of an intent to nonrenew. The commenter stated that a September 1 date would not give enough time for an organization to make necessary changes to come into compliance for the next contract year. This commenter also expressed concern about the inability of a plan to participate in the program for the following year because of the timeframes associated with Corrective Action Plans (CAPs) and appeal rights, potentially rendering a plan's appeal rights moot.

Response: We believe comments related to plan participation in the following calendar year based on CAP submission dates reflect a misunderstanding of our proposals in the proposed rule. We clarified in our proposed rule that we will offer plans an opportunity to submit an acceptable CAP *prior to notifying* them of our intent to nonrenew or terminate their

contract. If an acceptable CAP is submitted to us, we will not take action to nonrenew or terminate the sponsor or organization's contract. Once a sponsor or organization receives a nonrenewal notification from us (or a termination notice), the sponsor or organization is not entitled to an additional opportunity to submit another CAP. We will not be required to provide any additional time for a MA organization or Part D sponsor to come into compliance or cure deficiencies once we have notified a sponsor or organization of our intent to nonrenew (or terminate) its contract. We proposed this clarification in an effort to streamline the CAP and nonrenewal process. We have added additional language at § 422.506, § 422.510, § 423.507, and § 423.509 to expressly clarify that the opportunity to submit an acceptable CAP is afforded to a MA organization or Part D sponsor prior to our decision to nonrenew or terminate a contract.

With respect to the comment regarding ongoing administrative appeals, if a MA organization or Part D sponsor is in the process of appealing a nonrenewal or termination, and the appeal process has not been concluded, the organization will be able to participate in the program the following calendar year until such time during the following calendar year as the appeals process is concluded and appropriate notice is provided to beneficiaries. Therefore, appeal rights will not be moot.

Comment: Several commenters believed that the September 1 date would place an undue burden on pharmacies to join plan provider networks and the commenters recommended that we provide some sort of contingent renewal notice for organizations and sponsors to send to providers for the following year.

Response: MA organizations and Part D sponsors who have not received a request for a CAP from us as a result of deficiencies are not in jeopardy of receiving a nonrenewal notification, making the need for a contingent nonrenewal notice unnecessary. Furthermore, as explained above, we are changing the proposed September 1 nonrenewal notification date to August 1, affording pharmacies an additional month to make network decisions.

We proposed redesignating § 422.506(b)(3) as § 422.506(b)(4) and redesignating § 423.507(b)(3) as § 423.507(b)(4). We proposed adding a new paragraph at § 422.506(b)(3) and § 423.507(b)(3) which would clarify the CAP process for nonrenewals. The Act requires us to provide MA organizations and Part D plan sponsors with a reasonable opportunity to develop a CAP prior to terminating a contract, either through the termination process or the nonrenewal process. The CAP process for nonrenewals would be the same process as we proposed for terminations. We proposed a more defined process than currently exists and we proposed a process and timeframes for the submission and review of CAPs. Our proposal clarified that, in the future, once we issue a nonrenewal notice or a termination notice, the MA organization or Part D plan sponsor will not be entitled to an opportunity to submit a CAP. We will provide that opportunity to organizations and sponsors prior to issuing a notice of intent to nonrenew or terminate a contract. MA organizations and Part D plan sponsors should take very seriously any request from us to develop and implement a CAP since a failure to fully comply may result in a nonrenewal or termination action.

Comment: One commenter questioned whether the termination and CAP process applied to all contract years and if the termination would be retroactive to the beginning of a plan contract.

Response: The most recent finding of deficiencies and the request for a CAP would be relied upon to support a termination or other contract determination. Prior CAPs may provide additional information to us and support for our action if the MA organization or Part D sponsor has had continued compliance problems that have not been resolved, but would not be the basis of a contract determination if the prior CAPs have been accepted by us and implemented to our satisfaction. A termination action would affect the existing contract with us. Given that we have already adopted automatically renewable multi-year contracts, failure to substantially carry out a contract term necessarily would apply to the entire term of the contract (that is, the life of the contract). Part D and MA contracts are evergreen, so the existing contract is not just the current calendar year's contract, but is a continuing contract that existed during prior calendar years (assuming the Part D sponsor or MA organization participated in the program in prior calendar years).

We proposed time limits at § 422.506(b)(3) and § 423.507(b)(3) for the development and implementation of a CAP. We proposed to provide the MA organization or Part D plan sponsor 45 days in which to submit a CAP to us. If we find that the CAP is unacceptable, the MA organization or Part D plan sponsor would have an additional 30 days to revise and resubmit the CAP. If we then find the CAP acceptable, we would provide the MA organization or Part D plan sponsor with a deadline by which the CAP must be implemented. If we find that the second version of the CAP is unacceptable, we would be under no obligation to accept further revisions to the CAP and would have the discretion to proceed directly to issuing a notice of nonrenewal to the MA organization or Part D plan sponsor.

Comment: One commenter requested clarification on whether the timeframe is measured in business or calendar days. The commenter requested that we leave open lines of communication with organizations with respect to working to develop acceptable CAPs. The commenter was concerned that there would only be one chance to provide an acceptable CAP.

Response: We are clarifying here, and at §§ 422.506(3) and 423.507(3), that the CAP timeframes are measured in calendar days. We will provide MA organizations and Part D sponsors two opportunities to submit acceptable CAPs. Prior to requesting a CAP, or simultaneous with a request for a CAP, we will inform the MA organization or Part D sponsor about the deficiencies that must be addressed and corrected. If the first CAP submission is unacceptable to us, we will inform the MA organization or Part D sponsor as to what is unacceptable. The MA organization or Part D sponsor will then have a second opportunity to submit an acceptable CAP.

It is our intent to assist plans in submitting acceptable CAPs, while implementing a limit on the number of CAP submissions in order to bring some closure to this process when Part D sponsors or MA organizations are unable or unwilling to bring their organizations into compliance with our requirements. Aside from the clarification explained above regarding the use of calendar days, we are finalizing our proposed processes and timeframes for the submission and review of CAPs as proposed.

Sections 422.510 and 423.509—Termination of Contract by CMS

We proposed revising § 422.510(a)(1) and § 423.509(a)(1) to clarify one of the bases for contract termination. The existing provision states that we may terminate an MA organization or Part D plan sponsor's contract with us if the MA organization or Part D plan sponsor "failed substantially to carry out the terms of its contract with CMS." We proposed language to clarify that we may terminate an MA organization or Part D plan sponsor's contract if the organization substantially failed to carry

out the terms of its contract with us during the current calendar year or for a prior calendar year. This clarification is consistent with section 1857(c)(1) of the Act, which states that a contract must be for a period of at least 1 year with the contract being automatically renewable from term to term (that is, calendar year to calendar year), absent notice from either party of an intent to terminate the contract at the end of the current term. Given that we have already adopted automatically renewable multi-year contracts, failure to substantially carry out a contract term necessarily would apply to the entire term of the contract (that is, the life of the contract).

We have made a minor change to the regulatory text at §§ 422.510(a)(1) and 423.509(a)(1) to clarify our proposal. The change is a technical edit to accurately reflect the multi-year nature of our contracts with MA organizations and Part D sponsors.

We proposed revising § 422.510(b) and § 423.509(b) introductory text and revising the paragraph heading for § 422.510(b)(2) and § 423.509(b)(2) to delete the term "immediate" and replace it with "expedited". In addition, we proposed revising § 422.510(b)(2)(i) and § 423.509(b)(2)(i) to state that an expedited termination would take effect on a date specified by us. According to the existing regulations, an immediate termination takes effect once the MA organization or Part D plan sponsor receives notice that we intend to immediately terminate the plan's contract with us and a plan's enrollees are automatically disenrolled from the plan on the date such notice is received. The proposed change will provide greater protection for Medicare beneficiaries because we would have time between notifying a plan of an expedited termination decision and the actual date of termination to provide enrollees of the MA or Part D plan with enough information to enroll in another plan. We are finalizing this proposal without change.

Comment: We received a recommendation that we auto-enroll beneficiaries into another plan for seamless continuity of care, provided the beneficiary was able to make another health care choice. Another commenter felt that the effective date should be made in consultation with the terminated plan to better meet the needs of beneficiaries.

Response: We will take actions to ensure beneficiaries are protected and that continuity of care is a priority in our planning for all termination actions. We are not addressing beneficiary auto-enrollment in regulation since it is an operational issue. We have considered the suggestion that we involve the terminated plan in determining the effective date of the termination but believe that we are in the best position to determine the effective date of the termination. Determining the effective date of an expedited termination is a decision that should be made solely by us. We are finalizing the provision as proposed.

Comment: A few commenters did not believe we should be able to terminate a contract based on deficiencies during prior years. Commenters also stated that deficiencies that have been cured should not be the basis for a contract termination.

Response: We clarify here that failure to carry out contract terms means the MA organization or Part D sponsor is not currently in compliance. The failure to be in compliance currently may be a continuation of a failure to be in compliance in the previous year and/or the result of an incident(s) that occurred during the prior year or years. For example, a notice of intent to terminate provided to an organization in February of the current year might be based on the organization failing to provide an acceptable CAP for an audit that occurred in December of the previous year. In addition, the deficiencies found in December of the previous year may be unresolved deficiencies from a prior audit, never having been cured. We need the ability to look into previous contract terms for uncured deficiencies. We proposed the ability to terminate a contract based on current, open deficiencies, no matter how long they have been open deficiencies. It is not our intent to terminate a contract based on deficiencies that have been, and remain, cured.

Comment: One commenter recommended an expedited hearing process for expedited terminations.

Response: The current regulations provide for a hearing process to occur after an immediate, proposed expedited, termination has occurred. Current regulations do not provide for an expedited appeals process. Our proposed changes to the appeals process do not provide for an expedited appeals process. We do not believe an expedited appeals process is warranted. However, we note that eliminating the reconsideration process for all contract determinations, as we have proposed and are finalizing, will have the effect of accelerating the appeals process for all contract determinations. We are finalizing this provision as proposed.

Comment: One commenter requested guidance or examples of what we consider to be "imminent and serious risk to enrollees."

Response: We do not wish to provide examples of what "imminent and serious risk to enrollees" might entail because of the complexities of each and every expedited termination that may take place. Each case is different and we do not feel that past examples will necessarily help plans in preventing future expedited terminations.

We also proposed to clarify that we are able to invoke the expedited termination process when a determination regarding an MA organization is made according to § 422.510(a)(5). The existing regulations state that we invoke the current immediate termination process when a determination is made according to § 422.510(a)(4) for the MA program and § 423.509(a)(4) or (a)(5) for the Medicare Part D program. By adding (a)(5) as a basis for an expedited termination for MA organizations, the grounds for expedited terminations would be identical for the MA and Part D programs. The addition of § 422.510(a)(5) would provide consistency between the Part C regulations and the Part D regulations.

Comment: One commenter did not agree that expedited terminations should be based on instances where an MA organization or Part D sponsor provides "false" data without any fraudulent intent or knowledge that false data was provided. The commenter believes that expedited terminations should be reserved for instances of beneficiary harm and intentional fraud.

Response: We proposed in the Part C regulations, at 422.510, that the submission of false data may serve as the basis for an immediate termination (proposed name change to expedited termination) to correlate with existing Part D regulations. Our ability to immediately terminate based on the submission of false data has already been subject to notice and comment during the comment period for the existing Part D regulations. We now proposed this change to the Part C regulations to ensure that the Part C and Part D regulations mirror each other where appropriate. We believe that this change is necessary to ensure the integrity of the Part C program and to continue to ensure that conduct under both the Part C and Part D programs is handled similarly. Therefore, we are finalizing our proposal without modification.

We proposed to amend our procedures at § 422.510(c) and § 423.509(c) to more clearly define the process for the submission and review of CAPs prior to a termination action.

The Act requires us to provide MA organizations and Part D plan sponsors with a reasonable opportunity to develop and implement a CAP before we terminate the organization or sponsor's contract. The CAP process we proposed is the same process for nonrenewals outlined above and which we proposed at § 422.506 and § 423.507, providing for a more structured process and timeframes for the development and implementation of a CAP. We received comments concerning CAPs as applied to terminations, and have addressed them above in §§ 422.506 and 423.507, given that the CAP process is identical for nonrenewals and terminations.

Subpart N—Medicare Contract Determinations and Appeals

We proposed revisions to subpart N of 42 CFR part 422 and 42 CFR part 423 to coordinate and improve the contract determination and appeals processes for MA organizations and Part D plan sponsors. We proposed eliminating the reconsideration process for appeals of all types of contract determinations. We also proposed to make the appeals process consistent for all three types of contract determinations (terminations, nonrenewals, and decisions by us not to enter into a contract with an applicant). In addition, we proposed that the MA organization or Part D plan sponsor have the burden of proof in appealing a contract determination. Please see the proposed rule for a more detailed explanation of our proposals.

Sections 422.644 and 423.642—Notice of Contract Determination

We proposed to make conforming changes to § 422.644(b)(2) and § 423.642(b)(2) as a result of the changes we are making to the immediate termination process. Consistent with the proposed revisions we have previously described, we proposed to revise § 422.644(c) and § 423.642(c) to state that we would determine the effective date of an expedited termination. We also proposed adding § 422.510(a)(4) as a basis for which we may undertake an expedited termination. We are finalizing these provisions as proposed.

We also proposed to revise the provisions at § 422.644(d) and § 423.642(d) to conform to the proposed change previously described whereby we would provide notice of nonrenewal to MA organizations or Part D plan sponsors by September 1, rather than the current May 1. Please see above for a discussion of nonrenewal notification dates. We are finalizing these proposals with a modification to reflect the fact that we are finalizing the nonrenewal notification date as August 1, rather than September 1 as we proposed.

Sections 422.646 and 423.643—Effect of Contract Determination

We proposed making conforming changes to the provisions at § 422.646 and § 423.643 to reflect our proposal to eliminate the reconsideration process. The current regulations state that a contract determination is final unless an MA organization or Part D plan sponsor requests reconsideration. Since we proposed eliminating the reconsideration process, we also proposed a conforming change to indicate that a contract determination would be a final decision unless a timely request for a hearing is filed.

Comment: One commenter felt that eliminating a step for "informal collaboration" with us would create a process that is not in the best interest of beneficiaries. The commenter stated that by eliminating the reconsideration process, we appear to be eliminating opportunities to remedy potential problems prior to taking a formal contract action.

Response: We have reviewed the comment and have decided to finalize our proposal without modification. The commenter seems to be under the impression that the existing reconsideration process is an informal, collaborative process which provides the organization with another opportunity to come into compliance with our requirements. The commenter is misinformed about the nature of the current reconsideration process. The reconsideration is the first formal step in the administrative appeals process for organizations. The time for informal collaboration is prior to the commencement of an appeal, and prior to the seeking of reconsideration.

Sections 422.660 and 423.650—Right to a Hearing and Burden of Proof

We proposed conforming changes to the provisions at § 422.660(a) and 423.650(a) to reflect our proposal to eliminate the reconsideration process. These provisions would state that if we determine that an applicant is not qualified to enter into a contract with us and the applicant chooses to appeal the determination, a hearing before a CMS hearing officer would be the first step in the appeal process. We proposed to make similar conforming changes to § 422.660(b) and § 423.650(b), to indicate that a hearing before a CMS hearing officer would be the first step in appealing a nonrenewal determination or a termination decision. We did not receive any comments on these provisions and are revising them as proposed.

We proposed to add a new provision at § 422.660(c) and at § 423.650(c) to clarify that the burden of proof would be on the MA organization or Part D plan sponsor at a hearing appealing a CMS contract determination. The MA organization or Part D plan sponsor must demonstrate that they were in compliance at the stated time by a preponderance of the evidence. We believe case law supports our decision to place the burden of proof on the affected party in an administrative hearing on a contract determination involving a Part D plan sponsor or MA organization. See Hillman Rehabilitation Center, DAB No.1611 (1999), aff'd *Hillman Rehabilitation Center* v. *U.S.* No.98–3789 (GEB) (D.N.J. May 13, 1999).

Comment: We received comments related to our effort to clarify that burden of proof is on the MA Organization or Part D sponsor. Commenters stated that the burden of proof should be on us, and not the organization or sponsor, since we are taking the contract action and that imposing the burden of proof on the organization or sponsor is contrary to traditional principles of jurisprudence and is unfair. One commenter suggested that if the burden is on the organization or sponsor, then there should be a rebuttable presumption of non-compliance with the organization or sponsor assuming the burden of proof to rebut the presumption on a going forward basis. The commenter stated that if the organization or sponsor submits at least colorable evidence of substantial compliance the burden of persuasion should shift to CMS to prove non-compliance by clear and convincing evidence.

Another commenter stated that putting the burden of proof on the organization or sponsor effectively removes the organization or sponsor's ability to self-regulate and come into compliance once the compliance issue has been identified. The commenter stated that the date of compliance must allow for entities to fix identified deficiencies and cure the deficiencies.

Response: We have considered these comments and have determined that the proposed provision should be finalized without modification. Plans, following an audit, receive a report notifying the plan of any non-compliance. Following the report, plans have an opportunity to dispute the findings. For those compliance issues not related to formal audits, we continue to notify the plan about deficiencies of which we become aware, giving the plan an opportunity to

dispute the allegation. Whenever a plan is found to be non-compliant, we will request a CAP to cure the deficiencies. We are finalizing regulations that will provide a MA organization of Part D sponsor with an opportunity to submit an acceptable CAP before we decide to take contract action. It is important to understand that the date we notify an organization of our intent to take a termination or nonrenewal action is not the first time the organization learns that it is out of compliance with our requirements.

In addition, we also proposed that the MA organization or Part D sponsor must demonstrate substantial compliance with the relevant MA or Part D plan requirements as of the earliest of the following dates: (1) The date the organization or sponsor received written notice of the contract determination; (2) the date of the most recent on-site audit conducted as the basis of the termination; (3) or the date of the alleged breach of the current contract or past substantial noncompliance as determined by CMS.

Comment: We received a comment stating that the date of compliance should be the hearing date, not the earliest of the three dates proposed in the regulation. The commenter stated that using the earliest of the three dates violates due process.

Response: We have reviewed the comment and do not believe requiring compliance at the earliest of the three dates violates due process. MA organizations and Part D sponsors are required to be in compliance at all times. If we used the hearing date as the date by which we measured compliance, we would have absolutely no way of disputing a MA organizations or Part D sponsor's assertion that they are currently in compliance. Under no circumstance to we believe that the date for determining compliance should be after the date of termination notification. We are finalizing the proposal without modification.

Sections 422.662 and 423.651—Request for a Hearing

We proposed to revise § 422.662(b) and § 423.651(b) to conform to our proposed change to eliminate the reconsideration process. These provisions specify that a request for a hearing must be filed within 15 days after the date of the initial determination. We did not receive any comments on this provision and are adopting it as proposed.

Sections 422.664 and 423.652—Postponement of Effective Date of a Contract Determination When a Request for a Hearing Is Filed Timely

We proposed to revise § 422.664 and § 423.652 to postpone the effective date of a contract determination when an MA organization or Part D sponsor timely requests a hearing to appeal the contract determination. However, the postponement would not override the requirement that any final decision in favor of the plan or sponsor must be issued by July 15 for an initial contract to be effective for the upcoming year. Thus, if an organization's application is not approved and the hearing officer's decision is not provided until August, the applicant would not be able to have a contract for the next year. This is consistent with our current process. We do not currently postpone the effective date of termination in cases of immediate termination, and did not propose any change in policy with respect to expedited terminations. We did not receive any comments on this provision and are adopting it as proposed.

Sections 422.670 and 423.655—Time and Place of Hearing

We proposed revising § 422.670(a) and § 423.655(a), to require the hearing officer to send written notice to the parties specifying the general and specific issues to be resolved at the hearing, outlining the burden of proof and providing any information about the hearing procedures. In addition, the notice would inform the parties that they may conduct formal discovery. We did not receive any comments on this provision and are adopting it as proposed.

Sections 422.682 and 423.661—Discovery

We proposed revising § 422.682 and § 423.661, to clarify the scope of permissible discovery, and to require the hearing officer to conclude discovery and provide all documents to both the hearing officer and the opposing party at least 10 days prior to the hearing. We did not receive any comments on this provision and are adopting it as proposed.

Sections 422.684 and 423.662—Prehearing and Summary Judgment

We proposed to amend the provisions at § 422.684 and § 423.662 (and revise the section heading accordingly) to permit the hearing officer to rule on a motion for summary judgment filed by either of the parties to the hearing. In ruling on such a motion, we propose that the hearing officer would be bound by CMS regulations and general instructions. Where no factual dispute exists, the hearing officer may make a decision on the papers, without the need for a hearing. We did not receive any comments on this provision and are adopting it as proposed.

Sections 422.692 and 423.666—Review by the Administrator

The existing regulations only explicitly permit Administrator review of a hearing officer's decision in appeals of a contract termination. We clarify that this review is available for all appeals of CMS contract terminations, including decisions not to contract with an applicant and nonrenewals.

We proposed revising the provisions at § 422.692(a) and § 423.666(a) to allow us to request Administrator review of a hearing officer's decision regarding a contract determination. The existing regulations permit only the MA organization or Part D sponsor to request Administrator review. In addition, we proposed to amend the same provisions to permit both the parties to submit written arguments to the Administrator.

Comment: One commenter did not feel that we should be able to request an appeal to the Administrator.

Response: We believe that we should have the right to request a review by the Administrator. We feel that appeal rights should be provided to both parties to provide for an equal opportunity to be heard by the Administrator. Therefore, we are not making any changes to the proposed regulations based on these comments.

We proposed revising the provisions at § 422.692(b) and § 423.666(b), to permit the Administrator, upon receipt of a request for Administrator review, to accept or decline to review the hearing decision. The existing regulations require the Administrator to review the decision when a request for review is received. We believe that providing the Administrator with the discretion to accept or decline the request for review would lead to a more expeditious resolution of appeals of contract determinations.

Comment: We received a comment stating that the Administrator failing to take action within 30 days authorizes an unstructured, unrecorded exercise of the Administrators decision that can hide unequal treatment which evades review. The commenter stated that the Administrator taking no action does not afford the plan the level of review of other plans in which the Administrator reviews the appeal.

Response: We believe the Administrator has the authority to either

accept to review Hearing Officer decisions or to decline to review Hearing Officer decisions. This right is well-founded in current Provider Reimbursement Review Board policy. We are not making any changes to the proposed regulation as a result of this comment.

We proposed redesignating § 422.692(c) as § 422.692(e) and redesignating § 423.666(c) as § 423.666(e). We proposed adding a new § 422.692(c) and § 423.666(c), to require the Administrator to make a determination as to whether to accept or decline the request for review within 30 days of the request of the review. The failure of the Administrator to make a determination within 30 days of the request would be treated as a decision to decline the request for review. We believe that providing this timeline assists all parties in reaching a final decision in an expeditious manner. We did not receive any comments on this provision and are adopting it as proposed.

In addition, we proposed amending our existing regulations to add a new paragraph at § 422.692(d) and § 423.666(d) which specifies that Administrator review is based on the hearing record and any written arguments submitted by the parties. However, review would not be based on any new evidence, such as evidence that was not before the hearing officer. We believe the specified sources provide a sufficient basis for the Administrator to make a determination.

Comment: A commenter stated that Administrator review should not be limited to the record but should accept additional evidence.

Response: The Administrator review does allow for each party to submit additional arguments, but the current regulation does not provide for additional evidence to be submitted. We feel that the hearing record is sufficient, with enough information provided for the Administrator to make a determination. Therefore, we are not making any changes to the proposed regulations based on these comments.

Sections §§ 422.696 and 423.668—Reopening of Initial Contract Determination or Intermediate Sanction or Decision of a Hearing Officer of the Administrator

We proposed to revise the section headings for § 422.696 and § 423.668 from "Reopening of a contract or reconsidered determination or decision of a hearing officer or the Administrator" to "Reopening of an initial contract determination or decision of a hearing officer or the Administrator" to conform to our proposed elimination of the reconsideration process described above. We did not receive any comments on this provision and are adopting it as proposed.

Sections §§ 422.698 and 423.669—Effect of Revised Determination

We proposed a conforming change to reflect our proposed elimination of the reconsideration process by removing in its entirety § 422.698 and § 423.669, "Effect of revised determination." We did not receive any comments on this provision and are adopting it as proposed.

Subpart O—Intermediate Sanctions

We proposed several changes to our regulations in Subpart O—Intermediate Sanctions in 42 CFR Part 422 and 42 CFR Part 423, to clarify our policies and procedures for imposing intermediate sanctions and Civil Money Penalties (CMPs) on MA organizations and Part D sponsors. Specifically, we proposed to modify the appeals procedures for intermediate sanctions and clarify which set of procedures affected parties should use to appeal a CMP.

General Comments:

Comment: We received a few comments concerning bifurcated hearings for intermediate sanctions and/or CMPs. The commenters felt that one hearing should be used for both CMS imposed intermediate sanctions or CMPs and OIG imposed CMPs.

Another commenter expressed concern that there is no explanation as to when both CMS and OIG may impose CMPs based upon the same set of facts. The commenter stated that only in the most egregious cases should both CMS and the OIG impose CMPs.

Response: Appeals of CMS intermediate sanctions or CMPs and OIG imposed CMPs are governed by different regulatory processes and therefore cannot be combined in one hearing. In addition, CMS and OIG may impose sanctions/CMPs under different and independent authorities. The regulations currently provide for both OIG and CMS to impose sanctions on the same set of facts. We have considered the comment and are not making any changes to the regulations.

Sections §§ 422.750 and 423.750—Types of Intermediate Sanctions and Civil Monetary Penalties

We proposed reorganizing § 422.750 and § 423.750, to distinguish the three different types of intermediate sanctions from CMPs. We also proposed to clarify that each of the three intermediate sanctions, (suspension of enrollment, suspension of payment, and suspension of marketing) would remain in effect until we are satisfied that the reasons for the initial suspensions have been corrected and are not likely to reoccur. This revision reflects our current policy and practice.

Comment: We received a comment stating that the suspension of all marketing activities is too severe for "noncompliant behavior." The commenter stated that the suspension should only be for the particular MA or Part D plan that is non-compliant.

Response: We are revising § 422.750(a) and § 423.750(a) to clarify that the marketing sanctions will be imposed only on CMS-specified plans. We did not intend to expand the scope of the sanction with our proposed change. Therefore, we have changed the proposed regulatory language to be consistent with the existing provisions.

For clarity, we proposed specifying at § 422.750(b) and § 423.750(b) that we may impose CMPs in the dollar amounts specified in § 422.760 and § 423.760. We proposed to remove the prior reference at § 422.750(a)(1) and § 423.750(a)(1) to the range of CMPs because it is confusing. We did not receive any comments on this provision and are adopting it as proposed.

Sections §§ 422.752 and 423.752—Basis for Imposing Intermediate Sanctions and Civil Money Penalties

At § 422.752 and § 423.752, we proposed to reorganize the regulation to clarify the breakdown of responsibility between CMS and the OIG for imposing intermediate sanctions and CMPs based on the type of violation involved. Specifically, we clarify that CMS may impose a suspension of enrollment, payment, or marketing on an MA organization or Part D sponsor for violations specified in § 422.752(a)(1) through (a)(8) and for violations specified in § 423.752(a)(1) through (a)(6).

As part of the reorganization to the regulation, we also proposed to add a new § 422.752(c) and § 423.752(c), to clarify that in addition to the intermediate sanctions, we continue to have authority to impose CMPs for contract determinations made under § 422.510(a) and § 423.509(a). However, as specified in § 422.752(c)(2) and § 423.752(c)(2), OIG would continue to have sole authority to impose CMPs for any determinations concerning the MA organization or the Part D sponsor committing or participating in false, fraudulent, or abusive activities affecting the Medicare program, including the submission of false or

fraudulent data, as stated in § 422.510(a)(4) and § 423.509(a)(4). We did not receive any comments on this provision and are adopting it as proposed.

Sections §§ 422.756 and 423.756—Procedures for Imposing Intermediate Sanctions and Civil Money Penalties

At § 422.756 and § 423.756, we proposed to eliminate the existing informal reconsideration process used for review of a decision by CMS to impose an intermediate sanction, and allow an MA organization or Part D sponsor to proceed directly to a hearing, pursuant to the same procedures used to appeal contract determinations in Subpart N. (See § 422.660 through § 422.698 and § 423.650 through § 423.669.) We believe it would be more efficient and effective to allow the MA organization or Part D sponsor to proceed to a hearing in appealing an intermediate sanction. We note that a request to appeal an intermediate sanction before a hearing officer does not delay the intermediate sanction from taking effect on the date specified in the sanction notice. We did not receive any comments on this provision and are adopting it as proposed.

Because we proposed to eliminate the informal reconsideration process, we proposed that an MA organization or Part D sponsor have an opportunity to present information to us that may affect our decision to impose an intermediate sanction prior to the sanction taking effect. We recognize there may be occasions when we receive information that we previously did not have when making a decision to impose an intermediate sanction. Therefore, we proposed that MA organizations and Part D sponsors have an opportunity to submit a written rebuttal statement as specified at § 422.756(a)(2) and § 423.756(a)(2), and to require the rebuttal statement be provided to us within ten (10) calendar days after the MA organization or sponsor receives notice of the intermediate sanction. The 10 calendar days begin the day after the notice of intermediate sanction is mailed to the plan. A notice of intermediate sanction is sent by overnight mail and by e-mail or fax.

In some cases we may decide to take multiple actions, for example, contract termination, intermediate sanction, or CMP, against an MA organization or Part D sponsor. We proposed to have the appeals of CMPs go to an ALJ while the appeals of other actions, such as an intermediate sanction or a termination, will be before a CMS hearing official. Although the same underlying conduct may be the basis for both actions we believe that the separate processes would result in more consistent decision making by hearing officers and ALJs. We did not receive any comments on this provision and are adopting as proposed.

In addition, in preparing this final rule with comment period, we recognized that we inadvertently omitted some corresponding revisions to the existing regulatory text. These changes are necessary to implement the policies that we articulated in the proposed rule and are finalizing here. Specifically, we are revising § 422.756(c) and § 423.756(c) to reflect the fact that we have eliminated the reconsideration process and that an intermediate sanction imposed by CMS will go into effect on the date specified in the notice (15 days after the date of notification) and a reconsideration, or now an appeal to a hearing officer, will not delay the effective date of the sanction. See page 29379 of the proposed rule. We are also revising §§ 422.756(d) and 423.756(d) to reflect the fact that we have eliminated the reconsideration process, that an appeal will not delay the effective date of the sanction, and that where the exception at § 422.756(d)(2) or § 423.756(d)(2) applies, CMS may make the sanction effective on a specified date prior to 15 days after the date of notification. The changes to § 422.756(d)(2) and § 423.756(d)(2) are consistent with our existing authority. We interpret the existing provisions to allow us to make a sanction effective at any time when there is a serious threat to an enrollee's health and safety, including prior to 15 days after notification. It is critical that we continue to have the ability to protect the interests of Part C and D enrollees by taking immediate action in some cases.

In addition, upon review, we realized that some typographical corrections to the proposed regulatory text at § 423.756(f) were necessary. Specifically, in the proposed rule, we realized that we had typographical errors at § 423.756(f)(2) and (f)(2)(v). We have corrected the cross-reference to § 423.509(c)(1) and replaced it with a cross-reference to § 423.752(c)(1). We have also replaced the reference at (f)(2)(v) to § 423.650 with a reference to Subpart T since those are now the appeals provisions that govern appeals of CMPs.

Sections §§ 422.758 and 423.758—Collection of Civil Money Penalties Imposed by CMS

At § 422.758 and § 423.758 we proposed to revise the section heading "Maximum amount of civil money penalties imposed by CMS" to read "Collection of civil money penalties imposed by CMS." In addition, we proposed to revise § 422.758 and § 423.758. Specifically, we proposed that we would initiate collection of the CMPs if the MA organization or Part D sponsor does not timely request a hearing, or if our decision to impose a CMP is upheld by an ALJ. We did not receive any comments on this provision and are adopting as proposed.

Sections §§ 422.760 and 423.760—Determinations Regarding the Amount of Civil Money Penalties and Assessment Imposed By CMS

We proposed redesignating the existing § 422.760 as § 422.764 and redesignating the existing § 423.760 as § 423.764 because in this rule we have explicitly outlined the CMP appeals procedures in proposed subpart T in parts 422 and 423.

We proposed adding a new § 422.760 and § 423.760 to clarify that we use the statutory factors in section 1128(A) of the Act in determining the appropriate amount of civil money penalties or assessments to impose on an MA organization or Part D sponsor. These factors, if applicable, include the nature of the conduct, the degree of culpability, the prior history of offenses, the financial condition of the MA organization or Medicare Part D sponsor presenting the claims, and other matters as fair administration may require. These factors are based on the same statutory factors used in other Medicare enforcement programs, including the nursing facility enforcement context.

We also proposed to clarify, in § 422.760(b) and § 423.760(b), the amounts that may be assessed for CMPs that we impose.

Comment: We received a comment stating that we should provide for additional mitigating factors that would affect the penalty determination as a result of the MA organization or Part D sponsor's noncompliance/deficiencies. The commenter suggested that we review mitigating factors such as the corrective action that the organization has taken and the nature and extent to which the organization has cooperated with CMS.

Response: We have reviewed the comment and believe that consideration of mitigating factors is already included in the proposed provision. We state that factors that may be reviewed include the degree of culpability of the MA organization, the history of the prior offenses by the organization and other matters as justice may require. We believe these proposed factors provide sufficient opportunity for us to adjust

sanctions as warranted. We are finalizing our proposal without modification.

Sections §§ 422.762 and 423.762—Settlement of Penalties

We proposed to add a new § 422.762 and § 423.762 to clarify that in accordance with section 1128A(f) of the Act, we have the authority to settle CMPs imposed by us. This provision would make it explicit that the parties may agree to settle the dispute instead of litigating an appeal. We did not receive any comments on this provision and are adopting as proposed.

Sections §§ 422.764 and 423.764—Other Applicable Provisions

We proposed to redesignate § 422.760 and § 423.760 as § 422.764 and § 423.764 respectively to conform to the changes proposed at the new § 422.760 and § 423.760. No substantive changes to the text were proposed. We did not receive any comments on this provision and are adopting it as proposed.

Subpart T—Appeal Procedures for Civil Money Penalties

We proposed to reserve subparts P, Q, R, and S in Part 422. In addition, we proposed to add a new subpart T in Part 422 and Part 423, respectively. These new subparts would outline the CMP appeal procedures for MA organizations and Part D sponsors.

Our current MA and Part D regulations do not specify which procedures an MA organization or Part D sponsor must use to appeal a CMS-imposed penalty under either of these two programs. The regulations at 42 CFR part 422.760 and 42 CFR part 423.760 state only that the provisions of section 1128A of the Act (except paragraphs (a) and (b)) apply to CMPs under this subpart to the same extent that they apply to a CMP or procedure under section 1128A of the Act. Nor have we issued any guidance directing parties to the appropriate appeals procedures for MA and Part D CMPs.

Therefore, to ensure a consistent approach in this area, we proposed incorporating appeals procedures for parties to use when appealing a CMP imposed under the MA or Part D program in a new subpart T in Parts 422 and 423 respectively.

Based on certain statutory requirements and policy considerations, we proposed to adopt CMP appeals procedures almost identical to those in part 498 of Title 42, which are used by certain Medicare providers and suppliers to challenge adverse agency enforcement decisions. Part 498 sets forth the rules for administrative and judicial review of CMS determinations that affect participation in the Medicare and Medicaid programs for a wide array of medical providers of services. These rules, issued on June 12, 1987 (52 FR 22446), have been used by CMS for more than 20 years and provide established appeals procedures for various types of adverse agency determinations. including civil money penalties imposed on nursing facilities. For numerous reasons laid out in the proposed rule, we believe the part 498 appeals procedures are the most appropriate procedures to use for hearing disputes involving a wide range of violations. We did not receive any comments on this provision and are generally adopting it as proposed. We are making a technical revision to remove proposed paragraphs § 422.1004(a)(2) and (a)(3), and § 423.1004(a)(2) and (a)(3) because they were inadvertently retained from the part 498 procedures.

While the statute authorizing CMPs in the MA and Part D programs requires the provisions of section 1128A of the Act, (except for subsections (a) and (b)), to apply to MA and Part D CMP proceedings, it does not require that section 1128A's provisions apply to other CMP appeals procedures in the exact same manner, or without some consideration for the MA or Part D program's unique characteristics. In fact, section 1857(g)'s "same manner" language appears throughout the Act and serves as the statutory basis for several different types of CMP enforcement and appeals procedures. Because program violations may vary by the type and nature of the violation, we have modified our CMP appeal procedures when necessary. Since the MA and Part D programs differ from the nursing facility program, we proposed modifying certain sections of part 498 to take into account some of these differences.

For example, we proposed removing the reconsideration step in the MA and Part D CMP appeals procedures since this step in part 498 only applies to initial determinations made for prospective providers entering the Medicare or Medicaid program and is not applicable to CMP appeals. Removing the reconsideration step in subpart T would also help expedite the CMP appeals process.

Since it is not clearly stated in part 498's regulations, we proposed to make explicit in our regulations that in a hearing of a CMP appeal before an ALJ or the Departmental Appeals Board (DAB), the ultimate burden of persuasion would rest on the MA organization or Part D sponsor. See the proposed rule for instances when the DAB has held that in a provider termination proceeding by the Secretary, the facility bears the ultimate burden of proving it is in compliance with program requirements (Hillman Rehabilitation Center, DAB No.1611 (1999), aff'd *Hillman Rehabilitation Center* v. *U.S.* No.98–3789 (GEB) (D.N.J. May 13, 1999)). We believe the administrative caselaw supports our decision to place the burden of proof on the affected party in an administrative hearing on the imposition of MA and Part D CMPs. We did not receive any comments on this provision and are finalizing it as proposed.

III. Provisions of the Final Rule With Comment Period

In this final rule with comment period, we are adopting the provisions as set forth in the May 25, 2007 proposed rule with the following revisions:

Amend § 422.2, "Definitions," by—

- Revising the proposed definition of the term "downstream entity" to read as follows: *Downstream entity* means any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the MA benefit, below the level of the arrangement between an a MA organization (or applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

Amend § 422.503 "General Provisions" by—

- Revising proposed paragraph (b)(4)(vi)(G)*(3)* to read as follows: The MA organization should have procedures to voluntarily self-report potential fraud or misconduct related to the MA program to CMS or its designee.

Amend § 422.504 "Contract provisions" by—

- Revising proposed paragraph (e)(2) for clarity.
- Revising proposed paragraph (i)(2)(i) for clarity.
- Revising paragraphs (i)(3) introductory text, (i)(3)(ii), and (i)(3)(iii) for clarity, and by deleting the term "providers."
- Revising paragraph (i)(4) introductory text by deleting the phrase "provider or."

Amend § 422.506 by—

- Revising proposed paragraph (b)(2)(i) to make the date of notice of nonrenewal by CMS August 1.
- Revising proposed paragraph (b)(3)(i) to clarify that a MA organization will have an opportunity to submit a corrective action plan (CAP) prior to

CMS providing a notice of intent to nonrenew.

• Revising proposed paragraphs (b)(3)(i) and (b)(3)(ii) to clarify that CAP submission deadlines are measured in calendar days.

Amend § 422.510 "Termination of contract by CMS" by—

• Revising proposed paragraph (a)(1) for clarity.

• Revising proposed paragraph (c)(1) to clarify that MA organizations will have the opportunity to submit a CAP before CMS notifies them of an intent to terminate.

Amend § 422.644 by—

• Revising proposed paragraph (d) to clarify that a CMS notice of an intent to nonrenew will be sent to a MA organization by August 1.

Amend § 422.750 by—

• Revising proposed paragraph (a)(3) to clarify that suspension of all marketing activities to Medicare beneficiaries by an MA organization applies only to specified MA plans.

Amend § 422.752 by—

• Revising proposed paragraph (c)(2) to reference section 1003 of chapter V of this title.

Amend § 422.756 by—

• Revising paragraph (c) to reflect the fact that we have eliminated the reconsideration process, and that an intermediate sanction imposed by CMS will go into effect on the date specified by the notice, and that an appeal will not delay the effective date of the sanction.

• Revising paragraph (d) to reflect the fact we have eliminated the reconsideration process, that an appeal will not delay the effective date of the sanction, and that where the exception at § 422.756(d)(2) applies, CMS may make the sanction effective on a specified date prior to 15 days after the date of notification.

Amend § 422.1004 by—

• Deleting proposed paragraphs (a)(2) and (a)(3).

• Redesignating paragraph (a)(1) as paragraph (a).

Amend § 422.1070, "Removal of hearing to Departmental Appeals Board," by—

• Revising paragraph (a) to correct a typographical error. The revised paragraph now reads: "At any time before the ALJ receives oral testimony, the Board may remove to itself any pending request for a hearing."

Amend § 423.4, "Definitions," by—

• Revising the proposed definition of the term "downstream entity" to read as follows: *Downstream entity* means any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the Part D benefit, below the level of the arrangement between a Part D plan sponsor (or applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

Amend § 423.504, "General Provisions" by—

• Revising paragraph (b)(4)(vi)(C) for clarity.

• Revising proposed paragraph (b)(4)(vi)(G)*(3)* to read: The Part D plan sponsor should have procedures to voluntarily self-report potential fraud or misconduct related to the Part D program to CMS or its designee.

Amend § 423.505, "Contract Provisions," by—

• Revising proposed paragraph (e)(2) for clarity.

• Revising proposed paragraph (i)(2)(i) for clarity.

• Revising proposed paragraph (i)(3) introductory text to read as follows: All contracts or written arrangements between Part D sponsors and first tier, downstream, and related entities must contain the following:

• Revising proposed paragraph (i)(3)(ii) to read as follows: Accountability provisions that indicate that the Part D sponsor may delegate activities or functions to a first tier, downstream, or related entity, only in a manner consistent with requirements set forth at paragraph (i)(4) of this section.

• Revising proposed paragraph (i)(3)(iv) to read as follows: A provision requiring the Part D sponsor's first tier, downstream, and related entities to produce upon request by CMS or its designees any books, contracts, records, including medical records and documentation of the MA organization, relating to the Part D program to either the sponsor to provide to CMS, or directly to CMS or its designees.

• Revise proposed paragraph (i)(3)(v) to read as follows: All contracts or written arrangements must specify that the first tier, downstream, and related entities must comply with all applicable Federal laws, regulations, and CMS instructions.

• Revise proposed paragraph (i)(4) introductory text and paragraph (i)(4)(v) to remove the word pharmacy.

Amend § 423.507 "Nonrenewal of Contract" by—

• Revising proposed paragraph (b)(2)(i) to make the date of notice of nonrenewal by CMS August 1.

• Revising proposed paragraph (b)(3) to clarify that a Part D sponsor will have an opportunity to submit a CAP prior to receiving a letter of intent to nonrenew.

• Revise proposed paragraphs (b)(3)(ii) and (b)(3)(iii) to clarify that CAP submission deadlines are measured in calendar days.

Amend § 423.509 "Termination of contract by CMS" by—

• Revising proposed paragraph (a)(1) for clarity.

• Correcting a typographical error in paragraph (a)(9) by replacing the reference to § 423.128 with a reference to § 423.50.

• Revising proposed paragraph (b) introductory text for clarity.

• Revising paragraph (c)(1) to clarify that before providing an intent to terminate, CMS will provide a Part D sponsor with an opportunity to submit a CAP.

• Correcting a typographical error in paragraph (c)(1) by replacing the term "MA organization" with the term "Part D plan sponsor."

Amend § 423.642 by—

• Revising proposed paragraph (d) to clarify that a CMS notice of an intent to nonrenew will be sent to a MA organization by August 1.

Amend § 423.750 by—

• Revising proposed paragraph (a)(3) to clarify that suspension of all marketing activities to Medicare beneficiaries by a Part D plan sponsor applies only to specified Part D plans.

Amend § 422.752 by—

• Revising proposed paragraph (c)(2) to reference section 1003 of Chapter V of this title.

Amend § 423.756 by—

• Revising paragraph (c) to reflect the fact that we have eliminated the reconsideration process, and that an intermediate sanction imposed by CMS will go into effect on the date specified by the notice, and that an appeal will not delay the effective date of the sanction.

• Revising paragraph (d) to reflect the fact we have eliminated the reconsideration process, that an appeal will not delay the effective date of the sanction, and that where the exception at § 423.756(d)(2) applies, CMS may make the sanction effective on a specified date prior to 15 days after the date of notification.

• Revising paragraph (f) to correct typographical errors.

Amend § 423.1004 by—

• Deleting proposed paragraphs (a)(2) and (a)(3).

• Redesignating paragraph (a)(1) as paragraph (a).

Amend § 423.1070, "Removal of hearing to Departmental Appeals Board," by—

• Revising paragraph (a) to correct a typographical error. The revised paragraph now reads: "At any time

before the ALJ receives oral testimony, the Board may remove to itself any pending request for a hearing.''

IV. Collection of Information Requirements

We received no public comments concerning the collection of information requirements of the proposed rule. Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

The following information collection requirements included in this proposed rule and their associated burdens are subject to the PRA.

We solicited public comment on each of the issues for the following sections of this document that contain information collection requirements and are not currently approved by the OMB.

Section § 422.503 General Provisions

Sections 422.503(b)(4)(vi)(C) and (b)(4)(vi)(D) require a MA organization to have a compliance plan, which includes measures to detect, correct, and prevent fraud, waste, and abuse. The compliance plan shall include effective training and education between the compliance officer and the MA organization's employees, managers and directors, the MA organization's first tier, downstream, and related entities; and, effective lines of communication between the compliance officer, members of the compliance committee, the MA organization's employees, managers and directors, and the MA organization's first tier, downstream, and related entities.

The burden associated with this requirement is the time and effort put forth by the MA organization to prepare a compliance plan that meets the requirements of this section. While this requirement is subject to the PRA, it is currently approved under OMB #0938–1004.

Section 422.503(b)(4)(vi)(G)(*3*) recommends a MA organization to have procedures in place for voluntary self-reporting of potential fraud or misconduct related to the MA program to the appropriate government authority. We recommend that the MA organization report potential fraud or misconduct related to the MA program to the appropriate government authority.

The burden associated with this recommendation is the time and effort put forth by the MA organization to implement procedures for voluntary self-reporting. We estimate it would take one MA organization 40 hours to fulfill this recommendation. The total number of MA organizations affected by this recommendation is 393. The total one-time burden for this recommendation would be 15,720 hours. We cannot anticipate how many plans will report any potentially fraudulent activities to CMS. However, based on historical evidence, we believe that less than 10 MA organizations will self-report potential fraud or misconduct related to the MA program. While this burden is subject to the PRA, we expect that less than 10 entities will be affected. Therefore, we believe these collection recommendations are exempt as specified at 5 CFR 1320.3(c)(4).

Section 422.504 Contract Provisions

Section 422.504(e)(2) requires MA organizations to agree to allow HHS, the Comptroller General, or their designees to audit, evaluate, and inspect any books, contracts, records, including medical records and documentation of the MA organization, its first tier, downstream, related entity, or its transferee that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract, or as the Secretary may deem necessary to enforce the contract.

The burden associated with this requirement is the time and effort put forth by the MA organization to maintain appropriate records and documentation. While this requirement is subject to the PRA, it is currently approved under OMB #0938–1004.

Section 422.504(i)(2) requires the MA organization to require all first tier, downstream, and related entities to agree that HHS, the Comptroller General, or their designees have the right to audit, evaluate, and inspect any books, contracts, records, including medical records and documentation of the first tier, downstream, and related entities involving transactions related to CMS' contract with the MA organization.

The burden associated with this requirement is the time and effort put forth by the MA organization's first tier, downstream, and related entities to maintain appropriate records and documentation. While the burden associated with this requirement is subject to the PRA, it is currently approved under OMB #0938–1004.

Section 422.505 Effective Date and Term of Contract

Section 422.505(c) requires MA organizations who wish not to renew their contract to submit a notice of intent to CMS.

The burden associated with this requirement is the time and effort put forth by the MA organization to prepare the notice and submit it to CMS. While this requirement is subject to the PRA, it is currently approved under OMB #0938–0753.

Section 422.506 Nonrenewal of Contract

Section 422.506 provides a MA organization an opportunity to develop and submit a CAP to correct the deficiencies that are the basis of the termination decision. The MA organization must submit the CAP within 45 days of receiving notice of termination.

The burden associated with this requirement is the time and effort it would take for the MA organization to develop and submit a CAP. While this requirement is subject to the PRA, we expect less than 10 entities will be affected by receiving a notice of intent to nonrenew. Therefore, we believe these collection requirements are exempt as specified at 5 CFR 1320.3(c)(4).

Section 423.504 General Provisions

Sections 423.504(b)(4)(vi)(C) and (b)(4)(vi)(D) require Part D Sponsors to have a compliance plan, which includes measures to detect, correct, and prevent fraud, waste, and abuse. The compliance plan shall include effective training and education between the compliance officer and the Part D sponsor's employees, managers and directors, and the Part D plan sponsor's first tier, downstream, and related entities; and, effective lines of communication between the compliance officer, members of the compliance committee, the Part D sponsor's employees, managers and directors, and the Part D sponsor's first tier, downstream, and related entities.

The burden associated with this requirement is the time and effort put

forth by the Part D sponsor to prepare a compliance plan that meets the requirements of this section. While this requirement is subject to the PRA, it is currently approved under OMB #0938–1000.

Section 423.504(b)(4)(vi)(G)(*3*) recommends a Part D sponsor have procedures in place for voluntary self-reporting of potential fraud or misconduct related to the Part D program to the appropriate government authority. We recommend that the Part D sponsor report potential fraud or misconduct related to the Part D program to the appropriate government authority.

The burden associated with this recommendation is the time and effort put forth by the Part D sponsor to implement procedures for voluntary self-reporting. We estimate it will take one Part D sponsor 40 hours annually to fulfill this recommendation. The total number of Part D sponsors affected by this recommendation is 91. The total one-time burden would be 3,640 hours. We cannot anticipate how many plans will report any potentially fraudulent activities to CMS. However, in the event a Part D sponsor self-reports potential fraud or misconduct related to the Part D sponsor the total burden would be 5 hours annually. If every sponsor reports potential fraud or misconduct, the total burden would be 455 annual hours.

Section 423.505 Contract Provisions

Section 423.505(e)(2) requires Part D sponsors to make available its premises, physical facilities, equipment, and records that relate to its Medicare enrollees, and any additional relevant information that CMS may require. The Part D sponsor also agrees to make available any books, contracts, records, including medical records and documentation of its first tier, downstream, and related entities involving transactions related to CMS' contract with the Part D sponsor.

The burden associated with this requirement is the time and effort put forth by the Part D sponsor to make available records that relate to its Medicare enrollees. The burden associated with this requirement is currently approved under OMB #0938–1000.

Section 423.505(i)(2) requires the Part D sponsor to require all first tier, downstream, and related entities to agree that HHS, the Comptroller General, or their designees have the right to inspect, evaluate, and audit any books, contracts, records, including medical records and documentation of the first tier, downstream, and related entities involving transactions related to CMS' contract with the Part D sponsor.

The burden associated with this requirement is the time and effort put forth by the Part D sponsor's first tier, downstream, and related entities to maintain appropriate records and documentation. While this requirement is subject to the PRA, it is currently approved under OMB #0938–1000. However, we have prepared the following analysis of the costs and burden associated with our proposal to require sponsors to include a provision in their contracts requiring their first tier and downstream entities to produce or make available their books and records.

In the January 28, 2005 final rule that implemented the Medicare Prescription Drug Program (70 FR 4194), we noted that "The administrative cost estimates are based on taking into account the normal fixed costs associated with administering a prescription drug benefit, for example, such functions as claims processing, responding to customer inquiries, information, dissemination, appeals processes, pharmacy network negotiations, and contracting. The other factor taken into account when developing our estimate is that Prescription Drug Plans (PDPs) and Medicare Advantage Prescription Drug Plans (MA–PDs) will likely incur slightly higher administrative costs during the initial few years of the Part D benefit due to start-up costs related to implementation and initial operation for a new benefit." The narrative explains that the average administrative costs associated with insurance products are typically expressed as a percentage relative to net standard benefit expenses and that the administrative load is expected to decline slightly over time. For purposes of this analysis, the impact is presented in burden hours and broken out into requests for purposes of:

1. Provision in contracts;
2. BI Audit; and
3. Investigation of complaints.

1. Provision in Contracts

Ultimately, this additional provision would have to be discussed like all other provisions of a contract between a Part D sponsor and its first tier, downstream, and related entities. Since we have the authority to request this information and the Part D sponsor has attested to providing this data, we do not believe that this issue would be contentious or constitute negotiation discussion. We believe that, at the most, this provision would require 1 hour of attorney time to draft and discuss the provision.

2. BI Audit

Currently, there are a total of 650 Part D contracts (90 of those contracts represent PDPs and the remainder, 560 contracts, represents MA–PDs and employer groups). A further breakdown of those numbers out to the plan level would be: 4,927 total MA–PDs and PDP plans (including employer groups). We note that if employer groups are excluded, the actual number drops to 4,191.

Based on this information, it is believed that 16 percent of the plans will be audited during the course of a contract year. Of the plans audited, it is estimated that approximately 10 percent of the plans will be required to produce evidence or other supporting documentation related to "first tier, downstream and other related entities." It is further asserted that the labor hours required to produce the required documentation for those entities would be estimated at 10 hours per plan. Therefore, based on the number of Part D plans, the percentage of organizations that might be required to produce documentation for "first tier, downstream, and other related entities" and the number of labor hours required to produce this documentation we expect that the total impact would be 140 hours in administrative costs. The following table summarizes our calculation of the burden estimate for Part D plans:

Total number of Part D plans (PDP, MA–PD & Employer Groups)	650
Percentage of plans to be audited (16%)	104
Percentage of plans audited that would be required to produce additional documentation for "first tier, downstream and related entities" (10%)	10
Burden hours required to assemble documentation and submit to CMS (10 hours/plan)	100

3. Investigation of Complaints

Based on the past 18 months, we assume that investigation of complaints that require contacting a Part D plan to request documentation from first tier, downstream, and related entities would be approximately six instances. In the following table, we show our estimate of burden hours for downstream entities:

Total number of Part D plans (PDP, MA–PD & Employer Groups)	650
Percentage of plans to be audited (16%)	104

Percentage of plans audited that would be required to produce additional documentation for "first tier, downstream and related entities" (10%)	10
Average number of "downstream entities" (e.g. pharmacy network):	
Retail	55,000
Mail Order	1
Home Infusion	150
Long Term Care	593
I/T/U	329
Total burden hours required for downstream entities to assemble and submit documentation to the Part D organizations (hours/organization) at 3 hrs/downstream entity	166,440

Section 423.506 Effective Date and Term of Contract.

This section states that an entity is determined qualified to renew its contract annually only if the Part D sponsor has not provided CMS with a notice of intention not to renew and CMS has not provided the Part D sponsor with a notice of intention not to renew.

The burden associated with this requirement is the time and effort put forth by the Part D sponsor to prepare a notice of intent not to renew and submit it to CMS. While this requirement is subject to the PRA, it is currently approved under OMB #0938–0964.

Section 423.507 Nonrenewal of Contract.

Section 423.507 provides a Part D Plan Sponsor an opportunity to develop and submit a corrective action plan (CAP) to correct the deficiencies that are the basis of the termination decision. The Part D Sponsor must submit the CAP within 45 days of receiving notice of termination.

The burden associated with this requirement is the time and effort it would take for the Part D Sponsor to develop and submit a CAP. While this requirement is subject to the PRA, we expect less than 10 entities will be affected by receiving a notice of an intent to nonrenew; therefore, we believe these collection requirements are exempt as specified at 5 CFR 1320.3(c)(4).

As reflected in the table that follows, the aggregate annual burden associated with the collection of information section totals 73,236 hours.

OMB No.	Requirements	Number of respondents	Burden hours	Total annual burden
0938–1004	422.503(b)(4)(vi)(C) and (b)(4)(vi)(D), 422.504(e)(2) & 422.504(i)(2).	393	96 hours	12,576 hours (based on 131 responses per year).
None-requesting OMB approval.	422.503(b)(4)(vi)(G)(3)	393	40 hours	15,720 hours (based on every plan reporting fraud or misconduct).
0938–0753	422.505(c)	5–10	2 hours per notice	20 hours (estimated using 10 respondents).
None/Exempt	422.506	Less than 10	N/A	N/A.
0938–1000*	423.504(b)(4)(vi)(C) and (b)(4)(vi)(D), 423.505(e)(2), & 423.505(i)(2).	430	96 hours	41,280 hours.
None-requesting OMB approval.	423.504(b)(4)(vi)(G)(3)	91	40 hours	3,640 hours.
Exemption mentioned in 0938–0964.	423.506	Less than 10	N/A	N/A.
None/Exempt	423.507	Less than 10	N/A	N/A.
Total Annual Burden				73,236 hours.

*This package will be revised to reflect new respondent numbers & annual burden, which are previously discussed in this section (166,440 hours). The total annual burden of 73,236 hours includes 19,360 new hours, which added to 166,440 gives a total new burden of 185,800 hours which have not previously been approved.

If you comment on any of these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group, *Attn.:* Melissa Musotto, CMS–4124–F, Room C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850; and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, *Attn:* Carolyn Lovett, CMS Desk Officer, (CMS–4124–P), *carolyn_lovett@omb.eop.gov*. Fax (202) 395–6974.

V. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule. The provisions of this final rule with comment period would require MA and Part D sponsors to spend a total of approximately 186,000 additional hours on the functions addressed in this proposed rule. This includes our reestimates of burden. The details behind these estimates are presented in the preceding Paperwork Reduction Act section.

Assuming an average cost to plans and downstream entities of $37.50 [1] an

[1] The hourly rate of $37.50 for the burden requirement was developed using the Department of Labor May 2006 National Average wage for management analysts. The May 2006 rate for this

Continued

hour for staff time spent on auditing and related functions covered by this final rule with comment period, the total net incremental cost of this proposal would be approximately $7 million ($37.50 × 185,000 hours), far below the $100 million threshold for a major rule. This cost will be spread more or less evenly across participating plans, and hence would impose negligible burden on any plan in relation to existing administrative costs.

In the Regulatory Impact Analysis of the January 28, 2005 final rule that implemented the Medicare Prescription Drug Program (70 FR 4194), we noted that "The administrative cost estimates are based on taking into account the normal fixed costs associated with administering a prescription drug benefit, for example, such functions as claims processing, responding to customer inquiries, information, dissemination, appeals processes, pharmacy network negotiations, and contracting." This estimate included audit and related costs. The estimate was that administrative costs would constitute about one tenth of the cost of the program, or about $5 billion a year. (Similar estimates were prepared for the Medicare Advantage program's final rule.) Accordingly, the estimated cost of this final rule with comment period adds negligibly to the total administrative costs of these programs.

With respect to economic benefits, we have no reliable basis for estimating the effects of these proposals. It is important to understand that MA and Part D sponsors—not the government—bear the direct consequences of all their program costs, including unnecessary costs created by downstream entities. These plans are paid on a capitated basis and the amounts paid are not adjusted for realized costs. Hence, these plans already have strong incentives to prevent all forms of waste, including fraud and abuse. Accordingly, we estimate the benefits of these proposals as likely to be small, though larger than the costs involved. These benefits will accrue primarily to the plans themselves and, over time, to the participants who pay lower premiums as a result of plans' cost-reducing incentives.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 million to $29 million in any 1 year. For details, see the Small Business Administration's regulation that set forth the current size standards for health care industries (65 FR 69432). Individuals and States are not included in the definition of a small entity. As explained above, this final rule with comment period will not impose consequential costs on affected entities. Accordingly, we have determined that this final rule with comment period will not have a significant economic impact on a substantial number of small entities, and are not preparing an initial regulatory flexibility analysis.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $120 million. This rule will have no consequential effect on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications.

List of Subjects

42 CFR Part 422

Administrative practice and procedure, Grant programs-health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs-health, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 1. The authority citation for part 422 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A—General Provisions

■ 2. Section 422.2 is amended by adding the definitions "Downstream entity", "First tier entity", and "Related entity" to read as follows:

§ 422.2 Definitions.

* * * * *

Downstream entity means any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the MA benefit, below the level of the arrangement between an MA organization (or applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

First tier entity means any party that enters into a written arrangement, acceptable to CMS, with an MA organization or applicant to provide administrative services or health care services for a Medicare eligible individual under the MA program.

* * * * *

Related entity means any entity that is related to the MA organization by common ownership or control and

(1) Performs some of the MA organization's management functions under contract or delegation;

(2) Furnishes services to Medicare enrollees under an oral or written agreement; or

(3) Leases real property or sells materials to the MA organization at a cost of more than $2,500 during a contract period.

* * * * *

Subpart K—Contracts With Medicare Advantage Organizations

■ 3. Amend § 422.503 by—

■ A. Revising paragraph (b)(4)(vi) introductory text.

■ B. Revising paragraphs (b)(4)(vi)(C) and (b)(4)(vi)(D).

■ C. Adding paragraph (b)(4)(vi)(G)(*3*).

■ D. Removing paragraph (b)(4)(vi)(H).

The revisions and additions read as follows:

occupation was $37.15. The $37.50 rate accounts for an increase of approximately 1%.

§ 422.503 General provisions.

* * * * *

(b) * * *

(4) * * *

(vi) A compliance plan, which must include measures to detect, correct, and prevent fraud, waste, and abuse, shall include the following elements:

* * * * *

(C) Effective training and education between the compliance officer and the MA organization's employees, managers and directors, and the MA organization's first tier, downstream, and related entities.

(D) Effective lines of communication between the compliance officer, members of the compliance committee, the MA organization's employees, managers and directors, and the MA organization's first tier, downstream, and related entities.

* * * * *

(G) * * *

(3) The MA organization should have procedures to voluntarily self-report potential fraud or misconduct related to the MA program to CMS or its designee.

* * * * *

■ 4. Amend § 422.504 by—

■ A. Republishing paragraph (e) introductory text.

■ B. Revising paragraph (e)(1) introductory text.

■ C. Revising paragraph (i) heading and (i)(1).

■ D. Revising paragraph (i)(2) introductory text.

■ E. Revising paragraph (i)(2)(i).

■ F. Revising paragraph (i)(3) introductory text.

■ G. Revising paragraph (i)(3)(ii).

■ H. Revising paragraph (i)(3)(iii).

■ I. Revising paragraph (i)(4) introductory text.

The revisions and additions read as follows:

§ 422.504 Contract provisions.

* * * * *

(e) *Access to facilities and records.* The MA organization agrees to the following:

(1) HHS, the Comptroller General, or their designee may evaluate, through inspection, audit, or other means—

* * * * *

(2) HHS, the Comptroller General, or their designees have the right to audit, evaluate, and inspect any books, contracts, records, including medical records and documentation of the MA organization, its first tier, downstream, related entity(s), or its transferee that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract, or as the Secretary may deem necessary to enforce the contract.

* * * * *

(i) *MA organization relationship with first tier, downstream, and related entities.* (1) Notwithstanding any relationship(s) that the MA organization may have with first tier, downstream, and related entities, the MA organization maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS.

(2) The MA organization agrees to require all first tier, downstream, and related entities to agree that—

(i) HHS, the Comptroller General, or their designees have the right to audit, evaluate, and inspect any books, contracts, records, including medical records and documentation of the first tier, downstream, and related entities involving transactions related to CMS' contract with the MA organization.

* * * * *

(3) All contracts or written arrangements between MA organizations and first tier, downstream, and related entities must contain the following:

* * * * *

(ii) Accountability provisions that indicate that the MA organization may only delegate activities or functions to a first tier, downstream, or related entity, in a manner consistent with the requirements set forth at paragraph (i)(4) of this section.

(iii) A provision requiring that any services or other activity performed by a first tier, downstream, or related entity in accordance with a contract or written agreement are consistent and comply with the MA organization's contractual obligations.

(4) If any of the MA organizations' activities or responsibilities under its contract with CMS are delegated to other parties, the following requirements apply to any first tier, downstream and related entity:

* * * * *

■ 5. Amend § 422.505 by revising paragraph (c) to read as follows:

§ 422.505 Effective date and term of contract.

* * * * *

(c) *Renewal of contract.* In accordance with § 422.506, contracts are renewed annually only if the MA organization has not provided CMS with a notice of intention not to renew and CMS has not provided the MA organization with a notice of intention not to renew.

* * * * *

■ 6. Amend § 422.506 by—

■ A. Revising paragraph (b)(2) introductory text.

■ B. Revising paragraph (b)(2)(i).

■ C. Redesignating paragraph (b)(3) as (b)(4).

■ D. Adding a new paragraph (b)(3).

The revisions and additions read as follows:

§ 422.506 Nonrenewal of contract.

* * * * *

(b) * * *

(2) *Notice of non-renewal.* CMS provides notice of its decision not to authorize renewal of a contract as follows:

(i) To the MA organization by August 1 of the contract year.

* * * * *

(3) *Corrective action plan.*

(i) Before providing a notice of intent to non-renew the contract, CMS will provide the MA organization with a reasonable opportunity to develop and submit a corrective action plan (CAP).

(ii) The MA organization must develop and submit the CAP within 45 calendar days of receiving a request for a CAP.

(iii) If CMS determines the CAP is unacceptable, CMS will provide the MA organization with an additional 30 calendar days to submit a revised CAP.

(iv) If CMS determines the CAP is acceptable, CMS will notify the MA organization of a deadline by which the CAP must be fully implemented. CMS has sole discretion on whether the CAP is fully implemented.

(v) Failure to develop and implement a CAP within the timeframes specified in paragraphs (b)(3)(i) through (b)(3)(iii) of this section may result in the non-renewal of the MA contract.

* * * * *

■ 7. Amend § 422.510 by—

■ A. Republishing paragraph (a) introductory text.

■ B. Revising paragraph (a)(1).

■ C. Revising paragraph (b) introductory text.

■ D. Revising paragraph (b)(2) heading.

■ E. Revising paragraph (b)(2)(i).

■ F. Revising paragraph (c).

The revisions read as follows:

§ 422.510 Termination of contract by CMS.

(a) *Termination by CMS.* CMS may terminate a contract for any of the following reasons:

(1) The MA organization has failed substantially to carry out the terms of its current or previous contract terms with CMS.

* * * * *

(b) *Notice.* If CMS decides to terminate a contract for reasons other than the grounds specified in

§ 422.510(a)(4) or § 422.510(a)(5), it gives notice of the termination as follows:

* * * * *

(2) *Expedited termination of contract by CMS.*

(i) For terminations based on violations prescribed in § 422.510(a)(4) or § 422.510(a)(5), CMS notifies the MA organization in writing that its contract will be terminated on a date specified by CMS. If termination is effective in the middle of a month, CMS has the right to recover the prorated share of the capitation payments made to the MA organization covering the period of the month following the contract termination.

* * * * *

(c) *Corrective action plan.*

(1) *General.* Before providing a notice of an intent to terminate a contract for reasons other than the grounds specified in paragraphs (a)(4) or (a)(5) of this section, CMS will provide the MA organization with a reasonable opportunity to develop and submit a corrective action plan (CAP).

(i) The MA organization must develop and submit the CAP within 45 days of receiving a request for a CAP.

(ii) If CMS determines the CAP is unacceptable, CMS will provide the MA organization with an additional 30 days to submit a revised CAP.

(iii) If CMS determines the CAP is acceptable, CMS will notify the MA organization of a deadline by which the CAP must be fully implemented. CMS has sole discretion on whether the CAP is fully implemented.

(iv) Failure to develop and implement a CAP within the timeframes specified in paragraphs (c)(1)(i) through (c)(1)(iii) may result in the termination of the MA contract.

(2) *Exceptions.* If a contract is terminated under § 422.510(a)(4) or § 422.510(a)(5), the MA organization will not have the opportunity to submit a CAP.

* * * * *

Subpart N—Medicare Contract Determinations and Appeals

■ 8. Amend § 422.644 by—

■ A. Republishing paragraph (b) introductory text.

■ B. Revising paragraph (b)(2).

■ C. Revising paragraph (c).

■ D. Revising paragraph (d).

The revisions read as follows:

§ 422.644 Notice of contract determination.

* * * * *

(b) The notice specifies—

* * * * *

(2) The MA organization's right to request a hearing.

(c) For CMS-initiated terminations, CMS mails notice to the MA organization 90 calendar days before the anticipated effective date of the termination. For terminations based on determinations described at § 422.510(a)(4) or § 422.510(a)(5) CMS notifies the MA organization of the date that it will terminate the organization's MA contract.

(d) When CMS determines that it will not authorize a contract renewal, CMS mails the notice to the MA organization by August 1 of the current contract year.

■ 9. Section 422.646 is revised to read as follows:

§ 422.646 Effect of contract determination.

The contract determination is final and binding unless a timely request for a hearing is filed under § 422.662.

§ 422.648 [Removed]

■ 10. Section 422.648 is removed.

§ 422.650 [Removed]

■ 11. Section 422.650 is removed.

§ 422.652 [Removed]

■ 12. Section 422.652 is removed.

§ 422.654 [Removed]

■ 13. Section 422.654 is removed.

§ 422.656 [Removed]

■ 14. Section 422.656 is removed.

§ 422.658 [Removed]

■ 15. Section 422.658 is removed.

■ 16. Revise § 422.660 to read as follows:

§ 422.660 Right to a hearing and burden of proof.

(a) The following parties are entitled to a hearing:

(1) A contract applicant that has been determined to be unqualified to enter into a contract with CMS under Part C of Title XVIII of the Act pursuant to § 422.501.

(2) An MA organization whose contract has been terminated pursuant to § 422.510.

(3) An MA organization whose contract has not been renewed pursuant to § 422.506.

(4) An MA organization who has had an intermediate sanction imposed pursuant to § 422.752(a) through (b).

(b) The MA organization bears the burden of proof to demonstrate that it was in substantial compliance with the requirements of the MA program on the earliest of the following three dates:

(1) The date the organization received written notice of the contract determination or intermediate sanction.

(2) The date of the most recent on-site audit conducted by CMS.

(3) The date of the alleged breach of the current contract or past substantial noncompliance as determined by CMS.

(c) Notice of any decision favorable to the MA organization appealing a determination that it is not qualified to enter into a contract with CMS must be issued by July 15 for the contract in question to be effective on January 1 of the following year.

■ 17. Amend § 422.662 by revising paragraph (b) to read as follows:

§ 422.662 Request for hearing.

* * * * *

(b) *Time for filing a request.* A request for a hearing must be filed within 15 calendar days from the date CMS notifies the MA organization of its determination.

* * * * *

■ 18. Revise § 422.664 to read as follows:

§ 422.664 Postponement of effective date of a contract determination when a request for a hearing is filed timely.

(a) *Hearing.* When a request for a hearing is timely filed, CMS will postpone the proposed effective date of the contract determination listed at § 422.641 until a hearing decision is reached and affirmed by the Administrator following review according to § 422.692 in instances where an MA organization or CMS requests Administrator review and the Administrator accepts the matter for review.

(b) *Exceptions:* (1) If a final decision is not reached on CMS' determination for an initial contract by July 15, CMS will not enter into a contract with the applicant for the following year.

(2) A contract terminated in accordance with § 422.510(a)(4) or § 422.510(a)(5) will be terminated on the date specified by CMS and will not be postponed if a hearing is requested.

■ 19. Amend § 422.670 by revising paragraph (a) to read as follows:

§ 422.670 Time and place of hearing.

(a) The hearing officer fixes a time and place for the hearing, which is not to exceed 30 calendar days from the receipt of request for the hearing, and sends written notice to the parties. The notice informs the parties of—

(1) The general and specific issues to be resolved, the burden of proof, and information about the hearing procedure, and

(2) The ability to conduct formal discovery.

* * * * *

■ 20. Revise § 422.682 to read as follows:

§ 422.682 Discovery.

(a) Either party may make a request to another party for the production of documents for inspection and copying which are relevant and material to the issues before the hearing officer.

(b) The hearing officer will provide the parties with a reasonable time for inspection and reproduction of documents, provided that discovery is concluded at least 10 calendar days prior to the hearing.

(c) The hearing officer's order on discovery matters is final.

■ 21. Revise § 422.684 to read as follows:

§ 422.684 Prehearing and summary judgment.

(a) *Prehearing.* The hearing officer may schedule a prehearing conference if he or she believes that a conference would more clearly define the issues.

(b) *Summary judgment.* Either party to the hearing may ask the hearing officer to rule on a motion for summary judgment.

■ 22. Amend § 422.692 by—
■ A. Revising paragraph (a).
■ B. Revising paragraph (b).
■ C. Redesignating paragraph (c) as paragraph (e).
■ D. Adding a new paragraph (c).
■ E. Adding a new paragraph (d).

The revisions and additions read as follows:

§ 422.692 Review by Administrator.

(a) *Request for review by Administrator.* CMS or an MA organization that has received a hearing decision regarding a contract determination may request review by the Administrator within 15 calendar days of receiving the hearing decision as provided under § 422.690(b). Both the MA organization and CMS may provide written arguments to the Administrator for review.

(b) *Decision to review the hearing decision.* After receiving a request for review, the Administrator has the discretion to elect to review the hearing decision in accordance with paragraph (d) of this section or to decline to review the hearing decision.

(c) *Notification of Administrator determination.* The Administrator notifies both parties of his or her determination regarding review of the hearing decision within 30 calendar days of receiving the request for review. If the Administrator declines to review the hearing decision or the Administrator does not make a determination regarding review within 30 calendar days, the decision of the hearing officer is final.

(d) *Review by the Administrator.* If the Administrator elects to review the hearing decision regarding a contract determination, the Administrator shall review the hearing officer's decision and determine, based upon this decision, the hearing record, and any written arguments submitted by the MA organization or CMS, whether the determination should be upheld, reversed, or modified.

* * * * *

■ 23. Amend § 422.696 by—
■ A. Revising the section heading.
■ B. Revising paragraph (a).

The revisions read as follows:

§ 422.696 Reopening of an initial contract determination or decision of a hearing officer or the Administrator.

(a) *Initial determination.* CMS may reopen and revise an initial determination upon its own motion.

* * * * *

§ 422.698 [Removed]

■ 24. Section 422.698 is removed.

Subpart O—Intermediate Sanctions

■ 25. Revise § 422.750 to read as follows:

§ 422.750 Types of intermediate sanctions and civil money penalties.

(a) The following intermediate sanctions may be imposed and will continue in effect until CMS is satisfied that the deficiency on which the determination was based has been corrected and is not likely to reoccur:

(1) Suspension of enrollment of Medicare beneficiaries.

(2) Suspension of payment to the MA organization for Medicare beneficiaries who are enrolled in the MA plan.

(3) Suspension of all marketing activities to Medicare beneficiaries by an MA organization for specified MA plans.

(b) CMS may impose civil money penalties as specified in § 422.760.

■ 26. Amend § 422.752 by—
■ A. Revising the section heading.
■ B. Revising paragraph (a) introductory text.
■ C. Revising paragraph (b).
■ D. Adding a new paragraph (c).

The revisions and additions read as follows:

§ 422.752 Basis for imposing intermediate sanctions and civil money penalties.

(a) *All intermediate sanctions.* For the violations listed in this paragraph, CMS may impose one or more of the sanctions as specified in § 422.750(a) on any MA organization that has a contract in effect. The MA organization may also be subject to other applicable remedies available under law.

* * * * *

(b) *Suspension of enrollment and marketing.* If CMS makes a determination that could lead to a contract termination under § 422.510(a), CMS may impose the intermediate sanctions at § 422.750(a)(1) and (a)(3).

(c) *Civil Money Penalties.*

(1) *CMS.* In addition to, or in place of, any intermediate sanctions, CMS may impose civil money penalties in the amounts specified in § 422.760 for any of the determinations at § 422.510(a), except § 422.510(a)(4).

(2) *OIG.* In addition to, or in place of any intermediate sanctions imposed by CMS, the OIG, in accordance with part 1003 of Chapter V of this title, may impose civil money penalties for the following:

(i) Violations listed at § 422.752(a).

(ii) Determinations made pursuant to § 422.510(a)(4).

■ 27. Amend § 422.756 by—
■ A. Revising the section heading.
■ B. Revising paragraph (a).
■ C. Revising paragraph (b).
■ D. Revising paragraph (c).
■ E. Revising paragraph (d).
■ F. Revising paragraph (f).

The revisions read as follows:

§ 422.756 Procedures for imposing intermediate sanctions and civil money penalties.

(a) *Notice of intermediate sanction and opportunity to respond.*

(1) *Notice of intent.* Before imposing the intermediate sanction, CMS—

(i) Sends a written notice to the MA organization stating the nature and basis of the proposed intermediate sanction and the MA organization's right to a hearing as specified in paragraph (b) of this section; and

(ii) Sends the OIG a copy of the notice.

(2) *Opportunity to respond.* CMS allows the MA organization 10 calendar days from receipt of the notice to provide a written rebuttal. CMS considers receipt of notice as the day after notice is sent by fax, e-mail, or submitted for overnight mail.

(b) *Hearing.* The MA organization may request a hearing before a CMS hearing officer. A written request must be received by CMS within 15 calendar days of the MA organization receiving the notice of intent to impose an intermediate sanction. A request for a hearing under § 422.660 does not delay the date specified by CMS when the sanction becomes effective. The MA organization must follow the right to a

hearing procedure as specified at § 422.660 through § 422.684.

(c) If CMS determines that a MA organization has acted or failed to act as specified in § 422.752, CMS may—

(1) Require the MA organization to suspend acceptance of applications made by Medicare beneficiaries for enrollment in the sanctioned MA plan during the sanction period;

(2) In the case of a violation under § 422.752, suspend payments to the MA organization for Medicare beneficiaries enrolled in the sanctioned MA plan during the sanction period; and

(3) Require the MA organization to suspend all marketing activities for the sanctioned MA plan to Medicare enrollees.

(d) Effective date and duration of sanctions. (1) Effective date. Except as provided in paragraph (d)(2) of this section, a sanction is effective 15 calendar days after the date that the organization is notified of the decision to impose the sanction.

(2) Exception. If CMS determines that the MA organization's conduct poses a serious threat to an enrollee's health and safety, CMS may make the sanction effective on an earlier date that CMS specifies.

* * * * *

(f) Notice to impose *civil money penalties.*

(1) *CMS notice to OIG.* If CMS determines that an MA organization has failed to comply with a requirement as described in § 422.752, CMS notifies the OIG of this determination. OIG may impose a civil money penalty upon an MA organization as specified at § 422.752(c)(2).

(2) *CMS notice of civil money penalties to MA organizations.* If CMS makes a determination to impose a CMP as described in § 422.752(c)(1), CMS will send a written notice of the Agency's decision to impose a civil money penalty to include—

(i) A description of the basis for the determination.

(ii) The basis for the penalty.

(iii) The amount of the penalty.

(iv) The date the penalty is due.

(v) The MA organization's right to a hearing under subpart T of this part.

(vi) Information about where to file the request for hearing.

■ 28. Revise § 422.758 to read as follows:

§ 422.758 Collection of civil money penalties imposed by CMS.

(a) When an MA organization does not request a hearing, CMS initiates collection of the civil money penalty following the expiration of the timeframe for requesting an ALJ hearing as specified in Subpart T of this part.

(b) If an MA organization requests a hearing and CMS' decision to impose a civil money penalty is upheld, CMS may initiate collection of the civil money penalty once the administrative decision is final.

§ 422.760 [Redesignated as § 422.764]

■ 29. Amend § 422.760 by—

■ A. Redesignate § 422.760 as § 422.764.

■ B. Add a new § 422.760 to read as follows:

§ 422.760 Determinations regarding the amount of civil money penalties and assessment imposed by CMS.

(a) *Determining the appropriate amount of any penalty.* In determining the amount of penalty imposed under § 422.752(c)(1), CMS will consider as appropriate:

(1) The nature of the conduct;

(2) The degree of culpability of the MA organization;

(3) The harm which resulted or could have resulted from the conduct of MA organization;

(4) The financial condition of the MA organization;

(5) The history of prior offenses by the MA organization or principals of the MA organization; and,

(6) Such other matters as justice may require.

(b) *Amount of penalty.* CMS may impose civil money penalties in the following amounts:

(1) If the deficiency on which the determination is based has directly adversely affected (or has the substantial likelihood of adversely affecting) one or more MA enrollees—up to $25,000 for each determination.

(2) For each week that a deficiency remains uncorrected after the week in which the MA organization receives CMS' notice of the determination—up to $10,000.

(3) If CMS makes a determination that a MA organization has terminated its contract other than in a manner described under § 422.512 and that the MA organization has therefore failed to substantially carry out the terms of the contract—$250 per Medicare enrollee from the terminated MA plan or plans at the time the MA organization terminated its contract, or $100,000, whichever is greater.

■ 30. Add a new § 422.762 to read as follows:

§ 422.762 Settlement of penalties.

For civil money penalties imposed by CMS, CMS may settle civil money penalty cases at any time before a final decision is rendered.

Subpart P [Added and Reserved]

■ 31. Subpart P is added and reserved.

Subpart Q [Added and Reserved]

■ 32. Subpart Q is added and reserved.

Subpart R [Added and Reserved]

■ 33. Subpart R is added and reserved.

Subpart S [Added and Reserved]

■ 34. Subpart S is added and reserved.

■ 35. A new subpart T is added to read as follows:

Subpart T—Appeal Procedures for Civil Money Penalties

Sec.

Subpart T—Appeal procedures for Civil Money Penalties

§ 422.1000 Basis and scope.

(a) *Statutory basis.*

(1) Section 1128A(c)(2) of the Act provides that the Secretary may not collect a civil money penalty until the affected party has had notice and opportunity for a hearing.

(2) Section 1857(g) of the Act provides that, for MA organizations out of compliance with the requirements in part 422 specified remedies may be imposed instead of, or in addition to, termination of the MA organization's contract. Section 1857(g)(4) of the Act makes certain provisions of section 1128A of the Act applicable to civil money penalties imposed on MA organizations.

(b) [Reserved]

§ 422.1002 Definitions.

As used in this subpart—

Affected party means an MA organization impacted by an initial determination or if applicable, by any subsequent determination or decision issued under this part. For this definition, "*party*" means the affected party or CMS, as appropriate.

ALJ stands for Administrative Law Judge.

Departmental Appeals Board or Board means a Board established in the Office of the Secretary to provide impartial review of disputed decisions made by the operating components of the Department.

MA organization has the meaning given the term in § 422.2.

§ 422.1004 Scope and applicability.

(a) *Scope.* This subpart sets forth procedures for reviewing initial determinations that CMS makes with respect to the matters specified in paragraph (b) of this section.

(b) *Initial determinations by CMS.* CMS makes initial determinations with respect to the imposition of civil money penalties in accordance with part 422, subpart O.

§ 422.1006 Appeal rights.

(a) *Appeal rights of MA organizations.*

(1) Any MA organization dissatisfied with an initial determination as specified in § 422.1004, has a right to a hearing before an ALJ in accordance with this subpart and may request Departmental Appeals Board review of the ALJ decision.

(2) MA organizations may request judicial review of the Departmental Appeals Board's decision that imposes a CMP.

(b) [Reserved]

§ 422.1008 Appointment of representatives.

(a) An affected party may appoint as its representative anyone not disqualified or suspended from acting as a representative in proceedings before the Secretary or otherwise prohibited by law.

(b) If the representative appointed is not an attorney, the party must file written notice of the appointment with the ALJ or the Departmental Appeals Board.

(c) If the representative appointed is an attorney, the attorney's statement that he or she has the authority to represent the party is sufficient.

§ 422.1010 Authority of representatives.

(a) A representative appointed and qualified in accordance with § 422.1008 may, on behalf of the represented party—

(1) Give and accept any notice or request pertinent to the proceedings set forth in this part;

(2) Present evidence and allegations as to facts and law in any proceedings affecting that party to the same extent as the party; and

(3) Obtain information to the same extent as the party.

(b) A notice or request may be sent to the affected party, to the party's representative, or to both. A notice or request sent to the representative has the same force and effect as if it had been sent to the party.

§ 422.1012 Fees for services of representatives.

Fees for any services performed on behalf of an affected party by an attorney appointed and qualified in accordance with § 422.1008 are not subject to the provisions of section 206 of Title II of the Act, which authorizes the Secretary to specify or limit those fees.

§ 422.1014 Charge for transcripts.

A party that requests a transcript of prehearing or hearing proceedings or Board review must pay the actual or estimated cost of preparing the transcript unless, for good cause shown by that party, the payment is waived by the ALJ or the Departmental Appeals Board, as appropriate.

§ 422.1016 Filing of briefs with the Administrative Law Judge or Departmental Appeals Board, and opportunity for rebuttal.

(a) *Filing of briefs and related documents.* If a party files a brief or related document such as a written argument, contention, suggested finding of fact, conclusion of law, or any other written statement, it must submit an original and 1 copy to the ALJ or the Departmental Appeals Board, as appropriate. The material may be filed by mail or in person and must include a statement certifying that a copy has been furnished to the other party.

(b) *Opportunity for rebuttal.* (1) The other party will have 20 days from the date of mailing or personal service to submit any rebuttal statement or additional evidence. If a party submits a rebuttal statement or additional evidence, it must file an original and 1 copy with the ALJ or the Board and furnish a copy to the other party.

(2) The ALJ or the Board will grant an opportunity to reply to the rebuttal statement only if the party shows good cause.

§ 422.1018 Notice and effect of initial determinations.

(a) *Notice of initial determination.*— CMS, as required under § 422.756(f)(2), mails notice of an initial determination to the affected party, setting forth the basis or reasons for the determination, the effect of the determination, and the party's right to a hearing, and information about where to file the request for hearing.

(b) *Effect of initial determination.* An initial determination is binding unless—

(1) The affected party requests a hearing; or

(2) CMS revises its decision.

§ 422.1020 Request for hearing.

(a) *Manner and timing of request.*

(1) An MA organization is entitled to a hearing as specified in § 422.1006 and may file a request for a hearing with the Departmental Appeals Board office specified in the initial determination.

(2) The MA organization or its legal representative or other authorized official must file the request, in writing, to the appropriate Departmental Appeals Board office, with a copy to CMS, within 60 calendar days from

receipt of the notice of initial determination, to request a hearing before an ALJ to appeal any determination by CMS to impose a civil money penalty.

(b) *Content of request for hearing.* The request for hearing must—

(1) Identify the specific issues, and the findings of fact and conclusions of law with which the affected party disagrees; and

(2) Specify the basis for each contention that the finding or conclusion of law is incorrect.

§ 422.1022 Parties to the hearing.

The parties to the hearing are the affected party and CMS, as appropriate.

§ 422.1024 Designation of hearing official.

(a) The Chair of the Departmental Appeals Board, or his or her delegate designates an ALJ or a member or members of the Departmental Appeals Board to conduct the hearing.

(b) If appropriate, the Chair or the delegate may substitute another ALJ or another member or other members of the Departmental Appeals Board to conduct the hearing.

(c) As used in this part, "ALJ" includes a member or members of the Departmental Appeals Board who are designated to conduct a hearing.

§ 422.1026 Disqualification of Administrative Law Judge.

(a) An ALJ may not conduct a hearing in a case in which he or she is prejudiced or partial to the affected party or has any interest in the matter pending for decision.

(b) A party that objects to the ALJ designated to conduct the hearing must give notice of its objections at the earliest opportunity.

(c) The ALJ will consider the objections and decide whether to withdraw or proceed with the hearing.

(1) If the ALJ withdraws, another ALJ will be designated to conduct the hearing.

(2) If the ALJ does not withdraw, the objecting party may, after the hearing, present its objections to the Departmental Appeals Board as reasons for changing, modifying, or reversing the ALJ's decision or providing a new hearing before another ALJ.

§ 422.1028 Prehearing conference.

(a) At any time before the hearing, the ALJ may call a prehearing conference for the purpose of delineating the issues in controversy, identifying the evidence and witnesses to be presented at the hearing, and obtaining stipulations accordingly.

(b) On the request of either party or on his or her own motion, the ALJ may adjourn the prehearing conference and reconvene at a later date.

§ 422.1030 Notice of prehearing conference.

(a) *Timing of notice.* The ALJ will fix a time and place for the prehearing conference and mail written notice to the parties at least 10 calendar days before the scheduled date.

(b) *Content of notice.* The notice will inform the parties of the purpose of the conference and specify what issues are sought to be resolved, agreed to, or excluded.

(c) *Additional issues.* Issues other than those set forth in the notice of determination or the request for hearing may be considered at the prehearing conference if—

(1) Either party gives timely notice to that effect to the ALJ and the other party; or

(2) The ALJ raises the issues in the notice of prehearing conference or at the conference.

§ 422.1032 Conduct of prehearing conference.

(a) The prehearing conference is open to the affected party or its representative, to the CMS representatives and their technical advisors, and to any other persons whose presence the ALJ considers necessary or proper.

(b) The ALJ may accept the agreement of the parties as to the following:

(1) Facts that are not in controversy.

(2) Questions that have been resolved favorably to the affected party after the determination in dispute.

(3) Remaining issues to be resolved.

(c) The ALJ may request the parties to indicate the following:

(1) The witnesses that will be present to testify at the hearing.

(2) The qualifications of those witnesses.

(3) The nature of other evidence to be submitted.

§ 422.1034 Record, order, and effect of prehearing conference.

(a) *Record of prehearing conference.* (1) A record is made of all agreements and stipulations entered into at the prehearing conference.

(2) The record may be transcribed at the request of either party or the ALJ.

(b) *Order and opportunity to object.* (1) The ALJ issues an order setting forth the results of the prehearing conference, including the agreements made by the parties as to facts not in controversy, the matters to be considered at the hearing, and the issues to be resolved.

(2) Copies of the order are sent to all parties and the parties have 10 calendar days to file objections to the order.

(3) After the 10 calendar days have elapsed, the ALJ settles the order.

(c) *Effect of prehearing conference.* The agreements and stipulations entered into at the prehearing conference are binding on all parties, unless a party presents facts that, in the opinion of the ALJ, would make an agreement unreasonable or inequitable.

§ 422.1036 Time and place of hearing.

(a) The ALJ fixes a time and place for the hearing and gives the parties written notice at least 10 calendar days before the scheduled date.

(b) The notice informs the parties of the general and specific issues to be resolved at the hearing.

§ 422.1038 Change in time and place of hearing.

(a) The ALJ may change the time and place for the hearing either on his or her own initiative or at the request of a party for good cause shown, or may adjourn or postpone the hearing.

(b) The ALJ may reopen the hearing for receipt of new evidence at any time before mailing the notice of hearing decision.

(c) The ALJ gives the parties reasonable notice of any change in time or place or any adjournment or reopening of the hearing.

§ 422.1040 Joint hearings.

When two or more affected parties have requested hearings and the same or substantially similar matters are at issue, the ALJ may, if all parties agree, fix a single time and place for the prehearing conference or hearing and conduct all proceedings jointly. If joint hearings are held, a single record of the proceedings is made and a separate decision issued with respect to each affected party.

§ 422.1042 Hearing on new issues.

(a) *Basic rules.* (1) Within the time limits specified in paragraph (b) of this section, the ALJ may, at the request of either party, or on his or her own motion, provide a hearing on new issues that impinge on the rights of the affected party.

(2) The ALJ may consider new issues even if CMS has not made initial determinations on them, and even if they arose after the request for hearing was filed or after a prehearing conference.

(3) The ALJ may give notice of hearing on new issues at any time after the hearing request is filed and before the hearing record is closed.

(b) *Notice and conduct of hearing on new issues.*

(1) Unless the affected party waives its right to appear and present evidence,

notice of the time and place of hearing on any new issue will be given to the parties in accordance with § 422.1036.

(2) After giving notice, the ALJ will, except as provided in paragraph (c) of this section, proceed to hearing on new issues in the same manner as on an issue raised in the request for hearing.

(c) *Remand to CMS.* At the request of either party, or on his or her own motion, in lieu of a hearing under paragraph (b) of this section, the ALJ may remand the case to CMS for consideration of the new issue and, if appropriate, a determination. If necessary, the ALJ may direct CMS to return the case to the ALJ for further proceedings.

§ 422.1044 Subpoenas.

(a) *Basis for issuance.* The ALJ, upon his or her own motion or at the request of a party, may issue subpoenas if they are reasonably necessary for the full presentation of a case.

(b) *Timing of request by a party.* The party must file a written request for a subpoena with the ALJ at least 5 calendar days before the date set for the hearing.

(c) *Content of request.* The request must:

(1) Identify the witnesses or documents to be produced;

(2) Describe their addresses or location with sufficient particularity to permit them to be found; and

(3) Specify the pertinent facts the party expects to establish by the witnesses or documents, and indicate why those facts could not be established without use of a subpoena.

(d) *Method of issuance.* Subpoenas are issued in the name of the Secretary.

§ 422.1046 Conduct of hearing.

(a) *Participants in the hearing.* The hearing is open to the parties and their representatives and technical advisors, and to any other persons whose presence the ALJ considers necessary or proper.

(b) *Hearing procedures.* (1) The ALJ inquires fully into all of the matters at issue, and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(2) If the ALJ believes that there is relevant and material evidence available which has not been presented at the hearing, he may, at any time before mailing of notice of the decision, reopen the hearing to receive that evidence.

(3) The ALJ decides the order in which the evidence and the arguments of the parties are presented and the conduct of the hearing.

(4) CMS has the burden of coming forward with evidence related to disputed findings that is sufficient (together with any undisputed findings and legal authority) to establish a prima facie case that CMS has a legally sufficient basis for its determination.

(5) The affected party has the burden of coming forward with evidence sufficient to establish the elements of any affirmative argument or defense which it offers.

(6) The affected party bears the ultimate burden of persuasion. To prevail, the affected party must prove by a preponderance of the evidence on the record as a whole that there is no basis for the determination.

(c) *Review of the penalty.* When an administrative law judge finds that the basis for imposing a civil money penalty exists, as specified in § 422.752, the administrative law judge may not—

(1) Set a penalty of zero or reduce a penalty to zero, or

(2) Review the exercise of discretion by CMS to impose a civil money penalty.

§ 422.1048 Evidence.

Evidence may be received at the hearing even though inadmissible under the rules of evidence applicable to court procedure. The ALJ rules on the admissibility of evidence.

§ 422.1050 Witnesses.

Witnesses at the hearing testify under oath or affirmation. The representative of each party is permitted to examine his or her own witnesses subject to interrogation by the representative of the other party. The ALJ may ask any questions that he or she deems necessary. The ALJ rules upon any objection made by either party as to the propriety of any question.

§ 422.1052 Oral and written summation.

The parties to a hearing are allowed a reasonable time to present oral summation and to file briefs or other written statements of proposed findings of fact and conclusions of law. Copies of any briefs or other written statements must be sent in accordance with § 422.1016.

§ 422.1054 Record of hearing.

A complete record of the proceedings at the hearing is made and transcribed in all cases.

§ 422.1056 Waiver of right to appear and present evidence.

(a) *Waiver procedures.* (1) If an affected party wishes to waive its right to appear and present evidence at the hearing, it must file a written waiver with the ALJ.

(2) If the affected party wishes to withdraw a waiver, it may do so, for good cause, at any time before the ALJ mails notice of the hearing decision.

(b) *Effect of waiver.* If the affected party waives the right to appear and present evidence, the ALJ need not conduct an oral hearing except in one of the following circumstances:

(1) The ALJ believes that the testimony of the affected party or its representatives or other witnesses is necessary to clarify the facts at issue.

(2) CMS shows good cause for requiring the presentation of oral evidence.

(c) *Dismissal for failure to appear.* If, despite the waiver, the ALJ sends notice of hearing and the affected party fails to appear, or to show good cause for the failure, the ALJ will dismiss the appeal in accordance with § 422.1060.

(d) *Hearing without oral testimony.* When there is no oral testimony, the ALJ will—

(1) Make a record of the relevant written evidence that was considered in making the determination being appealed, and of any additional evidence submitted by the parties;

(2) Furnish to each party copies of the additional evidence submitted by the other party; and

(3) Give both parties a reasonable opportunity for rebuttal.

(e) Handling of briefs and related statements. If the parties submit briefs or other written statements of evidence or proposed findings of facts or conclusions of law, those documents will be handled in accordance with § 422.1016.

§ 422.1058 Dismissal of request for hearing.

(a) The ALJ may, at any time before mailing the notice of the decision, dismiss a hearing request if a party withdraws its request for a hearing or the affected party asks that its request be dismissed.

(b) An affected party may request a dismissal by filing a written notice with the ALJ.

§ 422.1060 Dismissal for abandonment.

(a) The ALJ may dismiss a request for hearing if it is abandoned by the party that requested it.

(b) The ALJ may consider a request for hearing to be abandoned if the party or its representative—

(1) Fails to appear at the prehearing conference or hearing without having previously shown good cause for not appearing; and

(2) Fails to respond, within 10 calendar days after the ALJ sends a "show cause" notice, with a showing of good cause.

§ 422.1062 Dismissal for cause.

On his or her own motion, or on the motion of a party to the hearing, the ALJ may dismiss a hearing request either entirely or as to any stated issue, under any of the following circumstances:

(a) *Res judicata.* There has been a previous determination or decision with respect to the rights of the same affected party on the same facts and law pertinent to the same issue or issues which has become final either by judicial affirmance or, without judicial consideration, because the affected party did not timely request reconsideration, hearing, or review, or commence a civil action with respect to that determination or decision.

(b) *No right to hearing.* The party requesting a hearing is not a proper party or does not otherwise have a right to a hearing.

(c) *Hearing request not timely filed.* The affected party did not file a hearing request timely and the time for filing has not been extended.

§ 422.1064 Notice and effect of dismissal and right to request review.

(a) Notice of the ALJ's dismissal action is mailed to the parties. The notice advises the affected party of its right to request that the dismissal be vacated as provided in § 422.1066.

(b) The dismissal of a request for hearing is binding unless it is vacated by the ALJ or the Departmental Appeals Board.

§ 422.1066 Vacating a dismissal of request for hearing.

An ALJ may vacate any dismissal of a request for hearing if a party files a request to that effect within 60 calendar days from receipt of the notice of dismissal and shows good cause for vacating the dismissal.

§ 422.1068 Administrative Law Judge's decision.

(a) *Timing, basis and content.* As soon as practical after the close of the hearing, the ALJ issues a written decision in the case. The decision is based on the evidence of record and contains separate numbered findings of fact and conclusions of law.

(b) *Notice and effect.* A copy of the decision is mailed to the parties and is binding on them unless—

(1) A party requests review by the Departmental Appeals Board within the time period specified in § 422.846, and the Board reviews the case;

(2) The Departmental Appeals Board denies the request for review and the party seeks judicial review by filing an action in a United States District Court or, in the case of a civil money penalty, in a United States Court of Appeals;

(3) The decision is revised by an ALJ or the Departmental Appeals Board; or

(4) The decision is a recommended decision directed to the Board.

§ 422.1070 Removal of hearing to Departmental Appeals Board.

(a) At any time before the ALJ receives oral testimony, the Board may remove to itself any pending request for a hearing.

(b) Notice of removal is mailed to each party.

(c) The Board conducts the hearing in accordance with the rules that apply to ALJ hearings under this subpart.

§ 422.1072 Remand by the Administrative Law Judge.

(a) If CMS requests remand, and the affected party concurs in writing or on the record, the ALJ may remand any case properly before him or her to CMS for a determination satisfactory to the affected party.

(b) The ALJ may remand at any time before notice of hearing decision is mailed.

§ 422.1074 Right to request Departmental Appeals Board review of Administrative Law Judge's decision or dismissal.

Either of the parties has a right to request Departmental Appeals Board review of the ALJ's decision or dismissal order, and the parties are so informed in the notice of the ALJ's action.

§ 422.1076 Request for Departmental Appeals Board review.

(a) *Manner and time of filing.* (1) Any party that is dissatisfied with an ALJ's decision or dismissal of a hearing request, may file a written request for review by the Departmental Appeals Board.

(2) The requesting party or its representative or other authorized official must file the request with the DAB within 60 calendar days from receipt of the notice of decision or dismissal, unless the Board, for good cause shown by the requesting party, extends the time for filing.

(b) *Content of request for review.* A request for review of an ALJ decision or dismissal must specify the issues, the findings of fact or conclusions of law with which the party disagrees, and the basis for contending that the findings and conclusions are incorrect.

§ 422.1078 Departmental Appeals Board action on request for review.

(a) *Request by CMS.* The Departmental Appeals Board may dismiss, deny, or grant a request made by CMS for review of an ALJ decision or dismissal.

(b) *Request by the affected party.* The Board may deny or grant the affected party's request for review or may dismiss the request for one of the following reasons:

(1) The affected party requests dismissal of its request for review.

(2) The affected party did not file timely or show good cause for late filing.

(3) The affected party does not have a right to review.

(4) A previous determination or decision, based on the same facts and law, and regarding the same issue, has become final through judicial affirmance or because the affected party failed to timely request reconsideration, hearing, Board review, or judicial review, as appropriate.

(c) *Effect of dismissal.* The dismissal of a request for Departmental Appeals Board review is binding and not subject to further review.

(d) *Review panel.* If the Board grants a request for review of the ALJ's decision, the review will be conducted by a panel of three members of the Board, designated by the Chair or Deputy Chair.

§ 422.1080 Procedures before the Departmental Appeals Board on review.

The parties are given, upon request, a reasonable opportunity to file briefs or other written statements as to fact and law, and to appear before the Departmental Appeals Board to present evidence or oral arguments. Copies of any brief or other written statement must be sent in accordance with § 422.1016.

§ 422.1082 Evidence admissible on review.

(a) The Departmental Appeals Board may admit evidence into the record in addition to the evidence introduced at the ALJ hearing, (or the documents considered by the ALJ if the hearing was waived), if the Board considers that the additional evidence is relevant and material to an issue before it.

(b) If it appears to the Board that additional relevant evidence is available, the Board will require that it be produced.

(c) Before additional evidence is admitted into the record—

(1) Notice is mailed to the parties (unless they have waived notice) stating that evidence will be received regarding specified issues; and

(2) The parties are given a reasonable time to comment and to present other evidence pertinent to the specified issues.

(d) If additional evidence is presented orally to the Board, a transcript is prepared and made available to any party upon request.

§ 422.1084 Decision or remand by the Departmental Appeals Board.

(a) When the Departmental Appeals Board reviews an ALJ's decision or order of dismissal, or receives a case remanded by a court, the Board may either issue a decision or remand the case to an ALJ for a hearing and decision or a recommended decision for final decision by the Board.

(b) In a remanded case, the ALJ initiates additional proceedings and takes other actions as directed by the Board in its order of remand, and may take other action not inconsistent with that order.

(c) Upon completion of all action called for by the remand order and any other consistent action, the ALJ promptly makes a decision or, as specified by the Board, certifies the case to the Board with a recommended decision.

(d) The parties have 20 calendar days from the date of a notice of a recommended decision to submit to the Board any exception, objection, or comment on the findings of fact, conclusions of law, and recommended decision.

(e) After the 20-calendar day period, the Board issues its decision adopting, modifying or rejecting the ALJ's recommended decision.

(f) If the Board does not remand the case to an ALJ, the following rules apply:

(1) The Board's decision—

(i) Is based upon the evidence in the hearing record and any further evidence that the Board receives during its review;

(ii) Is in writing and contains separate numbered findings of fact and conclusions of law; and

(iii) May modify, affirm, or reverse the ALJ's decision.

(2) A copy of the Board's decision is mailed to each party.

§ 422.1086 Effect of Departmental Appeals Board Decision.

(a) *General rule.* The Board's decision is binding unless—

(1) The affected party has a right to judicial review and timely files a civil action in a United States District Court or, in the case of a civil money penalty, in a United States Court of Appeals; or

(2) The Board reopens and revises its decision in accordance with § 422.862.

(b) *Right to judicial review.* Section 422.1006 specifies the circumstances under which an affected party has a right to seek judicial review.

(c) *Special Rules:* Civil Money Penalty—Finality of Board's decision. When CMS imposes a civil money penalty, notice of the Board's decision (or denial of review) is the final administrative action that initiates the 60-day period for seeking judicial review.

§ 422.1088 Extension of time for seeking judicial review.

(a) Any affected party that is dissatisfied with a Departmental Appeals Board decision and is entitled to judicial review must commence civil action within 60 calendar days from receipt of the notice of the Board's decision, unless the Board extends the time in accordance with paragraph (c) of this section.

(b) The request for extension must be filed in writing with the Board before the 60-calendar day period ends.

(c) For good cause shown, the Board may extend the time for commencing civil action.

§ 422.1090 Basis, timing, and authority for reopening an Administrative Law Judge or Board decision.

(a) *Basis and timing for reopening.* An ALJ of Departmental Appeals Board decision may be reopened, within 60 calendar days from the date of the notice of decision, upon the motion of the ALJ or the Board or upon the petition of either party to the hearing.

(b) *Authority to reopen.* (1) A decision of the Departmental Appeals Board may be reopened only by the Departmental Appeals Board.

(2) A decision of an ALJ may be reopened by that ALJ, by another ALJ if that one is not available, or by the Departmental Appeals Board. For purposes of this paragraph, an ALJ is considered to be unavailable if the ALJ has died, terminated employment, or been transferred to another duty station, is on leave of absence, or is unable to conduct a hearing because of illness.

§ 422.1092 Revision of reopened decision.

(a) *Revision based on new evidence.* If a reopened decision is to be revised on the basis of new evidence that was not included in the record of that decision, the ALJ or the Departmental Appeals Board—

(1) Notifies the parties of the proposed revision; and

(2) Unless the parties waive their right to hearing or appearance—

(i) Grants a hearing in the case of an ALJ revision; and

(ii) Grants opportunity to appear in the case of a Board revision.

(b) *Basis for revised decision and right to review.*

(1) If a revised decision is necessary, the ALJ or the Departmental Appeals Board, as appropriate, renders it on the basis of the entire record.

(2) If the decision is revised by an ALJ, the Departmental Appeals Board may review that revised decision at the request of either party or on its own motion.

§ 422.1094 Notice and effect of revised decision.

(a) *Notice.* The notice mailed to the parties states the basis or reason for the revised decision and informs them of their right to Departmental Appeals Board review of an ALJ revised decision, or to judicial review of a Board reviewed decision.

(b) *Effect*—(1) *ALJ revised decision.* An ALJ revised decision is binding unless it is reviewed by the Departmental Appeals Board.

(2) *Departmental Appeals Board revised decision.* A Board revised decision is binding unless a party files a civil action in a district court of the United States within the time frames specified in § 422.858.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 36. The authority citation for part 423 continues to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, and 1395hh).

Subpart A—General Provisions

■ 37. Section 423.4 is amended by adding the definitions of "Downstream entity", "First tier entity", and "Related entities" to read as follows:

§ 423.4 Definitions.

* * * * *

Downstream entity means any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the Part D benefit, below the level of the arrangement between a Part D plan sponsor (or applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

* * * * *

First tier entity means any party that enters into a written arrangement, acceptable to CMS, with a Part D plan sponsor or applicant to provide administrative services or health care services for a Medicare eligible individual under Part D.

* * * * *

Related entity means any entity that is related to the Part D sponsor by common ownership or control and

(1) Performs some of the Part D plan sponsor's management functions under contract or delegation;

(2) Furnishes services to Medicare enrollees under an oral or written agreement; or

(3) Leases real property or sells materials to the Part D plan sponsor at a cost of more than $2,500 during a contract period.

* * * * *

Subpart K—Application Procedures and Contracts With Part D Plan Sponsors

■ 39. Amend § 423.504 by—
■ A. Revising paragraph (b)(4)(vi) introductory text.
■ B. Revising paragraphs (b)(4)(vi)(C) and (b)(4)(vi)(D).
■ C. Adding paragraph (b)(4)(vi)(G)(*3*).
■ D. Removing paragraph (b)(4)(vi)(H).

The revisions and additions read as follows:

§ 423.504 General provisions.

* * * * *

(b) * * *

(4) * * *

(vi) A compliance plan, which must include measures to detect, correct, and prevent fraud, waste, and abuse, shall include the following elements:

* * * * *

(C) Effective training and education between the compliance officer and the Part D plan sponsor's employees, managers and directors, and the Part D plan sponsor's first tier, downstream, and related entities.

(D) Effective lines of communication between the compliance officer, members of the compliance committee. the Part D plan sponsor's employees, managers and directors, and the Part D plan sponsor's first tier, downstream, and related entities.

* * * * *

(G) * * *

(*3*) The Part D plan sponsor should have procedures to voluntarily self-report potential fraud or misconduct related to the Part D program to CMS or its designee.

* * * * *

■ 40. Amend § 423.505 by—
■ A. Republishing paragraph (b) introductory text.
■ B. Revising paragraph (b)(10).
■ C. Republishing paragraph (e) introductory text.
■ D. Revising paragraph (e)(1) introductory text.
■ E. Revising paragraph (e)(2).
■ F. Revising paragraph (i) heading and (i)(1).
■ G. Revising paragraph (i)(2) introductory text.
■ H. Revising paragraph (i)(2)(i).
■ I. Revising paragraph (i)(3) introductory text.
■ J. Revising paragraph (i)(3)(ii).
■ K. Revising paragraph (i)(3)(iii).
■ L. Adding paragraphs (i)(3)(iv) and (v).
■ M. Revising paragraph (i)(4) introductory text.
■ N. Revising paragraph (i)(4)(iv).

The revisions and additions read as follows:

§ 423.505 Contract provisions.

* * * * *

(b) *Requirements for contracts.* The Part D plan sponsor agrees to—

* * * * *

(10) Allow CMS to inspect and audit any books and records of a Part D plan sponsor and its delegated first tier, downstream and related entities, that pertain to the information regarding costs provided to CMS under paragraph (b)(9) of this section, or, if a fallback entity, the information submitted under subpart Q of this part.

* * * * *

(e) *Access to facilities and records.* The Part D plan sponsor agrees to the following:

(1) HHS, the Comptroller General, or their designee may evaluate, through audit, inspection, or other means—

* * * * *

(2) The Part D plan sponsor agrees to make available to HHS, the Comptroller General, or their designees, for the purposes specified in paragraph (d) of this section, its premises, physical facilities and equipment, records relating to its Medicare enrollees, and any additional relevant information that CMS may require. The Part D plan sponsor also agrees to make available any books, contracts, records and documentation of the Part D plan sponsor, first tier, downstream and related entity(s), or its transferee that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract, or as the Secretary may deem necessary to enforce the contract.

* * * * *

(i) *Relationship with first tier, downstream, and related entities.* (1) Notwithstanding any relationship(s) that the Part D plan sponsor may have with first tier, downstream, and related entities, the Part D sponsor maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS.

(2) The Part D sponsor agrees to require all first tier, downstream, and related entities to agree that—

(ii) HHS, the Comptroller General, or their designees have the right to audit, evaluate, and inspect any books, contracts, records including medical records, and documentation of the first tier, downstream, and related entities involving transactions related to CMS' contract with the Part D sponsor.

* * * * *

(3) All contracts or written arrangements between Part D sponsors and first tier, downstream, and related entities, must contain the following:

* * * * *

(ii) Accountability provisions that indicate that the Part D sponsor may delegate activities or functions to a first tier, downstream, or related entity only in a manner consistent with requirements set forth at paragraph (i)(4) of this section.

(iii) A provision requiring that any services or other activity performed by a related entity, first tier, downstream, and related entity in accordance with a contract or written agreement are consistent and comply with the Part D plan sponsor's contractual obligations.

(iv) A provision requiring the Part D sponsor's first tier, downstream, and related entities to produce upon request by CMS or its designees any books, contracts, records, including medical records and documentation of the MA organization, relating to the Part D program to either the sponsor to provide to CMS, or directly to CMS or its designees.

(v) All contracts or written arrangements must specify that first tier, downstream, and related entities must comply with all applicable Federal laws, regulations, and CMS instructions.

(4) If any of the Part D plan sponsors' activities or responsibilities under its contract with CMS is delegated to other parties, the following requirements apply to any first tier, downstream, and related entity:

* * * * *

(iv) All contracts or written arrangements must specify that the first tier, downstream, or related entity must comply with all applicable Federal laws, regulations, and CMS instructions.

* * * * *

■ 41. Amend § 423.506 by revising paragraph (c) to read as follows:

§ 423.506 Effective date and term of contract

* * * * *

(c) *Qualification to renew a contract.* In accordance with § 423.507, an entity is determined qualified to renew its contract annually only if the Part D plan sponsor has not provided CMS with a notice of intention not to renew and CMS has not provided the Part D

organization with a notice of intention not to renew.

* * * * *

■ 42. Amend § 423.507 by—
■ A. Revising paragraph (b)(2) introductory text.
■ B. Revising paragraph (b)(2)(i).
■ C. Redesignating paragraph (b)(3) as (b)(4).
■ D. Adding a new paragraph (b)(3).

The revisions and additions read as follows:

§ 423.507 Nonrenewal of contract.

* * * * *

(b) * * *

(2) *Notice of non-renewal.* CMS provides notice of its decision not to authorize renewal of a contract as follows:

(i) To the Part D plan sponsor by August 1 of the contract year.

* * * * *

(3) *Corrective action plan.* (i) Before providing a notice of an intent to nonrenew a contract, CMS will provide the Part D sponsor with a reasonable opportunity to develop and submit a corrective action plan (CAP).

(ii) The Part D sponsor must develop and submit the CAP within 45 calendar days of receiving a request for a CAP.

(iii) If CMS determines the CAP is unacceptable, CMS will provide the Part D sponsor with an additional 30 calendar days to submit a revised CAP.

(iv) If CMS determines the CAP is acceptable, CMS will notify the Part D sponsor of a deadline by which the CAP must be fully implemented. CMS has sole discretion on whether the CAP is fully implemented.

(v) Failure to develop and implement a CAP within the timeframes specified in paragraphs (b)(3)(i) through (b)(3)(iii) of this section may result in the nonrenewal of the Part D contract.

* * * * *

■ 43. Section 423.509 is amended by—
■ A. Revising paragraph (a)(1).
■ B. Revising paragraph (a)(9).
■ C. Revising paragraph (b) introductory text.
■ D. Revising paragraph (b)(2)(i).
■ E. Revising paragraph (c).

The revisions read as follows:

§ 423.509 Termination of contract by CMS.

(a) * * *

(1) The Part D plan sponsor has failed substantially to carry out the terms of its current or previous contract terms with CMS.

* * * * *

(9) Substantially fails to comply with the marketing requirements in § 423.50;

* * * * *

(b) *Notice.* If CMS decides to terminate a contract for reasons other than the grounds specified in § 423.509(a)(4) or § 423.509(a)(5), it gives notice of the termination as follows:

* * * * *

(2) *Expedited termination of contract by CMS.* (i) For terminations based on violations prescribed in § 423.509(a)(4) or § 423.509(a)(5), CMS notifies the Part D plan sponsor in writing that its contract will be terminated on a date specified by CMS. If termination is effective in the middle of a month, CMS has the right to recover the prorated share of the capitation payments made to the Part D plan sponsor covering the period of the month following the contract termination.

* * * * *

(c) *Corrective action plan*—(1) General. Before providing an intent to terminate a contract for reasons other than the grounds specified in paragraphs (a)(4) or (a)(5) of this section, CMS will provide the Part D plan sponsor with a reasonable opportunity to develop and submit a corrective action plan (CAP).

(i) The Part D plan sponsor must develop and submit the CAP within 45 calendar days of receiving a request for a CAP.

(ii) If CMS determines the CAP is unacceptable to CMS, the Part D plan sponsor will have an additional 30 calendar days to submit a revised CAP.

(iii) If CMS determines the CAP is acceptable, CMS will notify the Part D plan sponsor of a deadline by which the CAP must be fully implemented. CMS has sole discretion on whether the CAP is fully implemented.

(iv) Failure to develop and implement a CAP within the timeframes specified in paragraphs (c)(1)(i) through (c)(1)(iii) of this section, may result in the termination of the Part D contract.

(2) *Exceptions.* If a contract is terminated under § 423.509(a)(4) or § 423.509(a)(5), the Part D plan sponsor will not have the opportunity to submit a CAP.

* * * * *

Subpart N—Medicare Contract Determinations and Appeals

■ 44. Amend § 423.642 by—
■ A. Republishing paragraph (b) introductory text.
■ B. Revising paragraph (b)(2).
■ C. Revising paragraph (c).
■ D. Revising paragraph (d).

The revisions read as follows:

§ 423.642 Notice of contract determination

* * * * *

(b) The notice specifies the—

* * * * *

(2) The Part D sponsor's right to request a hearing.

(c) For CMS-initiated terminations, CMS mails notice to the Part D sponsor 90 calendar days before the anticipated effective date of the termination. For terminations based on determinations described at § 423.509(a)(4) or § 423.509(a)(5), CMS notifies the Part D sponsor of the date that it will terminate the organization's Part D contract.

(d) When CMS determines that it will not authorize a contract renewal, CMS mails the notice to the Part D sponsor by August 1 of the current contract year.

■ 45. Section 423.643 is revised to read as follows:

§ 423.643 Effect of contract determination.

The contract determination is final and binding unless a timely request for a hearing is filed under § 423.651.

§ 423.644 [Removed]

■ 46. Section 423.644 is removed.

§ 423.645 [Removed]

■ 47. Section 423.645 is removed.

§ 423.646 [Removed]

■ 48. Section 423.646 is removed.

§ 423.647 [Removed]

■ 49. Section 423.647 is removed.

§ 423.648 [Removed]

■ 50. Section 423.648 is removed.

§ 423.649 [Removed]

■ 51. Section 423.649 is removed.

■ 52. Revise § 423.650 to read as follows:

§ 423.650 Right to a hearing and burden of proof.

(a) The following parties are entitled to a hearing:

(1) A contract applicant that has been determined to be unqualified to enter into a contract with CMS pursuant to § 423.503.

(2) A Part D sponsor whose contract has been terminated pursuant to § 423.509.

(3) A Part D sponsor whose contract has not been renewed pursuant to § 423.507.

(4) A Part D sponsor who has had an intermediate sanction imposed according to § 423.752(a) and § 423.752(b).

(b) The Part D sponsor bears the burden of proof to demonstrate that it was in substantial compliance with the requirements of the Part D program on the earliest of the following three dates:

(1) The date the sponsor received written notice of the contract determination or intermediate sanction.

(2) The date of the most recent on-site audit conducted by CMS.

(3) The date of the alleged breach of the current contract or past substantial noncompliance as determined by CMS.

(c) Notice of any decision favorable to the Part D sponsor appealing a determination that it is not qualified to enter into a contract with CMS must be issued by July 15 for the contract in question to be effective on January 1 of the following year.

■ 53. Amend § 423.651 by revising paragraph (b) to read as follows:

§ 423.651 Request for hearing.

* * * * *

(b) *Time for filing a request.* A request for a hearing must be filed within 15 calendar days from the date CMS notifies the Part D sponsor of its determination.

* * * * *

■ 54. Revise § 423.652 to read as follows:

§ 423.652 Postponement of effective date of a contract determination when a request for a hearing is filed timely.

(a) *Hearing.* When a request for a hearing is timely filed, CMS will postpone the proposed effective date of the contract determination listed at § 423.641 until a hearing decision is reached and affirmed by the Administrator following review pursuant to § 423.666 in instances where a Part D sponsor or CMS requests Administrator review and the Administrator accepts the matter for review.

(b) *Exceptions:* (1) If a final decision is not reached on CMS' determination for an initial contract by July 15, CMS will not enter into a contract with the applicant for the following year.

(2) A contract terminated in accordance with § 423.509(a)(4) or § 423.509(a)(5) will be terminated on the date specified by CMS and will not be postponed if a hearing is requested.

■ 55. Amend § 423.655 by revising paragraph (a) to read as follows:

§ 423.655 Time and place of hearing.

(a) The hearing officer fixes a time and place for the hearing, which is not to exceed 30 calendar days from the receipt of request for the hearing, and sends written notice to the parties. The notice informs the parties of—

(1) The general and specific issues to be resolved, the burden of proof, and information about the hearing procedure, and

(2) The ability to conduct formal discovery.

* * * * *

■ 56. Revise § 423.661 to read as follows:

§ 423.661 Discovery.

(a) Either party may make a request to another party for the production of documents for inspection and copying which are relevant and material to the issues before the hearing office.

(b) The hearing officer will provide the parties with a reasonable time for inspection and reproduction of documents, provided that discovery concluded at least 10 calendar days prior to the hearing.

(c) The hearing officer's order on discovery matters is final.

■ 57. Revise § 423.662 to read as follows:

§ 423.662 Prehearing and summary judgment.

(a) *Prehearing.* The hearing officer may schedule a prehearing conference if he or she believes that a conference would more clearly define the issues.

(b) *Summdry judgment.* Either party to the hearing, may ask the hearing officer to rule on a motion for summary judgment.

■ 58. Amend § 423.666 by—

■ A. Revising paragraph (a).

■ B. Revising paragraph (b).

■ C. Redesignating paragraph (c) as paragraph (e).

■ D. Adding a new paragraph (c).

■ E. Adding a new paragraph (d).

The revisions and additions read as follows:

§ 423.666 Review by Administrator.

(a) *Request for review by Administrator.* CMS or a Part D sponsor that has received a hearing decision regarding a contract determination may request review by the Administrator within 15 calendar days of receiving the hearing decision as provided under § 423.665(b). Both the Part D sponsor and CMS may provide written arguments to the Administrator for review.

(b) *Decision to review the hearing decision.* After receiving a request for review, the Administrator has the discretion to elect to review the hearing determination in accordance with paragraph (d) of this section or to decline to review the hearing decision.

(c) *Notification of Administrator determination.* The Administrator notifies both parties of his or her determination regarding review of the hearing decision within 30 calendar days of receiving the request for review. If the Administrator declines to review the hearing decision or the Administrator does not make a determination regarding review within 30 calendar days, the decision of the hearing officer is final.

(d) *Review by the Administrator.* If the Administrator elects to review the hearing decision regarding a contract determination, the Administrator shall review the hearing officer's decision and determine, based upon this decision, the hearing record, and any written arguments submitted by the Part D sponsor or CMS, whether the determination should be upheld, reversed, or modified.

* * * * *

■ 59. Amend § 423.668 by—

■ A. Revising the section heading.

■ B. Revising paragraph (a).

The revisions read as follows:

§ 423.668 Reopening of an initial contract determination or decision of a hearing officer or the Administrator.

(a) *Initial determination.* CMS may reopen and revise an initial determination upon its own motion.

* * * * *

§ 423.669 [Removed]

■ 60. Section 423.669 is removed.

Subpart O—Intermediate Sanctions

■ 61. Revise § 423.750 to read as follows:

§ 423.750 Types of intermediate sanctions and civil money penalties.

(a) The following intermediate sanctions may be imposed and will continue in effect until CMS is satisfied that the deficiency on which the determination was based has been corrected and is not likely to reoccur.

(1) Suspension of enrollment of Medicare beneficiaries.

(2) Suspension of payment to the Part D plan sponsor for Medicare beneficiaries who are enrolled in the Part D plan.

(3) Suspension of all marketing activities to Medicare beneficiaries by a Part D plan sponsor for specified Part D plans.

(b) CMS may impose civil money penalties as specified in § 423.760.

■ 62. Amend § 423.752 by—

■ A. Revising the section heading.

■ B. Revising paragraph (a) introductory text.

■ C. Revising paragraph (b).

■ D. Adding a new paragraph (c).

The revisions and additions read as follows:

§ 423.752 Basis for imposing intermediate sanctions and civil money penalties.

(a) *All intermediate sanctions.* For the violations listed in this paragraph (a), CMS may impose one, or more, of the

sanctions as specified in § 423.750(a) on any Part D plan sponsor that has a contract in effect. The Part D plan sponsor may also be subject to other applicable remedies available under law.

* * * * *

(b) *Suspension of enrollment and marketing.* If CMS makes a determination that could lead to a contract termination under § 423.509(a), CMS may impose the intermediate sanctions at § 423.750(a)(1) and (a)(3).

(c) *Civil Money Penalties.* (1) *CMS.* In addition to, or in place of, any intermediate sanctions, CMS may impose civil money penalties in the amounts specified in § 423.760, for any of the determinations at § 423.509(a), except § 423.509(a)(4).

(2) *OIG.* In addition to, or in place of any intermediate sanctions imposed by CMS, the OIG, in accordance with part 1003 of Chapter V of this title, may impose civil money penalties for the following:

(i) Violations listed at § 423.752(a).

(ii) Determinations made pursuant to § 423.509(a)(4).

■ 63. Amend § 423.756 by—
■ A. Revising the section heading.
■ B. Revising paragraph (a).
■ C. Revising paragraph (b).
■ D. Revising paragraph (c).
■ E. Revising paragraph (d).
■ F. Revising paragraph (f)

The revisions read as follows:

§ 423.756 Procedures for imposing intermediate sanctions and civil money penalties.

(a) *Notice of intermediate sanction and opportunity to respond*—(1) *Notice of intent.* Before imposing the intermediate sanctions, CMS—

(i) Sends a written notice to the Part D plan sponsor stating the nature and basis of the proposed intermediate sanction, and the Part D plan sponsor's right to a hearing as specified in paragraph (b) of this section; and

(ii) Sends the OIG a copy of the notice.

(2) *Opportunity to respond.* CMS allows the Part D plan sponsor 10 calendar days from receipt of the notice to provide a written rebuttal. CMS considers receipt of notice as the day after notice is sent by fax, e-mail, or submitted for overnight mail.

(b) *Hearing.* The Part D sponsor may request a hearing before a CMS hearing officer. A written request must be received by CMS within 15 calendar days of the Part D sponsor receiving the notice of intent to impose an intermediate sanction. A request for a hearing under § 423.650 does not delay the date specified by CMS when the sanction becomes effective. The Part D sponsor must follow the right to a hearing procedure as specified at § 423.650 through § 423.662.

(c) If CMS determines that a Part D sponsor has acted or failed to act as specified in § 423.752, CMS may—

(1) Require the Part D sponsor to suspend acceptance of applications made by Medicare beneficiaries for enrollment in the sanctioned Part D plan during the sanction period:

(2) In the case of a violation under § 423.752, suspend payments to the Part D sponsor for Medicare beneficiaries enrolled in the sanctioned Part D plan during the sanction period; and

(3) Require the Part D sponsor to suspend all marketing activities for the sanctioned Part D plan to Medicare enrollees.

(d) Effective date and duration of sanctions. (1) Effective date. Except as provided in paragraph (d)(2) of this section, a sanction is effective 15 calendar days after the date that the organization is notified of the decision to impose the sanction.

(2) Exception. If CMS determines that the Part D sponsor's conduct poses a serious threat to an enrollee's health and safety, CMS may make the sanction effective on an earlier date that CMS specifies.

* * * * *

(f) *Notice to impose civil money penalties.* (1) *CMS notice to OIG.* If CMS determines that a Part D sponsor has committed an act or failed to comply with a requirement as described in § 423.752, CMS notifies the OIG of this determination. OIG may impose a civil money penalty upon a Part D sponsor as specified at § 423.752(c)(2).

(2) *CMS notice of civil money penalties to Part D plan sponsors.* If CMS makes a determination to impose a CMP described in § 423.752(c)(1), CMS will send a written notice of the Agency's decision to impose a civil money penalty to include—

(i) A description of the basis for the determination.

(ii) The basis for the penalty.

(iii) The amount of the penalty.

(iv) The date the penalty is due.

(v) The Part D sponsor's right to a hearing as specified under Subpart T of this part.

(vi) Information about where to file the request for hearing.

■ 64. Revise § 423.758 to read as follows:

§ 423.758 Collection of civil money penalties imposed by CMS.

(a) When a Part D plan sponsor does not request a hearing CMS initiates collection of the civil money penalty following the expiration of the timeframe for requesting an ALJ hearing as specified in Subpart T.

(b) If a Part D sponsor requests a hearing and CMS' decision to impose a civil money penalty is upheld, CMS may initiate collection of the civil money penalty once the administrative decision is final.

■ 65. Amend § 423.760 by—
■ A. Redesignating § 423.760 as § 423.764.
■ B. Adding a new § 423.760 to read as follows:

§ 423.760 Determinations regarding the amount of civil money penalties and assessment imposed by CMS.

(a) *Determining the appropriate amount of any penalty.* In determining the amount of penalty imposed under § 423.752(c)(1), CMS will consider as appropriate:

(1) The nature of the conduct;

(2) The degree of culpability of the Part D sponsor;

(3) The harm which resulted or could have resulted from the conduct of the Part D sponsor;

(4) The financial condition of the Part D sponsor;

(5) The history of prior offenses by the Part D sponsor or principals of the Part D sponsor; and,

(6) Such other matters as justice may require.

(b) *Amount of penalty.* CMS may impose civil money penalties in the following amounts:

(1) If the deficiency on which the determination is based has directly adversely affected (or has the substantial likelihood of adversely affecting) one or more Part D enrollees—up to $25,000 for each determination.

(2) For each week that a deficiency remains uncorrected after the week in which the Part D sponsor receives CMS' notice of the determination—up to $10,000.

(3) If CMS makes a determination that a Part D sponsor has terminated its contract other than in a manner described under § 423.510 and that the Part D sponsor has therefore failed to substantially carry out the terms of the contract, $250 per Medicare enrollee from the terminated Part D sponsor or plans at the time the Part D sponsor terminated its contract, or $100,000, whichever is greater.

■ 66. Add a new § 423.762 to read as follows:

§ 423.762 Settlement of penalties.

For civil money penalties imposed by CMS, CMS may settle civil money penalty cases at any time before a final decision is rendered.

■ 67. A new subpart T is added to read as follows:

Subpart T—Appeal Procedures for Civil Money Penalties

Sec.

Subpart T—Appeal Procedures for Civil Money Penalties

§ 423.1000 Basis and scope.

(a) *Statutory basis.* (1) Section 1128A(c)(2) of the Act provides that the Secretary may not collect a civil money penalty until the affected party has had notice and opportunity for a hearing.

(2) Section 1857 (g) of the Act provides that, for Part D sponsors found to be out of compliance with the requirements in part 423, specified remedies may be imposed instead of, or in addition to, termination of the Part D sponsor's contract. Section 1857(g)(4) of the Act makes certain provisions of section 1128A of the Act applicable to civil money penalties imposed on Part D sponsors.

(b) [Reserved]

§ 423.1002 Definitions.

As used in this subpart—

Affected party means any Part D sponsor impacted by an initial determination or if applicable, by any subsequent determination or decision issued under this part, and "*party*" means the affected party or CMS, as appropriate.

ALJ stands for Administrative Law Judge.

Departmental Appeals Board or Board means a Board established in the Office of the Secretary to provide impartial review of disputed decisions made by the operating components of the Department.

Part D sponsor has the meaning given the term in § 423.4.

§ 423.1004 Scope and applicability.

(a) *Scope.* This subpart sets forth procedures for reviewing initial determinations that CMS makes with respect to the matters specified in paragraph (b) of this section.

(b) *Initial determinations by CMS.* CMS makes initial determinations with respect to the imposition of civil money penalties in accordance with part 423, subpart O.

§ 423.1006 Appeal rights.

(a) *Appeal rights of Part D sponsors.* (1) Any Part D sponsor dissatisfied with an initial determination as specified in § 423.1004, has a right to a hearing before an ALJ in accordance with this subpart and may request Departmental Appeals Board review of the ALJ decision.

(2) Part D sponsors may request judicial review of the Departmental Appeals Board's decision that imposes a CMP.

(b) [Reserved]

§ 423.1008 Appointment of representatives.

(a) An affected party may appoint as its representative anyone not disqualified or suspended from acting as a representative in proceedings before the Secretary or otherwise prohibited by law.

(b) If the representative appointed is not an attorney, the party must file written notice of the appointment with the ALJ or the Departmental Appeals Board.

(c) If the representative appointed is an attorney, the attorney's statement that he or she has the authority to represent the party is sufficient.

§ 423.1010 Authority of representatives.

(a) A representative appointed and qualified in accordance with § 423.1008 may, on behalf of the represented party—

(1) Give and accept any notice or request pertinent to the proceedings set forth in this part;

(2) Present evidence and allegations as to facts and law in any proceedings affecting that party to the same extent as the party; and

(3) Obtain information to the same extent as the party.

(b) A notice or request may be sent to the affected party, to the party's representative, or to both. A notice or request sent to the representative has the same force and effect as if it had been sent to the party.

§ 423.1012 Fees for services of representatives.

Fees for any services performed on behalf of an attorney appointed and qualified in accordance with § 423.1008 are not subject to the provisions of section 206 of Title II of the Act, which authorizes the Secretary to specify or limit those fees.

§ 423.1014 Charge for transcripts.

A party that requests a transcript of prehearing or hearing proceedings or Board review must pay the actual or estimated cost of preparing the transcript unless, for good cause shown by that party, the payment is waived by the ALJ or the Departmental Appeals Board, as appropriate.

§ 423.1016 Filing of briefs with the Administrative Law Judge or Departmental Appeals Board, and opportunity for rebuttal.

(a) *Filing of briefs and related documents.* If a party files a brief or related document such as a written argument, contention, suggested finding

of fact, conclusion of law, or any other written statement, it must submit an original and 1 copy to the ALJ or the Departmental Appeals Board, as appropriate. The material may be filed by mail or in person and must include a statement certifying that a copy has been furnished to the other party.

(b) *Opportunity for rebuttal.* (1) The other party will have 20 calendar days from the date of mailing or personal service to submit any rebuttal statement or additional evidence. If a party submits a rebuttal statement or additional evidence, it must file an original and 1 copy with the ALJ or the Board and furnish a copy to the other party.

(2) The ALJ or the Board will grant an opportunity to reply to the rebuttal statement only if the party shows good cause.

§ 423.1018 Notice and effect of initial determinations.

(a) *Notice of initial determination*—(1) *General rule.* CMS, as required under 422.756(f)(2), mails notice of an initial determination to the affected party, setting forth the basis or reasons for the determination, the effect of the determination, the party's right to a hearing, and information about where to file the request for a hearing.

(b) *Effect of initial determination.* An initial determination is binding unless—

(1) The affected party requests a hearing; or

(2) CMS revises its decision.

§ 423.1020 Request for hearing.

(a) *Manner and timing of request.* (1) A Part D sponsor is entitled to a hearing as specified in § 423.1006 and may file a request with the Departmental Appeals Board office specified in the initial determination.

(2) The Part D sponsor or its legal representative or other authorized official must file the request, in writing, to the appropriate Departmental Appeals Board office, with a copy to CMS, within 60 calendar days from receipt of the notice of initial determination, to request a hearing before an ALJ to appeal any determination by CMS to impose a civil money penalty.

(b) *Content of request for hearing.* The request for hearing must—

(1) Identify the specific issues, and the findings of fact and conclusions of law with which the affected party disagrees; and

(2) Specify the basis for each contention that a CMS finding or conclusion of law is incorrect.

§ 423.1022 Parties to the hearing.

The parties to the hearing are the affected party and CMS, as appropriate.

§ 423.1024 Designation of hearing official.

(a) The Chair of the Departmental Appeals Board, or his or her delegate, designates an ALJ or a member or members of the Departmental Appeals Board to conduct the hearing.

(b) If appropriate, the Chair or the delegate may substitute another ALJ or another member or other members of the Departmental Appeals Board to conduct the hearing.

(c) As used in this part, "ALJ" includes a member or members of the Departmental Appeals Board who are designated to conduct a hearing.

§ 423.1026 Disqualification of Administrative Law Judge.

(a) An ALJ may not conduct a hearing in a case in which he or she is prejudiced or partial to the affected party or has any interest in the matter pending for decision.

(b) A party that objects to the ALJ designated to conduct the hearing must give notice of its objections at the earliest opportunity.

(c) The ALJ will consider the objections and decide whether to withdraw or proceed with the hearing.

(1) If the ALJ withdraws, another ALJ will be designated to conduct the hearing.

(2) If the ALJ does not withdraw, the objecting party may, after the hearing, present its objections to the Departmental Appeals Board as reasons for changing, modifying, or reversing the ALJ's decision or providing a new hearing before another ALJ.

§ 423.1028 Prehearing conference.

(a) At any time before the hearing, the ALJ may call a prehearing conference for the purpose of delineating the issues in controversy, identifying the evidence and witnesses to be presented at the hearing, and obtaining stipulations accordingly.

(b) On the request of either party or on his or her own motion, the ALJ may adjourn the prehearing conference and reconvene at a later date.

§ 423.1030 Notice of prehearing conference.

(a) *Timing of notice.* The ALJ will fix a time and place for the prehearing conference and mail written notice to the parties at least 10 calendar days before the scheduled date.

(b) *Content of notice.* The notice will inform the parties of the purpose of the conference and specify what issues are sought to be resolved, agreed to, or excluded.

(c) *Additional issues.* Issues other than those set forth in the notice of determination or the request for hearing may be considered at the prehearing conference if—

(1) Either party gives timely notice to that effect to the ALJ and the other party; or

(2) The ALJ raises the issues in the notice of prehearing conference or at the conference.

§ 423.1032 Conduct of prehearing conference.

(a) The prehearing conference is open to the affected party or its representative, to the CMS representatives and their technical advisors, and to any other persons whose presence the ALJ considers necessary or proper.

(b) The ALJ may accept the agreement of the parties as to the following:

(1) Facts that are not in controversy.

(2) Questions that have been resolved favorably to the affected party after the determination in dispute.

(3) Remaining issues to be resolved.

(c) The ALJ may request the parties to indicate the following:

(1) The witnesses that will be present to testify at the hearing.

(2) The qualifications of those witnesses.

(3) The nature of other evidence to be submitted.

§ 423.1034 Record, order, and effect of prehearing conference.

(a) *Record of prehearing conference.* (1) A record is made of all agreements and stipulations entered into at the prehearing conference.

(2) The record may be transcribed at the request of either party or the ALJ.

(b) *Order and opportunity to object.* (1) The ALJ issues an order setting forth the results of the prehearing conference, including the agreements made by the parties as to facts not in controversy, the matters to be considered at the hearing, and the issues to be resolved.

(2) Copies of the order are sent to all parties and the parties have 10 calendar days to file objections to the order.

(3) After the 10 calendar days have elapsed, the ALJ settles the order.

(c) *Effect of prehearing conference.* The agreements and stipulations entered into at the prehearing conference are binding on all parties, unless a party presents facts that, in the opinion of the ALJ, would make an agreement unreasonable or inequitable.

§ 423.1036 Time and place of hearing.

(a) The ALJ fixes a time and place for the hearing and gives the parties written notice at least 10 calendar days before the scheduled date.

(b) The notice informs the parties of the general and specific issues to be resolved at the hearing.

§ 423.1038 Change in time and place of hearing.

(a) The ALJ may change the time and place for the hearing either on his or her own initiative or at the request of a party for good cause shown, or may adjourn or postpone the hearing.

(b) The ALJ may reopen the hearing for receipt of new evidence at any time before mailing the notice of hearing decision.

(c) The ALJ gives the parties reasonable notice of any change in time or place or any adjournment or reopening of the hearing.

§ 423.1040 Joint hearings.

When two or more affected parties have requested hearings and the same or substantially similar matters are at issue, the ALJ may, if all parties agree, fix a single time and place for the prehearing conference or hearing and conduct all proceedings jointly. If joint hearings are held, a single record of the proceedings is made and a separate decision issued with respect to each affected party.

§ 423.1042 Hearing on new issues.

(a) *Basic rules.* (1) Within the time limits specified in paragraph (b) of this section, the ALJ may, at the request of either party, or on his or her own motion, provide a hearing on new issues that impinge on the rights of the affected party.

(2) The ALJ may consider new issues even if CMS has not made initial determinations on them, and even if they arose after the request for hearing was filed or after a prehearing conference.

(3) The ALJ may give notice of hearing on new issues at any time after the hearing request is filed and before the hearing record is closed.

(b) *Notice and conduct of hearing on new issues.*

(1) Unless the affected party waives its right to appear and present evidence, notice of the time and place of hearing on any new issue will be given to the parties in accordance with § 423.1036.

(2) After giving notice, the ALJ will, except as provided in paragraph (c) of this section, proceed to hearing on new issues in the same manner as on an issue raised in the request for hearing.

(c) *Remand to CMS.* At the request of either party, or on his or her own motion, in lieu of a hearing under paragraph (b) of this section, the ALJ may remand the case to CMS for consideration of the new issue and, if appropriate, a determination. If necessary, the ALJ may direct CMS to return the case to the ALJ for further proceedings.

§ 423.1044 Subpoenas.

(a) *Basis for issuance.* The ALJ, upon his or her own motion or at the request of a party, may issue subpoenas if they are reasonably necessary for the full presentation of a case.

(b) *Timing of request by a party.* The party must file a written request for a subpoena with the ALJ at least 5 calendar days before the date set for the hearing.

(c) *Content of request.* The request must:

(1) Identify the witnesses or documents to be produced;

(2) Describe their addresses or location with sufficient particularity to permit them to be found; and

(3) Specify the pertinent facts the party expects to establish by the witnesses or documents, and indicate why those facts could not be established without use of a subpoena.

(d) *Method of issuance.* Subpoenas are issued in the name of the Secretary.

§ 423.1046 Conduct of hearing.

(a) *Participants in the hearing.* The hearing is open to the parties and their representatives and technical advisors, and to any other persons whose presence the ALJ considers necessary or proper.

(b) *Hearing procedures.* (1) The ALJ inquires fully into all of the matters at issue, and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(2) If the ALJ believes that there is relevant and material evidence available which has not been presented at the hearing, he may, at any time before mailing of notice of the decision, reopen the hearing to receive that evidence.

(3) The ALJ decides the order in which the evidence and the arguments of the parties are presented and the conduct of the hearing.

(4) CMS has the burden of coming forward with evidence related to disputed findings that is sufficient (together with any undisputed findings and legal authority) to establish a prima facie case that CMS has a legally sufficient basis for its determination.

(5) The affected party has the burden of coming forward with evidence sufficient to establish the elements of any affirmative argument or defense which it offers.

(6) The affected party bears the ultimate burden of persuasion. To prevail, the affected party must prove by a preponderance of the evidence on the record as a whole that there is no basis for the determination.

(c) *Review of the penalty.* When an ALJ finds that the basis for imposing a civil money penalty exists, as specified in § 423.752, the ALJ may not—

(1) Set a penalty of zero or reduce a penalty to zero, or

(2) Review the exercise of discretion by CMS to impose a civil money penalty.

§ 423.1048 Evidence.

Evidence may be received at the hearing even though inadmissible under the rules of evidence applicable to court procedure. The ALJ rules on the admissibility of evidence.

§ 423.1050 Witnesses.

Witnesses at the hearing testify under oath or affirmation. The representative of each party is permitted to examine his or her own witnesses subject to interrogation by the representative of the other party. The ALJ may ask any questions that he or she deems necessary. The ALJ rules upon any objection made by either party as to the propriety of any question.

§ 423.1052 Oral and written summation.

The parties to a hearing are allowed a reasonable time to present oral summation and to file briefs or other written statements of proposed findings of fact and conclusions of law. Copies of any briefs or other written statements must be sent in accordance with § 423.1016.

§ 423.1054 Record of hearing.

A complete record of the proceedings at the hearing is made and transcribed in all cases.

§ 423.1056 Waiver of right to appear and present evidence.

(a) *Waiver procedures.* (1) If an affected party wishes to waive its right to appear and present evidence at the hearing, it must file a written waiver with the ALJ.

(2) If the affected party wishes to withdraw a waiver, it may do so, for good cause, at any time before the ALJ mails notice of the hearing decision.

(b) *Effect of waiver.* If the affected party waives the right to appear and present evidence, the ALJ need not conduct an oral hearing except in one of the following circumstances:

(1) The ALJ believes that the testimony of the affected party or its representatives or other witnesses is necessary to clarify the facts at issue.

(2) CMS shows good cause for requiring the presentation of oral evidence.

(c) *Dismissal for failure to appear.* If, despite the waiver, the ALJ sends notice of hearing and the affected party fails to appear, or to show good cause for the failure, the ALJ will dismiss the appeal in accordance with § 423.1058.

(d) *Hearing without oral testimony.* When there is no oral testimony, the ALJ will—

(1) Make a record of the relevant written evidence that was considered in making the determination being appealed, and of any additional evidence submitted by the parties;

(2) Furnish to each party copies of the additional evidence submitted by the other party; and

(3) Give both parties a reasonable opportunity for rebuttal.

(e) *Handling of briefs and related statements.* If the parties submit briefs or other written statements of evidence or proposed findings of facts or conclusions of law, those documents will be handled in accordance with § 423.1016.

§ 423.1058 Dismissal of request for hearing.

(a) The ALJ may, at any time before mailing the notice of the decision, dismiss a hearing request if a party withdraws its request for a hearing or the affected party asks that its request be dismissed.

(b) An affected party may request a dismissal by filing a written notice with the ALJ.

§ 423.1060 Dismissal for abandonment.

(a) The ALJ may dismiss a request for hearing if it is abandoned by the party that requested it.

(b) The ALJ may consider a request for hearing to be abandoned if the party or its representative—

(1) Fails to appear at the prehearing conference or hearing without having previously shown good cause for not appearing; and

(2) Fails to respond, within 10 calendar days after the ALJ sends a "show cause" notice, with a showing of good cause.

§ 423.1062 Dismissal for cause.

On his or her own motion, or on the motion of a party to the hearing, the ALJ may dismiss a hearing request either entirely or as to any stated issue, under any of the following circumstances:

(a) *Res judicata.* There has been a previous determination or decision with respect to the rights of the same affected party on the same facts and law pertinent to the same issue or issues which has become final either by judicial affirmance or, without judicial consideration, because the affected party did not timely request reconsideration, hearing, or review, or commence a civil action with respect to that determination or decision.

(b) *No right to hearing.* The party requesting a hearing is not a proper party or does not otherwise have a right to a hearing.

(c) *Hearing request not timely filed.* The affected party did not file a hearing request timely and the time for filing has not been extended.

§ 423.1064 Notice and effect of dismissal and right to request review.

(a) Notice of the ALJ's dismissal action is mailed to the parties. The notice advises the affected party of its right to request that the dismissal be vacated as provided in § 423.1066.

(b) The dismissal of a request for hearing is binding unless it is vacated by the ALJ or the Departmental Appeals Board.

§ 423.1066 Vacating a dismissal of request for hearing.

An ALJ may vacate any dismissal of a request for hearing if a party files a request to that effect within 60 calendar days from receipt of the notice of dismissal and shows good cause for vacating the dismissal.

§ 423.1068 Administrative Law Judge's decision.

(a) *Timing, basis and content.* As soon as practical after the close of the hearing, the ALJ issues a written decision in the case. The decision is based on the evidence of record and contains separate numbered findings of fact and conclusions of law.

(b) *Notice and effect.* A copy of the decision is mailed to the parties and is binding on them unless—

(1) A party requests review by the Departmental Appeals Board within the time period specified in § 423.1076, and the Board reviews the case;

(2) The Departmental Appeals Board denies the request for review and the party seeks judicial review by filing an action in a United States District Court or, in the case of a civil money penalty, in a United States Court of Appeals;

(3) The decision is revised by an ALJ or the Department Appeals Board; or

(4) The decision is a recommended decision directed to the Board.

§ 423.1070 Removal of hearing to Departmental Appeals Board.

(a) At any time before the ALJ receives oral testimony, the Board may remove to itself any pending request for a hearing.

(b) Notice of removal is mailed to each party.

(c) The Board conducts the hearing in accordance with the rules that apply to ALJ hearings under this subpart.

§ 423.1072 Remand by the Administrative Law Judge.

(a) If CMS requests remand, and the affected party concurs in writing or on the record, the ALJ may remand any case properly before him or her to CMS for a determination satisfactory to the affected party.

(b) The ALJ may remand at any time before notice of hearing decision is mailed.

§ 423.1074 Right to request Departmental Appeals Board review of Administrative Law Judge's decision or dismissal.

Either of the parties has a right to request Departmental Appeals Board review of the ALJ's decision or dismissal order, and the parties are so informed in the notice of the ALJ's action.

§ 423.1076 Request for Departmental Appeals Board review.

(a) *Manner and time of filing.* (1) Any party that is dissatisfied with an ALJ's decision or dismissal of a hearing request, may file a written request for review by the Departmental Appeals Board.

(2) The requesting party or its representative or other authorized official must file the request with the DAB within 60 calendar days from receipt of the notice of decision or dismissal, unless the Board, for good cause shown by the requesting party, extends the time for filing.

(b) *Content of request for review.* A request for review of an ALJ decision or dismissal must specify the issues, the findings of fact or conclusions of law with which the party disagrees, and the basis for contending that the findings and conclusions are incorrect.

§ 423.1078 Departmental Appeals Board action on request for review.

(a) *Request by CMS.* The Departmental Appeals Board may dismiss, deny, or grant a request made by CMS for review of an ALJ decision or dismissal.

(b) *Request by the affected party.* The Board may deny or grant the affected party's request for review or may dismiss the request for one of the following reasons:

(1) The affected party requests dismissal of its request for review.

(2) The affected party did not file timely or show good cause for late filing.

(3) The affected party does not have a right to review.

(4) A previous determination or decision, based on the same facts and law, and regarding the same issue, has become final through judicial affirmance or because the affected party failed to timely request reconsideration,

hearing, Board review, or judicial review, as appropriate.

(c) *Effect of dismissal.* The dismissal of a request for Departmental Appeals Board review is binding and not subject to further review.

(d) *Review panel.* If the Board grants a request for review of the ALJ's decision, the review will be conducted by a panel of three members of the Board, designated by the Chair or Deputy Chair.

§ 423.1080 Procedures before the Departmental Appeals Board on review.

The parties are given, upon request, a reasonable opportunity to file briefs or other written statements as to fact and law, and to appear before the Departmental Appeals Board to present evidence or oral arguments. Copies of any brief or other written statement must be sent in accordance with § 423.1016.

§ 423.1082 Evidence admissible on review.

(a) The Departmental Appeals Board may admit evidence into the record in addition to the evidence introduced at the ALJ hearing, (or the documents considered by the ALJ if the hearing was waived), if the Board considers that the additional evidence is relevant and material to an issue before it.

(b) If it appears to the Board that additional relevant evidence is available, the Board will require that it be produced.

(c) Before additional evidence is admitted into the record—

(1) Notice is mailed to the parties (unless they have waived notice) stating that evidence will be received regarding specified issues; and

(2) The parties are given a reasonable time to comment and to present other evidence pertinent to the specified issues.

(d) If additional evidence is presented orally to the Board, a transcript is prepared and made available to any party upon request.

§ 423.1084 Decision or remand by the Departmental Appeals Board.

(a) When the Departmental Appeals Board reviews an ALJ's decision or order of dismissal, or receives a case remanded by a court, the Board may either issue a decision or remand the case to an ALJ for a hearing and decision or a recommended decision for final decision by the Board.

(b) In a remanded case, the ALJ initiates additional proceedings and takes other actions as directed by the Board in its order of remand, and may take other action not inconsistent with that order.

(c) Upon completion of all action called for by the remand order and any other consistent action, the ALJ promptly makes a decision or, as specified by the Board, certifies the case to the Board with a recommended decision.

(d) The parties have 20 calendar days from the date of a notice of a recommended decision to submit to the Board any exception, objection, or comment on the findings of fact, conclusions of law, and recommended decision.

(e) After the 20-calendar day period, the Board issues its decision adopting, modifying or rejecting the ALJ's recommended decision.

(f) If the Board does not remand the case to an ALJ, the following rules apply:

(1) The Board's decision—

(i) Is based upon the evidence in the hearing record and any further evidence that the Board receives during its review;

(ii) Is in writing and contains separate numbered findings of fact and conclusions of law; and

(iii) May modify, affirm, or reverse the ALJ's decision.

(2) A copy of the Board's decision is mailed to each party.

§ 423.1086 Effect of Departmental Appeals Board Decision.

(a) *General rule.* The Board's decision is binding unless—

(1) The affected party has a right to judicial review and timely files a civil action in a United States District Court or, in the case of a civil money penalty, in a United States Court of Appeals; or

(2) The Board reopens and revises its decision in accordance with § 423.1092.

(b) *Right to judicial review.* Section 423.1006 specifies the circumstances under which an affected party has a right to seek judicial review.

(c) *Special rules: Civil money penalty.* Finality of Board's decision. When CMS imposes a civil money penalty, notice of the Board's decision (or denial of review) is the final administrative action that initiates the 60-calendar day period for seeking judicial review.

§ 423.1088 Extension of time for seeking judicial review.

(a) Any affected party that is dissatisfied with an Departmental Appeals Board decision and is entitled to judicial review must commence civil action within 60 calendar days from receipt of the notice of the Board's decision, unless the Board extends the time in accordance with paragraph (c) of this section.

(b) The request for extension must be filed in writing with the Board before the 60-calendar day period ends.

(c) For good cause shown, the Board may extend the time for commencing civil action.

§ 423.1090 Basis, timing, and authority for reopening an Administrative Law Judge or Board decision.

(a) *Basis and timing for reopening.* An ALJ of Departmental Appeals Board decision may be reopened, within 60 calendar days from the date of the notice of decision, upon the motion of the ALJ or the Board or upon the petition of either party to the hearing.

(b) *Authority to reopen.* (1) A decision of the Departmental Appeals Board may be reopened only by the Departmental Appeals Board.

(2) A decision of an ALJ may be reopened by that ALJ, by another ALJ if that one is not available, or by the Departmental Appeals Board. For purposes of this paragraph, an ALJ is considered to be unavailable if the ALJ has died, terminated employment, or been transferred to another duty station, is on leave of absence, or is unable to conduct a hearing because of illness.

§ 423.1092 Revision of reopened decision.

(a) Revision based on new evidence. If a reopened decision is to be revised on the basis of new evidence that was not included in the record of that decision, the ALJ or the Departmental Appeals Board—

(1) Notifies the parties of the proposed revision; and

(2) Unless the parties waive their right to hearing or appearance—

(i) Grants a hearing in the case of an ALJ revision; and

(ii) Grants opportunity to appear in the case of a Board revision.

(b) *Basis for revised decision and right to review.*

(1) If a revised decision is necessary, the ALJ or the Departmental Appeals Board, as appropriate, renders it on the basis of the entire record.

(2) If the decision is revised by an ALJ, the Departmental Appeals Board may review that revised decision at the request of either party or on its own motion.

§ 423.1094 Notice and effect of revised decision.

(a) *Notice.* The notice mailed to the parties states the basis or reason for the revised decision and informs them of their right to Departmental Appeals Board review of an ALJ revised decision, or to judicial review of a Board reviewed decision.

(b) *Effect*—(1) *ALJ revised decision.* An ALJ revised decision is binding

unless it is reviewed by the Departmental Appeals Board.

(2) *Departmental Appeals Board revised decision.* A Board revised decision is binding unless a party files a civil action in a district court of the United States within the time frames specified in § 423.858.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 14, 2007.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: October 26, 2007.

Michael O. Leavitt,

Secretary.

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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. 2089/P.L. 110–121

To designate the facility of the United States Postal Service located at 701 Loyola Avenue in New Orleans, Louisiana, as the "Louisiana Armed Services Veterans Post Office". (Nov. 30, 2007; 121 Stat. 1349)

H.R. 2276/P.L. 110–122

To designate the facility of the United States Postal Service located at 203 North Main Street in Vassar, Michigan, as the "Corporal Christopher E. Esckelson Post Office Building". (Nov. 30, 2007; 121 Stat. 1350)

H.R. 3297/P.L. 110–123

To designate the facility of the United States Postal Service located at 950 West Trenton Avenue in Morrisville, Pennsylvania, as the "Nate DeTample Post Office Building". (Nov. 30, 2007; 121 Stat. 1351)

H.R. 3307/P.L. 110–124

To designate the facility of the United States Postal Service located at 570 Broadway in Bayonne, New Jersey, as the "Dennis P. Collins Post Office Building". (Nov. 30, 2007; 121 Stat. 1352)

H.R. 3308/P.L. 110–125

To designate the facility of the United States Postal Service located at 216 East Main Street in Atwood, Indiana, as the "Lance Corporal David K. Fribley Post Office". (Nov. 30, 2007; 121 Stat. 1353)

H.R. 3325/P.L. 110–126

To designate the facility of the United States Postal Service located at 235 Mountain Road in Suffield, Connecticut, as the "Corporal Stephen R. Bixler Post Office". (Nov. 30, 2007; 121 Stat. 1354)

H.R. 3382/P.L. 110–127

To designate the facility of the United States Postal Service located at 200 North William Street in Goldsboro, North Carolina, as the "Philip A. Baddour, Sr. Post Office". (Nov. 30, 2007; 121 Stat. 1355)

H.R. 3446/P.L. 110–128

To designate the facility of the United States Postal Service located at 202 East Michigan Avenue in Marshall, Michigan, as the "Michael W. Schragg Post Office Building". (Nov. 30, 2007; 121 Stat. 1356)

H.R. 3518/P.L. 110–129

To designate the facility of the United States Postal Service located at 1430 South Highway 29 in Cantonment, Florida, as the "Charles H. Hendrix Post Office Building". (Nov. 30, 2007; 121 Stat. 1357)

H.R. 3530/P.L. 110–130

To designate the facility of the United States Postal Service located at 1400 Highway 41 North in Inverness, Florida, as the "Chief Warrant Officer Aaron Weaver Post Office Building". (Nov. 30, 2007; 121 Stat. 1358)

H.R. 3572/P.L. 110–131

To designate the facility of the United States Postal Service located at 4320 Blue Parkway in Kansas City, Missouri, as the "Wallace S. Hartsfield Post Office Building". (Nov. 30, 2007; 121 Stat. 1359)

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110th Congress

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