AUTHENTICATED U.S. GOVERNMENT INFORMATION GPO

Federal Register

9–18–08 Thursday
Vol. 73 No. 182 Sept. 18, 2008

Pages 54057–54288

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

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 532

RIN 3206–AL68

Prevailing Rate Systems; Redefinition of the New Orleans, LA, Appropriated Fund Federal Wage System Wage Area

AGENCY: U.S. Office of Personnel Management.

ACTION: Final rule.

SUMMARY: The U.S. Office of Personnel Management is issuing a final rule to add St. Charles and St. John the Baptist Parishes, Louisiana, to the survey area of the New Orleans, LA, appropriated fund Federal Wage System wage area. The purpose of this change is to ensure the lead agency for the New Orleans wage area is able to obtain wage data that best represent the prevailing rates paid by businesses in the area.

DATES: *Effective date:* This regulation is effective on September 18, 2008.

FOR FURTHER INFORMATION CONTACT: Madeline Gonzalez, (202) 606–2838; e-mail: *pay-performance-policy@opm.gov*; or Fax: (202) 606–4264.

SUPPLEMENTARY INFORMATION: On July, 9 2008, the U.S. Office of Personnel Management (OPM) issued an interim rule (73 FR 39213) to add St. Charles and St. John the Baptist Parishes, Louisiana, to the survey area of the New Orleans, LA, appropriated fund Federal Wage System (FWS) wage area. The interim rule had a 30-day public comment period, during which OPM received no comments.

This change will be effective for the next full-scale wage survey in the wage area, which is scheduled to begin in November 2008.

Regulatory Flexibility Act

I certify that these regulations will not have a significant economic impact on a substantial number of small entities because they will affect only Federal agencies and employees.

List of Subjects in 5 CFR Part 532

Administrative practice and procedure, Freedom of information, Government employees, Reporting and recordkeeping requirements, Wages.

U.S. Office of Personnel Management.

Michael W. Hager,

Acting Director.

■ Accordingly, under the authority of 5 U.S.C. 5343, the interim rule published on July 9, 2008, amending 5 CFR part 532 (73 FR 39213) is adopted as final with no changes.

[FR Doc. E8–21831 Filed 9–17–08; 8:45 am]

BILLING CODE 6325–39–P

DEPARTMENT OF AGRICULTURE

Agriculture Marketing Service

7 CFR Part 205

[Docket Number AMS–TM–08–0025; TM–08–05FR]

RIN 0581–AC81

National Organic Program; Amendment to the National List of Allowed and Prohibited Substances (Livestock)

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule amends the U.S. Department of Agriculture's (USDA) National List of Allowed and Prohibited Substances (National List) to reflect one recommendation submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB) on May 22, 2008. Consistent with the recommendation from the NOSB, this final rule revises the annotation of one substance on the National List, Methionine, to extend its use in organic poultry production until October 1, 2010.

DATES: This rule becomes effective September 19, 2008.

FOR FURTHER INFORMATION CONTACT: Richard H. Mathews, Chief, Standards Development and Review Branch, Telephone: (202) 720–3252; Fax: (202) 205–7808.

SUPPLEMENTARY INFORMATION:

I. Background

On December 21, 2000, the Secretary established, within the NOP [7 CFR part 205], the National List regulations §§ 205.600 through 205.607. This National List identifies the synthetic substances that may be used and the nonsynthetic (natural) substances that may not be used in organic production. The National List also identifies synthetic, nonsynthetic nonagricultural and nonorganic agricultural substances that may be used in organic handling. The Organic Foods Production Act of 1990 (OFPA), as amended, (7 U.S.C. 6501 *et seq.*), and NOP regulations, in § 205.105, specifically prohibit the use of any synthetic substance for organic production and handling unless the synthetic substance is on the National List. Section 205.105 also requires that any nonorganic agricultural and any nonsynthetic nonagricultural substance used in organic handling be on the National List.

Under the authority of the OFPA, as amended, (7 U.S.C. 6501 *et seq.*), the National List can be amended by the Secretary based on proposed amendments developed by the NOSB. Since established, the National List has been amended nine times, October 31, 2003 (68 FR 61987), November 3, 2003 (68 FR 62215), October 21, 2005 (70 FR 61217), June 7, 2006 (71 FR 32803), September 11, 2006 (71 FR 53299), June, 27, 2007 (72 FR 35137), October 16, 2007 (72 FR 58469), December 10, 2007 (72 FR 69569), and December 12, 2007 (72 FR 70479). Additionally, an amendment to the National List, proposed on July 14, 2008, (73 FR 40194), is currently pending.

This final rule amends the National List to reflect one recommendation submitted to the Secretary by the NOSB on May 22, 2008.

II. Overview of Proposed Amendment

The following provides an overview of the proposed amendment to § 205.603 of the National List:

Section 205.603 Synthetic Substances Allowed for Use in Organic Livestock Production

This final rule amends § 205.603(d)(1) by changing ''2008'' to ''2010''. Section 205.603(d)(1) now reads as follows:

DL—Methionine, DL—Methionine—hydroxyl analog, and DL—Methionine—hydroxyl analog calcium (CAS #–59–51–8; 63–68–3; 348–67–4)—for use only in organic poultry production until October 1, 2010.

III. Related Documents

On April 4, 2008, a notice was published in the **Federal Register** (73 FR 18491) announcing the meeting of the NOSB and its planned deliberations on recommendations involving the use of Methionine in organic poultry production. NOSB meetings are open to the public and allow for public participation. The recommendation to extend Methionine's use in organic poultry production included in this final rule was published as a proposed rule on July 14, 2008 (73 FR 40197).

IV. Statutory and Regulatory Authority

The OFPA, as amended (7 U.S.C. 6501 *et seq.*), authorizes the Secretary to make amendments to the National List based on proposed amendments developed by the NOSB. Sections 6518(k)(2) and 6518(n) of OFPA authorize the NOSB to develop proposed amendments to the National List for submission to the Secretary and establish a petition process by which persons may petition the NOSB for the purpose of having substances evaluated for inclusion on or deletion from the National List. The National List petition process is implemented under § 205.607 of the NOP regulations. The current petition process (72 FR 2167, January 18, 2007) can be accessed through the NOP Web site at *http://www.ams.usda.gov/nop/Newsroom/FedReg01_18_07NationalList.pdf.*

A. Executive Order 12866

This action has been determined not significant for purposes of Executive Order 12866, and therefore, has not been reviewed by the Office of Management and Budget.

B. Executive Order 12988

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. The final rule (68 FR 61987), dated October 31, 2003, adding Methionine to the National List was reviewed under this Executive Order and no additional related information has been obtained since then. This proposed rule is not intended to have a retroactive effect.

States and local jurisdictions are preempted under the OFPA from creating programs of accreditation for private persons or State officials who want to become certifying agents of organic farms or handling operations. A governing State official would have to apply to USDA to be accredited as a certifying agent, as described in § 2115(b) of the OFPA (7 U.S.C. 6514(b)). States are also preempted under §§ 2104 through 2108 of the OFPA (7 U.S.C. 6503 through 6507) from creating certification programs to certify organic farms or handling operations unless the State programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OFPA.

Pursuant to § 2108(b)(2) of the OFPA (7 U.S.C. 6507(b)(2)), a State organic certification program may contain additional requirements for the production and handling of organically produced agricultural products that are produced in the State and for the certification of organic farm and handling operations located within the State under certain circumstances. Such additional requirements must: (a) Further the purposes of the OFPA, (b) not be inconsistent with the OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

Pursuant to § 2120(f) of the OFPA (7 U.S.C. 6519(f)), this final rule would not alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspections Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*), concerning meat, poultry, and egg products, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 *et seq.*), nor the authority of the Administrator of the Environmental Protection Agency under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 *et seq.*).

Section 2121 of the OFPA (7 U.S.C. 6520) provides for the Secretary to establish an expedited administrative appeals procedure under which persons may appeal an action of the Secretary, the applicable governing State official, or a certifying agent under this title that adversely affects such person or is inconsistent with the organic certification program established under this title. The OFPA also provides that the U.S. District Court for the district in which a person is located has jurisdiction to review the Secretary's decision.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose is to fit regulatory actions to the scale of businesses subject to the action. Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

Pursuant to the requirements set forth in the RFA, AMS performed an economic impact analysis on small entities in the final rule published in the **Federal Register** on December 21, 2000 (65 FR 80548). The AMS has also considered the economic impact of this action on small entities. The impact on entities affected by this final rule would not be significant. The current approval for the use of Methionine in organic poultry production will expire October 1, 2008. The effect of this final rule is to allow the continued use of Methionine through October 1, 2010. The AMS concludes that this action would have minimal economic impact on small agricultural service firms. Accordingly, USDA certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Small agricultural service firms, which include producers, handlers, and accredited certifying agents, have been defined by the Small Business Administration (SBA) (13 CFR 121.201) as those having annual receipts of less than $6,500,000 and small agricultural producers are defined as those having annual receipts of less than $750,000.

The U.S. organic industry at the end of 2001 included nearly 6,949 certified organic crop and livestock operations. These operations reported certified acreage totaling more than 2.09 million acres of organic farm production. Data on the numbers of certified organic handling operations (any operation that transforms raw product into processed products using organic ingredients) were not available at the time of survey in 2001; but they were estimated to be in the thousands. By the end of 2005, the number of U.S. certified organic crop, livestock, and handling operations totaled about 8,500. Based on 2005 USDA, Economic Research Service, data

from USDA-accredited certifying agents, U.S. certified organic acreage increased to 4 million acres.

The U.S. sales of organic food and beverages have grown from $1 billion in 1990 to nearly $17 billion in 2006. The organic industry is viewed as the fastest growing sector of agriculture, representing almost 3 percent of overall food and beverage sales. Since 1990, organic retail sales have historically demonstrated a growth rate between 20 to 24 percent each year, including a 22 percent increase in 2006.

In 2005, U.S. retail sales of organic poultry products were $161 million. The growth rate for organic poultry retail sales is estimated at between 23 and 38 percent per year. Organic egg sales were $161 million in 2005 and are projected to grow at a rate of 8 to 13 percent per year. The organic industry, in 2005, raised approximately 13.8 million birds. Organic poultry is raised in 40 of the 50 states. In addition to being sold as whole products, organic eggs and poultry are used in the production of organic processed products such as eggnog, ice cream, soups, broth, noodles, French toast, pancakes, waffles, tartar sauce, hollandaise sauce, mayonnaise, salad dressing, cookies, cakes, cheese cakes, bread, and other bakery goods.

In addition, USDA has 95 accredited certifying agents who provide certification services to producers and handlers. A complete list of names and addresses of accredited certifying agents may be found on the AMS NOP Web site, at *http://www.ams.usda.gov/nop*. AMS believes that most of these entities would be considered small entities under the criteria established by the SBA.

D. Paperwork Reduction Act

No additional collection or recordkeeping requirements are imposed on the public by this final rule. Accordingly, OMB clearance is not required by section 350(h) of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, *et seq.*, or OMB's implementing regulations at 5 CFR part 1320.

The AMS is committed to compliance with the Government Paperwork Elimination Act (GPEA), which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible.

The 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.

E. Discussion of Comments Received

Six (6) comments were received on the proposed revision to extend the use of synthetic Methionine in organic poultry production until October 1, 2010. Comments were received from a consumer, a poultry producer, a trade association, a Cooperative, and 2 accredited certifying agents. Two (2) comments opposed and 4 supported extending the current authorization for the use of synthetic Methionine.

One or more of the comments in support of the extension either acknowledged the need to continue to look for substitutes or find alternatives for Methionine or supported the Board's efforts in this regard. Comments in opposition were received from a consumer and a poultry producer associated with an accredited certifying agent who forwarded a comment from the accredited certifying agent. The consumer opposed the use of synthetic substances in organic production in general. The poultry producer opposed extended authorization for the use of Methionine and claims to be raising broiler and breeder chickens and turkeys without the use of Methionine. Neither commenter provided any evidence that the National Organic Standards Board's recommendation to extend the authorization for Methionine was in error or that wholly natural substitute products are presently available in sufficient supplies to meet poultry producer needs. After full consideration of these comments, we have determined that the record supports extension of the authorized use of Methionine until October 1, 2010. This extension will provide the organic feed sector with the time to create sufficient supplies of wholly natural substitute products.

F. Effective Date

This final rule reflects recommendations submitted to the Secretary by the NOSB for extending the use of Methionine, a synthetic substance, in organic poultry production until October 1, 2010. The NOSB evaluated this substance using criteria in the OFPA. The substance's evaluation was initiated by a petition from the Methionine Task Force.

The NOSB determined that while wholly natural substitute products exist, they are not presently available in sufficient supplies to meet poultry producer needs. Therefore, synthetic Methionine is presently a necessary component of a nutritionally adequate diet for organic poultry. Loss of the use of Methionine, at this time, would disrupt the well-established organic poultry market and cause substantial economic harm to organic poultry operations, as well as to organic handling operations that rely on organic eggs and poultry in the production of organic processed products.

Accordingly, pursuant to 5 U.S.C. 553, it is found and determined that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** because this rulemaking should be completed before the use of Methionine expires for organic poultry operations on October 1, 2008.

List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agriculture, Animals, Archives and records, Imports, Labeling, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

■ For the reasons set forth in the preamble, 7 CFR part 205, subpart G is amended as follows:

PART 205—NATIONAL ORGANIC PROGRAM

■ 1. The authority citation for 7 CFR part 205 continues to read as follows:

Authority: 7 U.S.C. 6501–6522.

§ 205.603 [Amended]

■ 2. Section 205.603(d)(1) is amended by removing ''2008'' and adding ''2010''in its place.

Dated: September 12, 2008.

Lloyd C. Day,

Administrator, Agricultural Marketing Service.

[FR Doc. E8–21785 Filed 9–17–08; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 71, 77, 78, 79, and 80

[Docket No. APHIS–2008–0077]

RIN 0579–AC84

National Animal Identification System; Use of 840 Animal Identification Numbers for U.S.-Born Animals Only

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are amending the regulations concerning the interstate

movement of animals to limit the use of the animal identification number (AIN) with the 840 prefix to animals born in the United States. In addition, we are extending the restrictions on the removal of official identification devices to include devices applied to imported animals in their countries of origin. We are also requiring that if such a device is lost following importation into the United States, the animal may only be retagged with an official identification device using a numbering system other than an AIN beginning with an 840 prefix. These requirements are necessary to enhance our traceback capabilities for both domestic and imported animals in the event of a disease outbreak.

DATES: This interim rule is effective September 18, 2008. We will consider all comments that we receive on or before November 17, 2008.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2008-0077* to submit or view comments and to view supporting and related materials available electronically.
- *Postal Mail/Commercial Delivery:* Please send two copies of your comment to Docket No. APHIS–2008–0077, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. APHIS–2008–0077.

Reading Room: You may read any comments that we receive on this docket 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.

Other Information: Additional information about APHIS and its programs is available on the Internet at *http://www.aphis.usda.gov*.

FOR FURTHER INFORMATION CONTACT: Dr. John Wiemers, Senior Staff Officer, National Animal Identification Staff, VS, APHIS, 2100 S. Lake Storey Rd., Galesburg, IL 61401; (309) 344–1942.

SUPPLEMENTARY INFORMATION:

Background

As part of its ongoing efforts to safeguard animal health, the U.S. Department of Agriculture (USDA) initiated implementation of the National Animal Identification System (NAIS) in 2004. The NAIS is a cooperative State-Federal-industry program administered by the USDA's Animal and Plant Health Inspection Service (APHIS).

In an interim rule effective and published in the **Federal Register** on November 8, 2004 (69 FR 64644–64651, Docket No. 04–052–1), we amended the regulations to recognize the animal identification number (AIN) for the identification of individual animals in interstate commerce and State/Federal/industry cooperative disease control and eradication programs, the group/lot identification number (GIN) for the identification of groups or lots of animals, and the premises identification number (PIN) for the identification of premises where animals are managed or held. These numbering systems are key elements in the NAIS.

On July 18, 2007, APHIS adopted that interim rule as a final rule (72 FR 39301–39307, Docket No. 04–052–2) [1] with several changes. Neither the interim rule nor the final rule required the use of the newly recognized numbering systems.

The regulations established by the November 2004 interim and the July 2007 final rule describe the AIN as a number containing 15 digits, with the first 3 being the country code (840 for the United States), the alpha characters USA, or the numeric code assigned to the manufacturer of the identification device by the International Committee on Animal Recording. To the extent practical, we anticipate phasing out the USA and manufacturer's code numbering systems as we progress toward full implementation of the NAIS and recognizing as official only the AIN with the 840 prefix.

In this interim rule, we are amending the definition of *animal identification number (AIN)* in §§ 71.1, 77.2, 78.1, 79.1, and 80.1 to limit the use of the AIN with the 840 prefix to animals born in the United States. Limiting the use of the 840 AIN to animals born in the United States will help us to determine the origin of an officially identified domestic animal in a more timely fashion in the event of a disease outbreak. As was the case with the November 2004 interim rule and the July 2007 final rule, the current rulemaking does not require producers to use the 840 AIN for the identification of individual animals. The regulations governing the use of AINs with other prefixes (e.g., USA or a manufacturer's code), and of official eartags using other numbering systems (e.g., the National Uniform Eartagging System, a premises-based number system, etc.) remain unchanged.

The regulations in §§ 71.1, 77.2, 78.1, 79.1, and 80.1 have not contained a definition of the term *United States*. However, they all contain a definition of the term *State*. To accommodate the change to the AIN definition, we are also adding to each of these sections a definition of *United States*. Consistent with the Animal Health Protection Act (7 U.S.C. 8302), *United States* is defined as ''all of the States.''

Complementing the changes discussed above, we are amending the regulations in § 71.22 to require that if an official identification device applied to an imported animal in its country of origin is lost following importation into the United States, the animal may only be retagged with an official identification device using a numbering system other than an 840 AIN. In addition, we are adding language to § 71.22 to clarify that the restrictions contained therein on the removal of official identification devices extend to the removal of animal identification devices that are officially recognized by APHIS for animals entering the United States from other countries. Although additional official identification may be necessary for imported animals while they are in the United States, the retention of the foreign identification devices is essential for complete and proper traceability.

In addition to enhancing our traceback capabilities, the regulatory changes contained in this interim rule will aid in the implementation of country of origin labeling (COOL). Under provisions contained in the Farm Bill of 2002, covered commodities, including certain beef, lamb, chicken, goat, and pork cuts and products, will be subject to COOL requirements beginning September 30, 2008. In order for retailers to accurately label these products, producers must provide country of origin information about the livestock from which the products were derived. Animal identification that meets NAIS standards can play a valuable role in the COOL program. Such identification may include both the AIN and the GIN, the latter employing a format that includes a seven-digit PIN.

Immediate Action

Immediate action is necessary to enhance our animal traceback capabilities so that we may better contain animal disease outbreaks.

[1] To view the interim rule, the comments we received, and the subsequent final rule, go to *http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2004-0018*.

Immediate action will also allow producers to use the 840 AIN for puposes of the COOL program. Under these circumstances, the Administrator has determined that prior notice and opportunity for public comment are contrary to the public interest and that there is good cause under 5 U.S.C. 553 for making this action effective less than 30 days after publication in the **Federal Register**.

We will consider comments we receive during the comment period for this interim rule (see **DATES** above). After the comment period closes, we will publish another document in the **Federal Register**. The document will include a discussion of any comments we receive and any amendments we are making to the rule.

Executive Order 12866 and Regulatory Flexibility Act

This interim rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

In accordance with the Regulatory Flexibility Act, we have analyzed the potential economic effects of this action on small entities. The analysis is summarized below. The full analysis may be viewed on the Regulations.gov Web site (see **ADDRESSES** above for instructions for accessing Regulations.gov) or obtained from the person listed under **FOR FURTHER INFORMATION CONTACT**.

This interim rule amends the regulations concerning the interstate movement of animals to limit the use of the AIN with the 840 prefix to animals born in the United States. In addition, we are extending the restrictions on the removal of official identification devices to include devices applied to imported animals in their countries of origin. We are also requiring that if such a device is lost following importation into the United States, the animal may only be retagged with an official identification device using a numbering system other than an AIN beginning with an 840 prefix. These requirements are necessary to enhance our traceback capabilities for both domestic and imported animals in the event of a disease outbreak.

In addition to enhancing our traceback capabilities, this rulemaking also provides a convenient way for U.S. producers and retailers to comply with the COOL program. Under provisions contained in the Farm Bill of 2002, covered commodities, including certain beef, lamb, chicken, goat, and pork cuts and products, will be subject to COOL requirements beginning September 30, 2008. In order for retailers to accurately label these products, producers will need to provide information on the origins of their livestock. Animal identification that meets NAIS standards can play a valuable role in the COOL program. Such identification may include both the AIN and the GIN, the latter employing a format that includes a seven-digit PIN. This rule will allow producers to use the 840 AIN for puposes of the COOL program.

The Regulatory Flexibility Act requires that agencies specifically consider the economic impact of their rules on small entities. Those entities most likely to be affected by the rule are domestic producers of animal eartags and livestock producers. The Small Business Administration (SBA) has established guidelines for determining which establishments are considered small.

The SBA small-entity size standard for North American Industry Classification System (NAICS) code 326199, which comprises plastic product manufacturers not otherwise identified, is 500 or fewer employees.[2] According to the 2002 Economic Census, there were 7,892 establishments in this category engaged in the manufacturing of plastic products, with over 492,000 paid employees.[3] We do not currently have enough information to determine how many of these establishments engaged in the manufacture of plastic eartags, or how many have 500 or fewer employees. Limiting use of AINs beginning with the 840 prefix to U.S.-born animals should not affect the costs of producing tags. It may, however, enhance the marketability of these tags, as they can be used for purposes of the COOL program.

In 2006, there were a total of 971,400 cattle operations, 65,540 hog and pig operations, and 69,090 sheep and lamb operations in the United States.[4] The overwhelming majority of these operations are considered small entities according to SBA standards.[5] The interim rule is not expected to have significant economic effects on these livestock establishments, as it is not expected to affect the cost of animal eartags.

Limiting use of 840 AINs to U.S.-born animals is expected to benefit the livestock sector generally, and producers in particular, by enhancing APHIS' animal disease response capabilities. The interim rule will also provide a readily available, convenient, effective, and cost-effective means of complying with the COOL regulations and meeting requirements for State/Federal animal disease programs and interstate commerce. Use of the AIN with the 840 prefix will not be required, and other animal identification numbering systems currently permitted for use on official eartags, such as the National Uniform Eartagging System and premises-based number systems, will continue to be recognized as official. Therefore, no animals will be required to be retagged due to this rule.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are in conflict with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

[2] Table of Size Standards based on NAICS 2002. Washington, DC: U.S. Small Business Administration, effective October 1, 2007. Note: NAICS code 326199 comprises establishments primarily engaged in manufacturing plastic products (except film, sheet, bags, profile shapes, pipes, pipe fittings, laminates, foam products, bottles, plumbing fixtures, and resilient floor coverings).

[3] *2002 Economic Census—Manufacturing Series.* Washington, DC: U.S. Census Bureau, December 2004.

[4] USDA-National Agricultural Statistics Service, *2007 Agricultural Statistics, Tables 7–18, 7–26, and 7–53.* Washington, DC: National Agricultural Statistics Service.

[5] The small entity definition for livestock producers (NAICS codes: 112111, 112120, 112210, 112410, and 112420) is one that has $750,000 or less in annual receipts, according to the SBA's Table of Size Standards.

List of Subjects

9 CFR Part 71

Animal diseases, Livestock, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements, Transportation.

9 CFR Part 77

Animal diseases, Bison, Cattle, Reporting and recordkeeping requirements, Transportation, Tuberculosis.

9 CFR Part 78

Animal diseases, Bison, Cattle, Hogs, Quarantine, Reporting and recordkeeping requirements, Transportation.

9 CFR Part 79

Animal diseases, Quarantine, Sheep, Transportation.

9 CFR Part 80

Animal diseases, Livestock, Transportation.

■ Accordingly, we are amending 9 CFR parts 71, 77, 78, 79, and 80 as follows:

PART 71—GENERAL PROVISIONS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

■ 2. Section 71.1 is amended by revising the definition of *animal identification number (AIN)* and by adding a definition of *United States* to read as follows:

§ 71.1 Definitions.

* * * * *

Animal identification number (AIN). A numbering system for the official identification of individual animals in the United States providing a nationally unique identification number for each animal. The AIN contains 15 digits, with the first 3 being the country code (840 for the United States), the alpha characters USA, or the numeric code assigned to the manufacturer of the identification device by the International Committee on Animal Recording. The AIN beginning with the 840 prefix may be used only on animals born in the United States.

* * * * *

United States. All of the States.

* * * * *

■ 3. Section 71.22 is revised to read as follows:

§ 71.22 Removal and loss of official identification devices.

Official identification devices are intended to provide permanent identification of livestock and to ensure the ability to find the source of animal disease outbreaks. Removal of these devices, including devices applied to imported animals in their countries of origin and recognized by the Administrator as official, is prohibited except at the time of slaughter. If an official identification device is lost and it is necessary to retag an animal with a new official number, every effort should be made to correlate the new official number with the previous official number of the animal. If an official identification device applied to an imported animal in its country of origin is lost following importation into the United States, the animal may only be retagged with an official identification device using a numbering system other than an animal identification number beginning with the 840 prefix.

PART 77—TUBERCULOSIS

■ 4. The authority citation for part 77 continues to read as follows:

Authority: 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

■ 5. Section 77.2 is amended by revising the definition of *animal identification number (AIN)* and by adding a definition of *United States* to read as follows:

§ 77.2 Definitions.

* * * * *

Animal identification number (AIN). A numbering system for the official identification of individual animals in the United States providing a nationally unique identification number for each animal. The AIN contains 15 digits, with the first 3 being the country code (840 for the United States), the alpha characters USA, or the numeric code assigned to the manufacturer of the identification device by the International Committee on Animal Recording. The AIN beginning with the 840 prefix may be used only on animals born in the United States.

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United States. All of the States.

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PART 78—BRUCELLOSIS

■ 6. The authority citation for part 78 continues to read as follows:

Authority: 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

■ 7. Section 78.1 is amended by adding ''animal identification number (AIN)'' and ''United States'' to the list of terms, by revising the definition of *animal identification number (AIN)* to read as follows, and by adding a definition of *United States* to read as follows:

§ 78.1 Definitions.

* * * * *

Animal identification number (AIN). A numbering system for the official identification of individual animals in the United States providing a nationally unique identification number for each animal. The AIN contains 15 digits, with the first 3 being the country code (840 for the United States), the alpha characters USA, or the numeric code assigned to the manufacturer of the identification device by the International Committee on Animal Recording. The AIN beginning with the 840 prefix may be used only on animals born in the United States.

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United States. All of the States.

* * * * *

PART 79—SCRAPIE IN SHEEP AND GOATS

■ 8. The authority citation for part 79 continues to read as follows:

Authority: 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

■ 9. Section 79.1 is amended by revising the definition of *animal identification number (AIN)* and by adding a definition of *United States* to read as follows:

§ 79.1 Definitions.

* * * * *

Animal identification number (AIN). A numbering system for the official identification of individual animals in the United States providing a nationally unique identification number for each animal. The AIN contains 15 digits, with the first 3 being the country code (840 for the United States), the alpha characters USA, or the numeric code assigned to the manufacturer of the identification device by the International Committee on Animal Recording. The AIN beginning with the 840 prefix may be used only on animals born in the United States.

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United States. All of the States.

* * * * *

PART 80—JOHNE'S DISEASE IN DOMESTIC ANIMALS

■ 10. The authority citation for part 80 continues to read as follows:

Authority: 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

■ 11. Section 80.1 is amended by revising the definition of *animal*

identification number (AIN) and by adding a definition of *United States* to read as follows:

* * * * *

§ 80.1 Definitions.

* * * * *

Animal identification number (AIN). A numbering system for the official identification of individual animals in the United States providing a nationally unique identification number for each animal. The AIN contains 15 digits, with the first 3 being the country code (840 for the United States), the alpha characters USA, or the numeric code assigned to the manufacturer of the identification device by the International Committee on Animal Recording. The AIN beginning with the 840 prefix may be used only on animals born in the United States.

* * * * *

United States. All of the States.

Done in Washington, DC, this 12th day of September 2008.

Cindy J. Smith,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E8–21787 Filed 9–17–08; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 77

[Docket No. APHIS–2008–0067]

Tuberculosis; Amend the Status of California From Accredited Free to Modified Accredited Advanced

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are amending the regulations to remove California from the list of accredited-free States for bovine tuberculosis and reclassify the State as modified accredited advanced. Because two affected cattle herds have been detected in California since November 2007, the State no longer meets our requirements for accredited-free status. This action is necessary to reduce the likelihood of the spread of bovine tuberculosis within the United States.

DATES: This interim rule is effective September 18, 2008. We will consider all comments that we receive on or before November 17, 2008.

Compliance Date: The date for complying with certain requirements of 9 CFR 77.10 for sexually intact heifers, steers, and spayed heifers moving interstate from California is delayed until further notice (*see* ''Delay in Compliance'' under **SUPPLEMENTARY INFORMATION**). The compliance date for all other provisions in 9 CFR part 77 applicable to the interstate movement of cattle and bison from the State of California is September 18, 2008.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2008-0067* to submit or view comments and to view supporting and related materials available electronically.
- *Postal Mail/Commercial Delivery:* Please send two copies of your comment to Docket No. APHIS–2008–0067, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. APHIS–2008–0067.

Reading Room: You may read any comments that we receive on this docket 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.

Other Information: Additional information about APHIS and its programs is available on the Internet at *http://www.aphis.usda.gov*.

FOR FURTHER INFORMATION CONTACT: Dr. C. William Hench, Senior Staff Veterinarian, National Tuberculosis Eradication Program, Veterinary Services, APHIS, 2150 Centre Ave., Bldg. B, MSC 3E20, Ft. Collins, CO 80526; (970) 494–7378.

SUPPLEMENTARY INFORMATION:

Background

Bovine tuberculosis is a contagious and infectious granulomatous disease caused by the bacterium Mycobacterium bovis. Although commonly defined as a chronic debilitating disease, bovine tuberculosis can occasionally assume an acute, rapidly progressive course. While any body tissue can be affected, lesions are most frequently observed in the lymph nodes, lungs, intestines, liver, spleen, pleura, and peritoneum. Although cattle are considered to be the true hosts of *M. bovis,* the disease has been reported in several other species of both domestic and nondomestic animals, as well as in humans.

At the beginning of the past century, tuberculosis caused more losses of livestock than all other livestock diseases combined. This prompted the establishment in the United States of the National Cooperative State/Federal Bovine Tuberculosis Eradication Program for tuberculosis in livestock.

In carrying out the national eradication program, the Animal and Plant Health Inspection Service issues and enforces regulations. The regulations require the testing of cattle and bison for tuberculosis, define the Federal tuberculosis status levels for States or zones (accredited-free, modified accredited advanced, modified accredited, accreditation preparatory, and nonaccredited), provide the criteria for attaining and maintaining those status levels, and contain testing and movement requirements for cattle and bison leaving States or zones of a particular status level. These regulations are contained in 9 CFR part 77 and in the Bovine Tuberculosis Eradication Uniform Methods and Rules, 1999, which is incorporated by reference into the regulations.

Section 77.7 of the regulations lists accredited-free States and zones and also contains requirements for retention of accredited-free status. Under § 77.7(c), if two or more affected herds are detected in an accredited-free State or zone within a 48-month period, that State or zone will be removed from the list of accredited-free States or zones and will be reclassified as modified accredited advanced.

The State of California has been listed in § 77.7(a) as an accredited-free State for bovine tuberculosis. An epidemiological investigation of a tuberculosis-positive cow found through slaughter surveillance in December 2007 resulted in the confirmation of an affected dairy herd in California. The State continued to conduct epidemiological investigations to detect bovine tuberculosis in domestic cattle herds, and a second affected dairy herd was recently identified in California. The finding of the second affected herd within a 48-month period means that California no longer meets the requirements for accredited-free status. Therefore, we are reclassifying the State as modified accredited advanced. This action is necessary to reduce the likelihood of the spread of tuberculosis within the United States.

As a result of this action, cattle or bison being moved interstate from anywhere in California will now have to

meet the testing requirements that apply to animals from modified accredited advanced States or zones. Under the regulations in § 77.10, cattle or bison that originate in a modified accredited advanced State or zone, and are not known to be infected with or exposed to tuberculosis, may be moved interstate only under one of the following conditions:

- The cattle or bison are moved directly to slaughter at an approved slaughtering establishment (§ 77.10(a));
- The cattle or bison are sexually intact heifers moved to an approved feedlot, or are steers or spayed heifers; and are either officially identified or identified by premises of origin identification (§ 77.10(b));
- The cattle or bison are from an accredited herd and are accompanied by a certificate stating that the accredited herd completed the testing necessary for accredited status with negative results within 1 year prior to the date of movement (§ 77.10(c)); or
- The cattle or bison are sexually intact animals, are not from an accredited herd, are officially identified, and are accompanied by a certificate stating that they were negative to an official tuberculin test conducted within 60 days prior to the date of movement (§ 77.10(d)).

Delay in Compliance

Previous rulemaking changing the tuberculosis classifications of the States of Texas, California, New Mexico, and Minnesota from accredited free to modified accredited advanced allowed for delayed compliance with certain provisions of § 77.10. The interim rule that amended the classification of Texas was effective June 3, 2002, and published in the **Federal Register** on June 6, 2002 (67 FR 38841–38844, Docket No. 02–021–1); in a document published in the **Federal Register** on December 31, 2002, the date for Texas to comply with certain provisions of § 77.10 was extended from January 1, 2003, to September 30, 2003 (67 FR 79836–79837, Docket No. 02–021–3). The interim rule that amended the classification of California was effective and published in the **Federal Register** on April 25, 2003 (68 FR 20333–20336, Docket No. 03–005–1).[1] The interim rule that amended the classification of New Mexico was effective and published in the **Federal Register** on July 24, 2003 (68 FR 43618–43621, Docket No. 03–044–1). The 2003 interim rules changing the statuses of California and New Mexico from accredited-free to modified accredited advanced also allowed for a delay in the compliance date for certain provisions of § 77.10 until September 30, 2003.

The specific provisions of § 77.10 for which we delayed the compliance date were as follows:

- The identification of sexually intact heifers moving to approved feedlots and steers and spayed heifers moving to any destination (§ 77.10(b));
- The identification requirements for sexually intact heifers moving to feedlots that are not approved feedlots (§ 77.10(d)); and
- Because identification is required for certification, the certification requirements for sexually intact heifers moving to unapproved feedlots (§ 77.10(d)).

Initially, we had delayed the date of compliance with these requirements for the State of Texas until September 30, 2003, for two reasons. First, the size of the cattle industry in Texas necessitated additional time to implement the identification requirements of the regulations. Second, some cattle that had begun moving through channels prior to the change in Texas' tuberculosis status would not have been identified at their premises of origin. The compliance date was delayed for California and New Mexico to provide equitable treatment for producers in those States.

Based on the comments that we received on the interim rule for Texas, we concluded that the tuberculosis risk associated with the movement of nonbreeding cattle from modified accredited advanced States or zones through feeder channels to slaughter is low and that identification requirements for certain cattle destined for slaughter may be unnecessary. Therefore, on March 22, 2004, we published in the **Federal Register** (69 FR 13218–13219, Docket No. 03–072–2) an interim rule further delaying the date for compliance with the identification and certification requirements of § 77.10(b) and (d) for nonbreeding cattle from the States of Texas, California, and New Mexico, until further notice. The interim rule published in the **Federal Register** on January 30, 2006 (71 FR 4808–4810, Docket No. APHIS–2006–0004) changing the status of Minnesota from accredited-free to modified accredited advanced also allowed for a delay in the compliance date for certain provisions of § 77.10 until further notice. This delay of the date for compliance with the provisions of § 77.10 listed above also applies to the current rulemaking changing the tuberculosis status of California from accredited-free to modified accredited advanced.

Emergency Action

This rulemaking is necessary on an emergency basis to prevent the spread of bovine tuberculosis within the United States. Under these circumstances, the Administrator has determined that prior notice and opportunity for public comment are contrary to the public interest and that there is good cause under 5 U.S.C. 553 for making this rule effective less than 30 days after publication in the **Federal Register**.

We will consider comments we receive during the comment period for this interim rule (*see* **DATES** above). After the comment period closes, we will publish another document in the **Federal Register**. The document will include a discussion of any comments we receive and any amendments we are making to the rule.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. For this action, the Office of Management and Budget has waived its review under Executive Order 12866.

This emergency situation makes timely compliance with section 603 of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) impracticable. We are currently assessing the potential economic effects of this action on small entities. Based on that assessment, we will either certify that the rule will not have a significant economic impact on a substantial number of small entities or publish a regulatory flexibility analysis.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are in conflict with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This rule contains no new information collection or recordkeeping requirements under the Paperwork

[1] California's previous accredited-free status was then restored in a subsequent interim rule effective and published in the **Federal Register** on April 15, 2005 (70 FR 19877–19878, Docket No. 05–010–1).

Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 9 CFR Part 77

Animal diseases, Bison, Cattle, Reporting and recordkeeping requirements, Transportation, Tuberculosis.

■ Accordingly, we are amending 9 CFR part 77 as follows:

PART 77—TUBERCULOSIS

■ 1. The authority citation for part 77 continues to read as follows:

Authority: 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

§ 77.7 [Amended]

■ 2. In § 77.7, paragraph (a) is amended by removing the word ''California,''.

§ 77.9 [Amended]

■ 3. In § 77.9, paragraph (a) is amended by adding the words ''California and'' before the words ''New Mexico''.

Done in Washington, DC, this 12th day of September 2008.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E8–21814 Filed 9–17–08; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2008–0748 Directorate Identifier 2008–CE–041–AD; Amendment 39–15677; AD 2008–19–10]

RIN 2120–AA64

Airworthiness Directives; EADS SOCATA Model TBM 700 Airplanes

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

ACTION: Final rule.

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

It has been discovered that a risk of mechanical interference exists in the movement of the emergency landing gear by-pass selector, due to an insufficient functional gap between a floor panel attachment lug and the landing gear control button.

This condition, if not corrected, causes mechanical interference which could result in a situation where, during emergency procedures, the landing gear cannot be extended.

We are issuing this AD to require actions to correct the unsafe condition on these products.

DATES: This AD becomes effective October 23, 2008.

On October 23, 2008, the Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD.

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov* or in person at Document Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Albert Mercado, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4119; fax: (816) 329–4090.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM was published in the **Federal Register** on July 8, 2008 (73 FR 38935). That NPRM proposed to correct an unsafe condition for the specified products. The MCAI states:

It has been discovered that a risk of mechanical interference exists in the movement of the emergency landing gear by-pass selector, due to an insufficient functional gap between a floor panel attachment lug and the landing gear control button.

This condition, if not corrected, causes mechanical interference which could result in a situation where, during emergency procedures, the landing gear cannot be extended.

For the reasons described above, this EASA Emergency Airworthiness Directive (AD) requires a check of the gap between the landing gear control button and the floor panel and, if the gap is found to be insufficient, modification of the floor panel.

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

We reviewed the available data and determined that air safety and the public interest require adopting the AD as proposed.

Differences Between This AD and the MCAI or Service Information

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

We might also have required different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are highlighted in a NOTE within the AD.

Costs of Compliance

We estimate that this AD will affect 72 products of U.S. registry. We also estimate that it will take about 1 work-hour per product to comply with basic requirements of this AD. The average labor rate is $80 per work-hour (no labor cost; work-hour warranty given by manufacturer until May 31, 2009).

Based on these figures, we estimate the cost of this AD to the U.S. operators to be $5,760 or $80 per product.

Authority for This Rulemaking

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

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

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between

the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this AD:

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

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

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

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

Examining the AD Docket

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2008–19–10 EADS SOCATA: Amendment 39–15677; Docket No. FAA–2008–0748; Directorate Identifier 2008–CE–041–AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective October 23, 2008.

Affected ADs

(b) None.

Applicability

(c) This AD applies to TBM 700 airplanes, serial numbers 364, 367, and 370 through 439, certificated in any category.

Subject

(d) Air Transport Association of America (ATA) Code 53: Fuselage.

Reason

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

''It has been discovered that a risk of mechanical interference exists in the movement of the emergency landing gear by-pass selector, due to an insufficient functional gap between a floor panel attachment lug and the landing gear control button.

This condition, if not corrected, causes mechanical interference which could result in a situation where, during emergency procedures, the landing gear cannot be extended.

For the reasons described above, this EASA Emergency Airworthiness Directive (AD) requires a check of the gap between the landing gear control button and the floor panel and, if the gap is found to be insufficient, modification of the floor panel.''

Actions and Compliance

(f) For airplanes that have had the floor panel removed for maintenance or if it cannot be positively determined that the floor panel has not been removed at any time, do the following actions, unless already done:

(1) Before further flight after October 23, 2008 (the effective date of this AD), inspect the gap between the landing gear control button and the floor panel. Do the inspection following paragraph A of the Accomplishment Instructions in EADS SOCATA Mandatory TBM Aircraft Service Bulletin SB 70–154, dated April 2008.

(2) If the gap is below the limits specified in paragraph A of EADS SOCATA Mandatory TBM Aircraft Service Bulletin SB 70–154, dated April 2008, before further flight after the inspection required in paragraph (f)(1) of this AD, modify the floor panel following paragraph C of the Accomplishment Instructions in EADS SOCATA Mandatory TBM Aircraft Service Bulletin SB 70–154, dated April 2008.

(3) If the gap is at or above the limits specified in paragraph A of EADS SOCATA Mandatory TBM Aircraft Service Bulletin SB 70–154, dated April 2008, before further flight after the inspection required in paragraph (f)(1) of this AD, recondition the airplane following paragraph D of the Accomplishment Instructions in EADS SOCATA Mandatory TBM Aircraft Service Bulletin SB 70–154, dated April 2008.

(g) For airplanes in which it can be positively determined that the floor panel has not been removed at any time, within the next 30 days after October 23, 2008 (the effective date of this AD), do the following actions, unless already done:

(1) Inspect the gap between the landing gear control button and the floor panel. Do the inspection following paragraph A of the Accomplishment Instructions in EADS SOCATA Mandatory TBM Aircraft Service Bulletin SB 70–154, dated April 2008.

(2) If the gap is below the limits specified in paragraph A of EADS SOCATA Mandatory TBM Aircraft Service Bulletin SB 70–154, dated April 2008, before further flight after the inspection required in paragraph (g)(1) of this AD, modify the floor panel following paragraph C of the Accomplishment Instructions in EADS SOCATA Mandatory TBM Aircraft Service Bulletin SB 70–154, dated April 2008.

(3) If the gap is at or above the limits specified in paragraph A of EADS SOCATA Mandatory TBM Aircraft Service Bulletin SB 70–154, dated April 2008, before further flight after the inspection required in paragraph (g)(1) of this AD, recondition the airplane following paragraph D of the Accomplishment Instructions in EADS SOCATA Mandatory TBM Aircraft Service Bulletin SB 70–154, dated April 2008.

FAA AD Differences

Note: This AD differs from the MCAI and/or service information as follows: No differences.

Other FAA AD Provisions

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

(1) Alternative Methods of Compliance (AMOCs): The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Albert Mercado, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4119; fax: (816) 329–4090. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

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

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

Special Flight Permit

(i) A single ferry flight of the airplane with landing gear extended is allowed in order to reach the nearest maintenance facility where the inspection and modification is to be done.

Related Information

(j) Refer to MCAI European Aviation Safety Agency (EASA) Emergency AD No. 2008–0081–E, dated April 25, 2008; and EADS SOCATA Mandatory TBM Aircraft Service

Bulletin SB 70–154, dated April 2008 for related information.

Material Incorporated by Reference

(k) You must use EADS SOCATA Mandatory TBM Aircraft Service Bulletin SB 70–154, dated April 2008 to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact EADS SOCATA, Direction des Services, 6921 Tarbes Cedex 9, France; or SOCATA AIRCRAFT, INC., North Perry Airport, 7501 South Airport Road, Pembroke Pine, Florida 33023.

(3) You may review copies at the FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri 64106; 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/cfr/ibr-locations.html.*

Issued in Kansas City, Missouri, on September 8, 2008.

Kim Smith,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8–21359 Filed 9–17–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2008–0974; Directorate Identifier 2008–CE–048–AD; Amendment 39–15673; AD 2008–19–06]

RIN 2120–AA64

Airworthiness Directives; EADS SOCATA Model TBM 700 Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

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

Following the rupture of an alternator and vapour cycle cooling system pulley drive assembly, the AD 2008–0067–E had been published to require the replacement of the pulley drive assembly by a new one of an improved design.

Recent cases of rupture of the alternator and vapour cycle cooling system compressor drive shaft and of cracks on the standby-alternator and compressor support have reportedly been found.

Such failures could lead to the loss of the alternator and of the vapour cycle cooling systems, and could also cause mechanical damage inside the powerplant compartment.

This AD requires actions that are intended to address the unsafe condition described in the MCAI.

DATES: This AD becomes effective October 8, 2008.

On October 8, 2008, the Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD.

We must receive comments on this AD by October 20, 2008.

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

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

Examining the AD Docket

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

FOR FURTHER INFORMATION CONTACT: Albert Mercado, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4119; fax: (816) 329–4090.

SUPPLEMENTARY INFORMATION:

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA Emergency AD No.: 2008–0129R1–E, dated July 31, 2008 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

Following the rupture of an alternator and vapour cycle cooling system pulley drive assembly, the AD 2008–0067–E had been published to require the replacement of the pulley drive assembly by a new one of an improved design.

Recent cases of rupture of the alternator and vapour cycle cooling system compressor drive shaft and of cracks on the standby-alternator and compressor support have reportedly been found.

Such failures could lead to the loss of the alternator and of the vapour cycle cooling systems, and could also cause mechanical damage inside the powerplant compartment.

To address this condition, this AD supersedes AD 2008–0067–E and mandates the removal, as a temporary measure, of the compressor drive belt and of the torque limiter, the conditional replacement of the pulley drive shear shaft, and repetitive inspections for cracks of the pulley drive assembly and of the alternator/compressor support.

Revision 1 of this AD introduces an alternative temporary solution with the aim to restore the capability to make use of the air conditioning system. This solution consists in replacing the original pulley drive assembly by a time-limited assembly of a new design, corresponding to the EADS SOCATA modification MOD 70–0240–21.

A definitive solution is still under consideration to correct this condition. You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

EADS SOCATA has issued EADS SOCATA Mandatory TBM Aircraft Alert Service Bulletin SB No. 70–161, Amendment 2, and EADS SOCATA Mandatory TBM Aircraft Alert Service Bulletin SB No. 70–161, Amendment 3, both dated July 2008. The actions described in the service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of the AD

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

Differences Between This AD and the MCAI or Service Information

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

We might have also required different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are described in a separate paragraph of the AD. These requirements take precedence over those copied from the MCAI.

FAA's Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of this AD. The FAA has found that the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because recent cases of rupture of the alternator and vapor cycle cooling system compressor drive shaft and of cracks on the standby generator and compressor support have reportedly been found. Such failures could lead to loss of the alternator and of the vapor cycle cooling systems and could also cause mechanical damages inside the powerplant compartment.

Therefore, we determined that notice and opportunity for public comment before issuing this AD are impracticable and that good cause exists for making this amendment effective in fewer than 30 days.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not precede it by notice and opportunity for public comment. We invite you to send any written relevant data, views, or arguments about this AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2008–0974; Directorate Identifier 2008–CE–048–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this AD. We will consider all comments received by the closing date and may amend this AD because of those comments.

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify that this AD:

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

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

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2008–19–06 EADS SOCATA: Amendment 39–15673; Docket No. FAA–2008–0974; Directorate Identifier 2008–CE–048–AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective October 8, 2008.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Models TBM 700 airplanes, all serial numbers beginning with 434, certificated in any category.

Subject

(d) Air Transport Association of America (ATA) Code 24: Electric Power.

Reason

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

''Following the rupture of an alternator and vapour cycle cooling system pulley drive assembly, the AD 2008–0067–E had been published to require the replacement of the pulley drive assembly by a new one of an improved design.

Recent cases of rupture of the alternator and vapour cycle cooling system compressor drive shaft and of cracks on the standby-alternator and compressor support have reportedly been found.

Such failures could lead to the loss of the alternator and of the vapour cycle cooling systems, and could also cause mechanical damage inside the powerplant compartment.

To address this condition, this AD supersedes AD 2008–0067–E and mandates the removal, as a temporary measure, of the compressor drive belt and of the torque limiter, the conditional replacement of the pulley drive shear shaft, and repetitive inspections for cracks of the pulley drive assembly and of the alternator/compressor support.

Revision 1 of this AD introduces an alternative temporary solution with the aim to restore the capability to make use of the air conditioning system. This solution consists in replacing the original pulley drive assembly by a time-limited assembly of a new design, corresponding to the EADS SOCATA modification MOD 70–0240–21.''

A definitive solution is still under consideration to correct this condition.

Actions and Compliance

(f) Unless already done, for airplanes S/N 434 through 459 only, before further flight after October 8, 2008 (the effective date of this AD), do the following actions following EADS SOCATA Mandatory TBM Aircraft Alert Service Bulletin SB 70–161, amendment 2, dated July 2008:

(1) Remove the pulley drive assembly, the torque limiter, the compressor drive belt, and the alternator/compressor support.

(2) Inspect for cracks on the pulley drive surfaces and the alternator/compressor support welds.

(i) If any crack is detected, replace the pulley drive assembly or conditionally repair the cracked unit following the accomplishment instructions in section D.2 of EADS SOCATA Mandatory TBM Aircraft Alert Service Bulletin SB 70–161, amendment 2, dated July 2008.

(ii) Replacement of the assembly incorporates replacement of the pulley drive sheer shaft required by paragraph (f)(3) of this AD for airplanes with 30 hours TIS or more with the torque limiter installed on the pulley drive shear shaft.

(3) Replace any pulley drive shear shaft that has accumulated 30 hours TIS or more with the torque limiter installed. This action is not required if you replaced the whole assembly per paragraph (f)(2)(i) of this AD.

(4) Re-install the pulley drive assembly and the alternator/compressor support, without re-installing the compressor drive belt or the torque limiter.

(5) Install on the instrument panel and in the pilot's primary field of vision, the following placard:

''AIR COND'' INOPERATIVE

RECOMMENDED ''AIR COND'' SWITCH POSITION: ''MANUAL''

and insert EADS SOCATA Mandatory TBM Aircraft Alert Service Bulletin SB 70–161, amendment 2, dated July 2008 in the limitations section of the pilot's operating handbook.

(g) For all serial number airplanes;

(1) Within 100 hours TIS after October 8, 2008 (the effective date of this AD), and thereafter at intervals not to exceed 100 hours TIS, inspect for cracks on the pulley drive surfaces and the alternator/compressor support welds, following EADS SOCATA Mandatory TBM Aircraft Alert Service Bulletin SB 70–161, amendment 2, dated July 2008. For accomplishment of the repetitive inspections required by paragraph (g)(1) of this AD, paragraph C.2 of the accomplishment instructions of EADS SOCATA Mandatory TBM Aircraft Alert Service Bulletin SB 70–161, amendment 2, dated July 2008, does not apply since the torque limiter has already been removed.

(2) If cracks are found during any of these inspections, before further flight, replace the assembly or conditionally repair the unit following EADS SOCATA Mandatory TBM Aircraft Alert Service Bulletin SB 70–161, amendment 2, dated July 2008. The 100-hour TIS repetitive inspections are still required after replacement or repair.

(h) As an alternative to the requirements of paragraphs (f) and (g) of this AD, do the following actions before further flight after October 8, 2008 (the effective date of this AD), following EADS SOCATA Mandatory TBM Aircraft Alert Service Bulletin SB 70–161, amendment 3, dated July 2008:

(1) Install a zero-timed pulley drive assembly P/N T700G215510000000 following the accomplishment instructions in section D.1, I and J of EADS SOCATA Mandatory TBM Aircraft Alert Service Bulletin SB 70–161, amendment 3, dated July 2008.

(2) Within 100 hours TIS after the installation required in paragraph (h)(1) of this AD and repetitively thereafter at intervals not to exceed 100 TIS, inspect the alternator/compressor support welds for cracks following the accomplishment instructions in sections B,G, H, I, and J of EADS SOCATA Mandatory TBM Aircraft Alert Service Bulletin SB 70–161, amendment 3, dated July 2008.

(3) If any crack is detected in the inspection required in paragraph (h)(2) of this AD, before further flight, replace or repair the cracked unit following EADS SOCATA Mandatory TBM Aircraft Alert Service Bulletin SB 70–161, amendment 3, dated July 2008.

(4) Upon the accumulation of 400 hours TIS, replace each pulley drive assembly, P/N T700G215510000000, with a zero-timed one.

Note 1: Compliance with the requirements of paragraph (h) of this AD restores the capability to make use of the air conditioning system.

FAA AD Differences

Note 2: This AD differs from the MCAI and/or service information as follows: No differences.

Other FAA AD Provisions

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

(1) Alternative Methods of Compliance (AMOCs): The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Albert Mercado, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4119; fax: (816) 329–4090. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

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

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

Related Information

(j) Refer to MCAI EASA Emergency AD No.: 2008–0129R1–E, dated July 31, 2008; EADS SOCATA Mandatory TBM Aircraft Alert Service Bulletin SB 70–161, amendment 2, and EADS SOCATA Mandatory TBM Aircraft Alert Service Bulletin SB 70–161, amendment 3, both dated July 2008, for related information.

Material Incorporated by Reference

(k) You must use EADS SOCATA Mandatory TBM Aircraft Alert Service Bulletin SB 70–161, amendment 2, or EADS SOCATA Mandatory TBM Aircraft Alert Service Bulletin SB 70–161, amendment 3, both dated July 2008, to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact EADS SOCATA—Direction des Services, 65921 Tarbes Cedex 9, France; telephone: +33 (0)5 62 41 73 00; fax: +33 (0)5 62 41 7–54; or in the United States contact EADS SOCATA North America, Inc., North Perry Airport, 7501 South Airport Road., Pembroke Pines, Florida 33023; telephone: (954) 893–1400; fax: (954) 964–4141.

(3) You may review copies at the FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri 64106; 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/cfr/ibr-locations.html.*

Issued in Kansas City, Missouri, on September 8, 2008.

Kim Smith,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8–21429 Filed 9–17–08; 8:45 am]

BILLING CODE 4910–13–P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Parts 3 and 30

RIN 3038–AC26

Exemption From Registration for Certain Firms With Regulation 30.10 Relief

AGENCY: Commodity Futures Trading Commission.

ACTION: Final rule.

SUMMARY: The Commodity Futures Trading Commission (''Commission'') has amended the regulation concerning the registration of firms located outside the U.S. that are engaged in commodity interest activities with respect to trading on U.S. designated contract markets (''DCMs'') and U.S. derivatives transaction execution facilities (''DTEFs'').[1] The amended regulation

[1] Commission regulations referred to herein are found at 17 CFR Ch. I (2007) and may be accessed through the Commission's Web site, *http://www.cftc.gov/lawandregulation/index.htm.*

codifies past actions of the Commission's staff to permit certain foreign firms that have confirmed relief from registration as futures commission merchants (''FCMs'') in accordance with the regulations to introduce to registered FCMs certain U.S. customers in connection with trading futures and commodity options listed on, or subject to the rules of, a U.S. DCM or DTEF without having to register as an introducing broker (''IB'') pursuant to Section 4d of the Commodity Exchange Act (''Act''). The Commission also has revoked the regulation regarding quarterly reporting requirements for foreign futures and foreign options transactions.

DATES: *Effective Date:* October 20, 2008.

FOR FURTHER INFORMATION CONTACT: Andrew V. Chapin, Associate Director, at (202) 418–5430, Division of Clearing and Intermediary Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Electronic mail: *achapin@cftc.gov*.

SUPPLEMENTARY INFORMATION:

I. The Proposal

Part 3 of the Commission's regulations governs the registration of intermediaries engaged in the offer and sale of, and providing advice concerning, futures and commodity options traded on U.S. markets, including both DCMs and DTEFs. Regulation 3.10 sets forth the manner in which FCMs, IBs, commodity pool operators (''CPOs''), commodity trading advisors (''CTAs''), and leverage transaction merchants must apply for registration with the Commission. Regulation 3.10(c) also provides an exemption from registration for certain persons. For example, Regulation 3.10(c)(3) provides an exemption from registration to any foreign person engaged in the activity of an IB, CPO or CTA solely on behalf of customers located outside the U.S., provided that all commodity interest transactions are submitted for clearing to a registered FCM.[2] Part 30 of the Commission's regulations governs the offer and sale to U.S. persons of futures and option contracts entered into on or subject to the rules of a foreign board of trade.

On January 25, 2008, the Commission published for comment proposed amendments to Regulations 3.10 and 30.8 (the ''Proposal'').[3] Specifically, the Commission proposed new Regulation 3.10(c)(4) to exempt from registration as an IB the foreign affiliate of a registered FCM that introduces eligible contract participants (''ECPs'') to a registered FCM for the purpose of trading U.S. exchange-traded futures and options. Among other conditions, the registration relief described in the Proposal was predicated upon the foreign affiliate obtaining an exemption from FCM registration pursuant to Regulation 30.10 (''Regulation 30.10 firm'') and the affiliated FCM's acknowledgment that it would be jointly and severally liable for any violations of the Act or the Commission's regulations by the foreign affiliate in connection with those activities, even if the FCM did not submit the trade for clearing.

As explained in the Proposal, the Commission sought to codify past no-action positions taken by Commission staff that provided a limited-purpose exemption from IB registration only to those foreign affiliates of registered FCMs engaged in global futures brokerage activities on behalf of institutional customers located in the U.S. In doing so, the Commission recognized that institutional U.S. customers who trade globally throughout the 24-hour trading day may achieve greater operational and economic efficiencies by eliminating the need to use multiple order entry systems to execute transactions both domestically and abroad.

The Commission also proposed to revoke Regulation 30.8 requiring each FCM to provide the National Futures Association (''NFA'') with a quarterly report containing data for the total volume of foreign futures and options contracts effected on foreign boards of trade. In the Proposal, the Commission stated that the Regulation 30.8 reporting requirement was overly burdensome in lieu of other extensive reporting and recordkeeping requirements applicable to FCMs as set forth in Part 1 of its regulations.

II. Comments Regarding the Proposal

A. The Comments

The Commission received four comment letters. All of the commenters supported the adoption of Regulation 3.10(c)(4). The two commenters on the proposal to revoke Regulation 30.8 similarly supported that action.

One commenter, a registered FCM, requested the Commission to preserve the position taken in Staff Letter 07–16, applicable to one of the FCM's foreign affiliates.[4] In contrast to other recipients of prior no-action relief, the FCM's foreign affiliate was exempt from IB registration pursuant to Regulation 30.5 and not Regulation 30.10. As such, the FCM's foreign affiliate would not be eligible for the IB registration exemption under the Proposal until such time that either its foreign regulator or self-regulatory organization filed a petition with the Commission in accordance with Regulation 30.10. Another commenter, a membership organization comprised of FCMs and other futures industry participants, commented that FCMs' foreign affiliates in non-30.10 jurisdictions may be interested in obtaining exemptive relief consistent with Regulation 3.10(c)(4) and, accordingly, it requested that the Commission consider addressing those foreign affiliates in the final rulemaking.

B. The Commission's Response

The Commission does not believe it is appropriate at this time to extend the proposed IB registration exemption for trading on domestic markets as set forth in Regulation 3.10(c)(4) to those foreign affiliates exempt from IB registration pursuant to Regulation 30.5. This is because, while the limited-purpose exemption from IB registration set forth in Regulation 3.10(c)(4) is predicated on the existence of a comparable regulatory program in the jurisdiction in which the Regulation 30.10 firm is located, the exemption available in Regulation 30.5 is not. The Commission's determination to limit the relief set forth in Regulation 3.10(c)(4) to Regulation 30.10 firms will benefit U.S. customers by requiring any firm not registered with the Commission as an IB to be subject to a comparable regulatory program in lieu of compliance with the provisions of the Act and Commission regulations applicable to IBs. As set forth in Appendix A to Part 30, the Commission's review of each Regulation 30.10 firm's regulatory program, among other requirements, addresses the foreign laws and regulations applicable to registration and fitness, recordkeeping and reporting, and minimum sales practice standards.

III. Final Rulemaking

Accordingly, the Commission has determined to adopt Regulation 3.10(c)(4) as proposed. As the Commission indicated would be the case in the Proposal, the adoption of Regulation 3.10(c)(4) will supersede the following Staff Letters: 03–28, 04–09, 04–14, 05–06, 07–05, 07–08, 07–16, 07–

[2] *See* 72 FR 63976 (Nov. 14, 2007).

[3] 73 FR 4499 (Jan. 25, 2008).

[4] CFTC Staff Letter 07–16, [Current Transfer Binder] Comm. Fut. L. Rep. (CCH) ¶ _____ (Aug. 21, 2007). CFTC Staff Letters issued since 1995 may be accessed through *http://www.cftc.gov/lawandregulation/exemptivenoactionandinterpretativeletters/index.htm*.

17, 07–20, and 07–23 (the ''Prior Staff Letters'').

Regulation 3.10(c)(4)(iii) requires that the FCM affiliated with the Regulation 30.10 firm seeking relief thereunder file with NFA an acknowledgment of joint and several liability with the 30.10 Firm. Notwithstanding that the Prior Staff Letters have been superseded by the adoption of Regulation 3.10(c)(4), by this **Federal Register** release the Commission confirms that any FCM that previously filed an acknowledgment of joint and several liability pursuant to the conditions of a Prior Staff Letter is not required to file a new acknowledgment with NFA—provided that the previously filed acknowledgment complies with Regulation 3.10(c)(4)(iii).

For the reasons provided in the Proposal, and in the absence of any comments to the contrary, the Commission similarly has determined to revoke and reserve Regulation 30.8.

IV. Related Matters

A. Regulatory Flexibility Act

The Regulatory Flexibility Act (''RFA''), 5 U.S.C. 601–611, requires that agencies, in proposing regulations, consider the impact of those regulations on small businesses. The Commission has previously established certain definitions of ''small entities'' to be used by the Commission in evaluating the impact of its regulations on such entities in accordance with the RFA.[5] The Commission previously has determined that registered FCMs are not small entities for the purpose of the RFA because each FCM has an underlying fiduciary relationship with its customers, regardless of the size of the FCM.[6] The Commission notes that certain foreign persons affected by the changes to the Commission's regulations would be registered as FCMs if not for the exemption provided therein and, as such, would maintain a fiduciary relationship with customers similar to the relationship maintained by each registered FCM.

With respect to IBs, the Commission has stated that it would evaluate within the context of a particular rule whether all or some affected IBs would be considered to be small entities and, if so, the economic impact on them of any rule.[7] The Commission does not believe that any affected global IBs would be considered to be small entities. Moreover, the Commission invited public comment on the impact these proposed rules may have on small entities and received no comments.

Therefore, the Acting Chairman, on behalf of the Commission, hereby certifies, pursuant to 5 U.S.C. 605(b), that these regulations will not have a significant economic impact on a substantial number of small entities. No comment was received regarding the impact of these amendments on small businesses.

B. Paperwork Reduction Act

As required by the Paperwork Reduction Act of 1995,[8] the Commission submitted a copy of the proposed rule amendments to the Office of Management and Budget for its review. The Commission did not receive any public comments relative to its analysis of paperwork burdens associated with this rulemaking.

C. Cost-Benefit Analysis

Section 15(a) of the Act requires the Commission to consider the costs and benefits of its actions before issuing new regulations under the Act. The Commission published an analysis of costs and benefits when it proposed the rule amendments that it is now adopting.[9] It did not receive any public comments pertaining to the analysis.

List of Subjects

17 CFR Part 3

Definitions, Foreign futures, Consumer protection, Foreign options, Registration requirements.

17 CFR Part 30

Definitions, Foreign futures, Consumer protection, Foreign options, Registration requirements.

■ In consideration of the foregoing, and pursuant to the authority contained in the Commodity Exchange Act and, in particular, Sections 2(a)(1), 4(b), 4c and 8a thereof, 7 U.S.C. 2, 6(b), 6c and 12a (1982), and pursuant to the authority contained in 5 U.S.C. 552 and 552b (1982), the Commission hereby amends Chapter I of Title 17 of the Code of Federal Regulations as follows:

PART 3—REGISTRATION

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

Authority: 5 U.S.C. 522, 522b; 7 U.S.C. 1a, 2, 4, 6, 6a, 6b, 6c, 6d, 6e, 6f, 6g, 6h, 6i, 6k, 6m, 6n, 6o, 6p, 8, 9, 9a, 12, 12a, 13b, 13c, 16a, 18, 19, 21, 23, unless otherwise noted.

■ 2. Section 3.10 is amended by adding paragraph (c)(4) to read as follows:

§ 3.10 Registration of futures commission merchants, introducing brokers, commodity trading advisors, commodity pool operators and leverage transaction merchants.

* * * * *

(c) * * *

(4) A person located outside the United States, its territories or possessions that is exempt from registration as a futures commission merchant in accordance with § 30.10 of this chapter is not required to register as an introducing broker in accordance with section 4d of the Act if:

(i) Such a person is affiliated with a futures commission merchant registered in accordance with section 4d of the Act;

(ii) Such a person introduces, on a fully-disclosed basis in accordance with § 1.57 of this chapter, any institutional customer, as defined in § 1.3(g) of this chapter, to a registered futures commission merchant for the purpose of trading on a designated contract market or derivatives execution facility;

(iii) Prior to a person located outside the United States, its territories or possessions, that is exempt from registration as a futures commission merchant pursuant to § 30.10 of this chapter, engaging in the introducing activities described in this paragraph, the affiliated futures commission merchant has filed with the National Futures Association (ATTN: Vice President, Compliance) an acknowledgement that it will be jointly and severally liable for any violations of the Act or the Commission's regulations committed by such person in connection with those introducing activities, whether or not the affiliated futures commission merchant submits for clearing any trades resulting from those introducing activities; and

(iv) Such person does not solicit any person located in the United States, its territories or possessions for trading on a designated contract market or derivatives transaction execution facility, nor does such person handle the customer funds of any person located in the United States, its territories or possessions for the purpose of trading on any designated contract market or derivatives transaction execution facility.

(v) For the purposes of this paragraph, a person shall be affiliated with a futures commission merchant if such a person:

(A) Owns 50 percent or more of the futures commission merchant;

(B) Is owned 50 percent or more by the futures commission merchant; or

(C) Is owned 50 percent or more by a third person that also owns 50 percent

[5] 47 FR 18618–18621 (Apr. 30, 1982).

[6] 47 FR 18619–18620.

[7] 47 FR 18618; *see also* 48 FR 35276 (Aug. 3, 1983).

[8] Pub. L. 104–13 (May 13, 1995).

[9] 73 FR at 4502.

or more of the futures commission merchant.

* * * * *

PART 30—FOREIGN FUTURES AND FOREIGN OPTIONS TRANSACTIONS

■ 3. The authority citation for part 30 continues to read as follows:

Authority: 7 U.S.C. 1a, 2, 4, 6, 6c, and 12a, unless otherwise noted.

§ 30.8 [Removed and reserved]

■ 4. Section 30.8 is removed and reserved.

Dated: September 12, 2008.

By the Commission.

David Stawick,

Secretary of the Commission.

[FR Doc. E8–21857 Filed 9–17–08; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2008–0760]

Drawbridge Operation Regulation; Atlantic Intracoastal Waterway, Jay Jay, FL

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Seventh Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the NASA Railroad bridge across the Atlantic Intracoastal Waterway, mile 876.6, at Jay Jay, FL. The deviation is necessary to perform rehabilitation work on the bridge. This deviation allows the bridge to not open to vessel traffic from 7 a.m. until 11 a.m. and from 1 p.m. until 5 p.m., Monday through Friday except Federal holidays until October 19, 2008. All other times the bridge will continue to operate in accordance with 33 CFR 117.261(j).

DATES: This deviation is effective from September 18, 2008 until October 19, 2008.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2008–0760 and are available online at *http://www.regulations.gov.* They are also available for inspection or copying at two locations: the 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, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays, and the Commander (dpb), Seventh Coast Guard District, 909 SE 1st Avenue, Room 432, Miami, Florida 33131–3028 between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call Mr. Barry Dragon, Bridge Branch, Seventh Coast Guard District, at 305–415–6743. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION: This deviation was requested by NASA, the bridge owner, in order to complete rehabilitation of the NASA Bridge, mile 876.6, of the Atlantic Intracoastal Waterway, Jay Jay, FL. The bridge has a vertical clearance of 7 feet in the closed position and a horizontal clearance of 90 feet. The work will require four hours of continuous closure followed by two hours for vessel passage followed by four hours of continuous closure, Monday through Friday except Federal holidays. All other times the bridge will operate in accordance with 33 CFR 117.261(j). This deviation period begins September 18, 2008 and ends on October 19, 2008. 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.

Dated: August 1, 2008.

Gregory E. Shapley,

Chief, Bridge Branch, Commander, Seventh Coast Guard District.

[FR Doc. E8–21891 Filed 9–17–08; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

33 CFR Part 334

Restricted Area at Blount Island Command and Marine Corps Support Facility—Blount Island, Jacksonville, FL

AGENCY: United States Army Corps of Engineers, Department of Defense.

ACTION: Final rule.

SUMMARY: The U.S. Army Corps of Engineers (Corps) is amending the existing regulations for a restricted area at Blount Island Command, located on Marine Corps Support Facility—Blount Island, Jacksonville, Florida. Blount Island Command is responsible for managing the United States Marine Corps Prepositioning Programs. Due to the importance of this mission, the current restricted area in this section must be extended due to Department of Defense (DoD) directives that require the implementation of specified force protection measures by all DoD components. This amendment to the existing regulation is necessary to protect U.S government personnel, equipment, and facilities from potential terrorist attack by providing stand-off corridors encompassing the waters immediately contiguous to Marine Corps Support Facility—Blount Island.

DATES: *Effective Date:* October 20, 2008.

ADDRESSES: U.S. Army Corps of Engineers, Attn: CECW–CO (David B. Olson), 441 G Street, NW., Washington, DC 20314–1000.

FOR FURTHER INFORMATION CONTACT: Mr. David Olson, Headquarters, Operations and Regulatory Community of Practice, Washington, DC at 202–761–4922 or Mr. Jon M. Griffin, U.S. Army Corps of Engineers, Jacksonville District, Regulatory Division, at 904–232–1680.

SUPPLEMENTARY INFORMATION: Pursuant to its authorities in Section 7 of the Rivers and Harbors Act of 1917 (40 Stat 266; 33 U.S.C. 1) and Chapter XIX of the Army Appropriations Act of 1919 (40 Stat 892; 33 U.S.C. 3) the Corps is amending the regulations in 33 CFR part 334 by modifying § 334.515. The modification to the existing restricted area is described below.

The proposed rule was published in the June 10, 2008, issue of the **Federal Register** (73 FR 32665), and its regulations.gov docket number is COE–2007–0037. No comments were received in response to the proposed rule.

The amendment to this regulation will allow the Commanding Officer, Blount Island Command and Marine Corps Support Facility—Blount Island to restrict passage of persons, watercraft, and vessels in waters contiguous to this Command, thereby ensuring that DoD force protection requirements are met and antiterrorism measures are properly implemented as required by DoD directives.

Procedural Requirements

a. *Review Under Executive Order 12866.* This rule is issued with respect to a military function of the Defense Department and the provisions of Executive Order 12866 do not apply.

b. *Review Under the Regulatory Flexibility Act.* The rule has been reviewed under the Regulatory

Flexibility Act (Pub. L. 96–354) which requires the preparation of a regulatory flexibility analysis for any regulation that will have a significant economic impact on a substantial number of small entities (i.e., small businesses and small governments). The Corps determined that the economic impact of the amendment of this restricted area would have practically no impact on the public, or result in no anticipated navigational hazard or interference with existing waterway traffic. This rule will have no significant economic impact on small entities.

c. *Review Under the National Environmental Policy Act.* This regulation will not have a significant impact to the quality of the human environment and, therefore, preparation of an environmental impact statement will not be required. An environmental assessment has been prepared. It may be reviewed at the district office listed at the end of **FOR FURTHER INFORMATION CONTACT**, above.

d. *Unfunded Mandates Act.* This rule does not impose an enforceable duty among the private sector and, therefore, is not a Federal private sector mandate and is not subject to the requirements of section 202 or 205 of the Unfunded Mandates Reform Act (Pub. L. 104–4, 109 Stat. 48, 2 U.S.C. 1501 *et seq.*). We have also found under Section 203 of the Act, that small governments will not be significantly or uniquely affected by this rule.

List of Subjects in 33 CFR Part 334

Danger zones, Navigation (water), Restricted areas, Waterways.

■ For the reasons set out in the preamble, the Corps amends 33 CFR part 334 as follows:

PART 334—DANGER ZONE AND RESTRICTED AREA REGULATIONS

■ 1. The authority citation for part 334 continues to read as follows:

Authority: 40 Stat. 266 (33 U.S.C. 1) and 40 Stat. 892 (33 U.S.C. 3).

■ 2. Revise § 334.515 to read as follows:

§ 334.515 Blount Island Command and Marine Corps Support Facility–Blount Island; Jacksonville, Florida restricted areas.

(a) *The areas.* (1) The restricted areas shall encompass all navigable waters of the United States, as defined at 33 CFR 329, contiguous to the area identified as Blount Island Command and Marine Corps Support Facility–Blount Island (MCSF–BI). The three areas are contiguous but each area is described separately below for clarification.

(2) *Area 1.* Commencing from the shoreline at the northwest portion of the facility, at latitude 30°24′46.10″ N, longitude 81°32′19.01″ W, thence proceed 200 yards in a northwesterly direction to latitude 30°24′49.84″ N, longitude 81°32′23.12″ W. From this point the line meanders irregularly, following the shoreline at a distance of 200 yards from the mean high water line to a point at latitude 30°23′36.75″ N, longitude 81°30′26.42″ W, thence southwesterly to a point at latitude 30°23′34.44″ N, longitude 81°30′28.80″ W, thence west southwesterly to a point at latitude 30°23′33.68″ N, longitude 81°30′32.61″ W.

(3) *Area 2.* This includes all waters within the area generally identified as the U.S. Marine Corps Slipway but which is also known as the Back River area and the waters out to a distance of 100 yards from the entranceway. From the last point identified in paragraph (a)(2) of this section, latitude 30°23′33.68″ N, longitude 81°30′32.61″ W, proceed west southwesterly to a point at latitude 30°23′30.93″ N, longitude 81°30′57.14″ W.

(4) *Area 3.* From the last point identified in paragraph (a)(3) of this section, latitude 30°23′30.93″ N, longitude 81°30′57.14″ W, the line meanders irregularly in a westerly direction, following the shoreline at a distance of 100 yards from the mean high water line to a point at latitude 30°23′26.34″ N, longitude 81°31′49.73″ W, thence proceed north to terminate at a point on the shoreline at latitude 30°23′29.34″ N, longitude 81°31′49.79″ W.

(b) *The regulations.* (1) With the exception of local, State and federal law enforcement entities, all persons, vessels, and other craft are prohibited from entering, transiting, anchoring, or drifting within the areas described in paragraph (a) of this section for any reason without the permission of the Commanding Officer, Marine Corps Support Facility–Blount Island, Jacksonville, Florida, or his/her authorized representative.

(2) The restriction noted in paragraph (b)(1) of this section is in effect 24 hours a day, 7 days a week.

(3) Warning signs will be posted near the MCSF–BI shoreline advising boaters of the restrictions in this section.

(c) *Enforcement.* (1) The regulations in this section shall be enforced by the Commanding Officer, Marine Corps Support Facility–Blount Island, Jacksonville, Florida, and/or such persons or agencies as he/she may designate.

(2) Enforcement of the regulations in this section will be accomplished utilizing the Department of Defense Force Protection Condition (FPCON) System. From the lowest security level to the highest, Force Protection Conditions levels are titled Normal, Alpha, Bravo, Charlie and Delta. The regulations in this section will be enforced as noted in paragraph (b) of this section, or at the discretion of the Commanding Officer.

Dated: September 12, 2008.

James R. Hannon, Jr.,

Acting Chief, Operations, Directorate of Civil Works.

[FR Doc. E8–21895 Filed 9–17–08; 8:45 am]

BILLING CODE 3710–92–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 417

Health Maintenance Organizations, Competitive Medical Plans, and Health Care Prepayment Plans

CFR Correction

In title 42 of the Code of Federal Regulations, parts 414 to 429, revised as of October 1, 2007, on page 127, in § 417.150, remove the definition of ''Health benefits''.

[FR Doc. E8–21926 Filed 9–17–08; 8:45 am]

BILLING CODE 1505–01–D

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 08–70; MB Docket No. 07–78; RM–11366; RM–11383]

Radio Broadcasting Services; Beeville, Christine, George West, and Tilden, TX

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Audio Division grants a Petition for Rule Making issued at the request of Katherine Pyeatt, proposing the allotment of Channel 245C3 at Christine, Texas, as its first local aural transmission service. The reference coordinates for Channel 245C3 at Christine are 28–40–00 NL and 98–30–15 WL, located 13.6 kilometers (8.4 miles) south of Christine. Additionally, a counterproposal filed by Linda Crawford was dismissed, requesting the allotments of Channel 245A at Christine, Texas, and Channel 250A at Tilden, Texas, as first local aural transmission services. To accommodate

the proposed Tilden allotment, the counterproposal requests the substitution of Channel 296A for vacant Channel 250A at George West, Texas, which in turn requires the substitution of Channel 246A for Channel 296A at Beeville, Texas, and modification of the Station KRXB(FM) license. We hereby change the effective date of this final rule in compliance with 47 CFR 1.427 because the final rule was never published in the **Federal Register**. Accordingly, the *Report and Order* is made effective 30 days from the time the final rule for the above caption proceeding is published in the **Federal Register**.

DATES: Effective October 20, 2008.

ADDRESSES: Federal Communications Commission, 445 Twelfth Street, SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Rolanda F. Smith, Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Report and Order*, MB Docket No. 07–78, adopted January 9, 2008, and January 11, 2008. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Information Center, 445 Twelfth Street, SW., Washington, DC 20554. The complete text of this decision may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 1–800–378–3160 or *http://www.BCPIWEB.com*. The Commission will send a copy of this *Report and Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.

■ As stated in the preamble, the Federal Communications Commission amends 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334, 336.

§ 73.202 [Amended]

■ 2. Section 73.202(b), the Table of FM Allotments under Texas, is amended by adding Christine, Channel 245C3.

Federal Communications Commission.

John A. Karousos,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. E8–21739 Filed 9–17–08; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 97

Amateur Radio Service

CFR Correction

In title 47 of the Code of Federal Regulations, part 80 to end, revised as of October 1, 2007, on page 594, in § 97.109, remove paragraph (e).

[FR Doc. E8–21929 Filed 9–17–08; 8:45 am]

BILLING CODE 1505–01–D

Proposed Rules

Federal Register
Vol. 73, No. 182
Thursday, September 18, 2008

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.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 752

RIN 3206–AL39

Adverse Actions

AGENCY: Office of Personnel Management.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Office of Personnel Management (OPM) proposes to amend its regulations governing Federal adverse actions. The proposed amendments would clarify the adverse action rules regarding reductions in pay and indefinite suspension. In addition, OPM proposes to remove unnecessary subparts pertaining to statutory requirements, make a number of technical corrections, and utilize consistent language for similar regulatory requirements. OPM also proposes various revisions to make the regulations more readable.

DATES: Submit comments on or before November 17, 2008.

ADDRESSES: Send or deliver written comments to Ana A. Mazzi, Deputy Associate Director for Workforce Relations and Accountability Policy, Office of Personnel Management, 1900 E Street, NW., Room 7H28, Washington, DC 20415; by FAX to 202–606–2613; or by e-mail to *CWRAP@opm.gov.*

FOR FURTHER INFORMATION CONTACT: Sharon L. Mayhew by telephone at (202) 606–2930; by FAX at (202) 606–2613; or by e-mail at *CWRAP@opm.gov.*

SUPPLEMENTARY INFORMATION: Sections 7504, 7514, and 7543(a) of title 5, United States Code (U.S.C.), provide the statutory authority for OPM to prescribe regulations pertaining to adverse actions. These regulations are found at title 5, Code of Federal Regulations (CFR), part 752, and are the subject of this proposed rule.

Amendment To Clarify Adverse Action Rules Regarding Reduction in Pay

A reduction in pay is an adverse action covered by chapter 75 of title 5, United States Code. (See 5 U.S.C. 7512(4).) Under current adverse action regulations, ''pay'' is defined as the rate of basic pay exclusive of additional pay of any kind. (See definition of ''pay'' in 5 CFR 752.402.) Thus any pay supplement, such as a locality payment or special rate supplement is not considered part of basic pay in determining whether a reduction in pay and thus an adverse action has occurred.

The Federal Workforce Flexibility Act of 2004 (the Act) (Pub. L. 108–411, October 30, 2004) created new pay administration rules for Federal employees covered by chapter 53 of title 5, United States Code—i.e., employees in the General Schedule (GS) pay system and the Federal Wage System (FWS). Among other purposes, this Act modified pay administration rules to correct anomalies that created unwarranted pay increases or reductions for certain employees. The Act also established the principle that, in cases where an employee's official duty station is moved to a new location where different pay schedules apply, the employee's pay will be treated as if the position he or she is leaving were at the new location, before processing other pay actions. (See 5 U.S.C. 5305(i), 5334(g), and 5363(c) and OPM regulations published on May 31, 2005, 70 FR 31278.)

Implementation of the Act's provisions on locality pay, special rates, and pay retention resolves the problem of unwarranted increases and reductions. However, in certain limited situations, the new pay rules established under the Act, by design, can result in a reduction of an employee's ''basic'' or base rate of pay even while protecting the employee's total salary rate. Such a reduction may occur when a personnel action changes an employee's pay entitlement from a rate of basic pay without any supplement to an adjusted rate of basic pay consisting of a base rate and a basic pay supplement (i.e., locality payment or special rate supplement for a GS employee).

For example, an employee may change positions and move from the Federal Wage System (FWS), in which the locality pay adjustment is essentially incorporated within the rate of basic pay, to the GS pay system, which often provides a separate supplement (locality payment or special rate supplement) on top of the rate of basic pay. Under the new pay administration rules in effect as a result of Public Law 108–411, the FWS rate (after applying geographic pay conversion as necessary) is compared to GS supplement-adjusted rates. If an FWS-to-GS movement is involuntary, pay retention would apply and the GS total pay rate (including any supplement) would be set at a rate equal to or greater than the FWS rate. However, the new GS basic rate excluding the supplement may be lower than the FWS rate.

Another example involves a change of pay entitlements within the same pay system. A GS employee may be entitled to a retained rate, which is a rate of basic pay without any supplement, and then, as the result of a personnel or pay action, the employee may cease to be entitled to the retained rate. In such case, the employee would receive an adjusted rate consisting of a base rate and a supplement. If the supplement is not considered, the employee could be viewed as having a reduction in basic pay—even though there is no reduction in the total rate of pay and the rate is being correctly set in accordance with the new applicable pay administration rules.

Public Law 108–411 also provided that pay retention would no longer apply when an FWS employee is involuntarily reassigned to a different geographic location where a lower wage schedule applies. While the FWS employee keeps the same grade and step, the employee's wage rate will be lower. Under 5 U.S.C. 5363, as amended by Public Law 108–411, the FWS employee is not entitled to pay retention when the reduction is attributable to a geographic move. This is consistent with the treatment of GS employees who may become entitled to a lower locality payment due to a geographic move and who are also not entitled to pay retention. Thus, the FWS employee's pay reduction occurs by operation of law as a result of geographic pay conversion.

In the examples cited above, pay is being correctly set under the new law and applicable pay administration rules. While paragraph (b)(15) of 5 CFR

752.401 currently excludes from adverse action coverage any ''[r]eduction of an employee's rate of basic pay from a rate that is contrary to law or regulation,'' we believe the clarity of the regulations would be enhanced by specifically excluding from coverage those actions that result from compliance with the new pay-setting requirements of Public Law 108–411.

Accordingly, we are proposing to amend 5 CFR 752.401(b)(15), to clarify that a reduction in an employee's rate of basic pay resulting from the application of Public Law 108–411 and implementing regulations is excluded from adverse action coverage.

Amendments To Clarify Adverse Action Rules Regarding Indefinite Suspension

Background

Indefinite suspensions involve the placing of an employee in a temporary status without duties and pay pending an investigation, inquiry, or further agency action. An indefinite suspension continues for an indeterminate period of time and ends with the completion of the pending condition subsequent set forth in the notice of proposed action. That pending condition may include, for example, a criminal or administrative investigation and any subsequent administrative action taken.

An indefinite suspension is an infrequently utilized but critical option when public employees are being investigated or charged with serious criminal offenses, or are under investigation for other serious or egregious misconduct. With these regulations and supplementary materials, OPM clarifies that a portion of 5 U.S.C. 7513(b)(1), frequently referred to as the ''crime provision,'' is exclusively a notice provision. It does not set a higher standard for indefinite suspensions than for other adverse actions.

Specifically, in the vast majority of adverse actions, thirty (30) days' advance written notice to the employee is required. However, the law carves out a narrow exception to that 30 days' advance notice requirement in those limited situations where there is reasonable cause to believe that the employee has committed a crime for which a sentence of imprisonment may be imposed. This notice exception has sometimes been erroneously interpreted to establish an entirely new and different ''reasonable cause'' review standard for indefinite suspensions in general. That standard, however, only applies to the determination of whether the 30-day notice period may be shortened. Like all other adverse actions, indefinite suspensions must meet the statutory requirement of promoting the efficiency of the service. Moreover, indefinite suspensions are not restricted to occasions when employees have been indicted for a criminal offense. Indefinite suspensions may also be warranted when an employee is under investigation for other serious misconduct that, if proven to be true, would warrant removal when, for example, the employee is under investigation for an allegation of conduct posing a significant risk to the life, health or safety of others, government or public property, the effective accomplishment of the agency's operations, national security or privacy interests. An indefinite suspension with a 30-day notice period in these instances may be appropriate to ensure the efficiency of the service by maintaining public trust in the Federal workforce. It may also be appropriate when, for example, the employee is under investigation based on an allegation that the employee poses a risk to the health or safety of others, the employee's security clearance has been suspended or revoked, or the employee's fitness-for-duty examination or determination is pending.

OPM's interpretation of the ''crime provision'' in 5 U.S.C. 7513(b) recently was affirmed by the U.S. Court of Appeals for the Federal Circuit in *Perez* v. *Department of Justice,* 480 F.3d 1309, 1313 (Fed.Cir. 2007). In this case, the Court held that section 7513(b) ''is solely a notice provision, and it provides an exception to the 30-day notice requirement for all the types of adverse actions specified in 5 U.S.C. 7512(2) if the agency has reasonable cause to believe an employee has committed a crime for which imprisonment may be imposed.'' *Id.* Thus, reasonable cause is only required if the agency provides the employee less than a 30-day notice period in its notice of proposed action. *Id.* The Federal Circuit further confirmed that adverse actions, including indefinite suspensions, must ''promote the efficiency of the service,'' noting that arbitrary action against an employee would not satisfy that standard. *Id.*

Accordingly, to clarify that the ''crime provision'' is only an exception to the general 30-day notice requirement for taking adverse actions and is not a separate standard of proof for indefinite suspensions, OPM therefore proposes to specify in paragraph (a) of 5 CFR 752.403 that an indefinite suspension is an adverse action an agency may take to promote the efficiency of the service. OPM also proposes to include the term ''indefinite suspension'' in paragraph (b)(1) of 5 CFR 752.404, ''Notice of proposed action,'' to emphasize that an indefinite suspension is to be taken in the same manner as any other adverse action under that subpart. Additionally, OPM proposes to add a new paragraph (c) to 5 CFR 752.403, ''Standard for Action,'' to clarify the applicable standard for indefinite suspensions when 30 days notice is provided to the employee.

Amendments To Modify and Clarify Adverse Actions Rules Under the Senior Executive Service

Section 752.604 sets forth the procedures to be followed for SES adverse actions under 5 U.S.C. chapter 75. Revising the regulations to make them more comprehensible, OPM proposes to delete redundant sections and change the placement of some information to make it more clear and accessible to agencies and employees.

We further propose four additional amendments to the SES regulations. First, we propose to add a new § 752.604(f), ''Agency review of medical information,'' to explain agency authority and responsibilities in obtaining and reviewing medical information as provided under 5 CFR 339.301 and 339.302. Second, we propose to add a new § 752.604(h) to address applications for disability retirement and their effect on adverse actions. These two sections mirror the provisions currently provided in the regulations applicable to non-SES employees. Third, as a result of adding these new sections, we have redesignated the former § 752.604(f) as § 752.604(g), and added language to clarify procedural rights. Fourth, we propose to modify § 752.606 *Agency Records* to specify the documentation that should be maintained in the agency's record, and we are proposing a similar modification to the provisions applicable to non-SES employees (§ 752.406).

Amendments To Update Definitions Formatting

The *Federal Register Document Drafting Handbook* recommends a particular format for CFR definitions sections. Accordingly, we take this opportunity to propose revising §§ 752.201 and 752.402 by removing the letter designations and placing the terms in alphabetical order.

Amendments To Correct Statutory and Regulatory References

Section 752.201 addresses actions excluded from coverage under 5 U.S.C. chapter 75. Section 752.201(c)(2) excludes actions taken for national

security reasons but erroneously cites 5 U.S.C. 7531 as the authority under which an agency may take action. Section 7531 of title 5, U.S. Code, addresses the definition of ''agency.'' The correct citation is 5 U.S.C. 7532, which describes suspensions and removals for national security reasons. Accordingly, we propose to correct the citation.

In addition, section 752.201(c)(3) excluded actions taken under a provision of statute, *other* than one codified in title 5, U.S. Code, which excepts the action from subchapter I, chapter 75 of title 5, U.S. Code. In light of recent statutory amendments authorizing establishment of alternative personnel systems *within* title 5, U.S. Code, such as for the Department of Homeland Security and the Department of Defense, this exclusion is too narrow. We propose to modify this section to exclude actions excepted by law, regardless of whether such law is codified in title 5, U.S. Code. For the same reason, we propose to make the same modification in § 752.401(b)(7).

Section 752.203 describes procedures for actions taken under 5 U.S.C. chapter 75. Section 752.203(f), ''Grievances,'' erroneously cites 5 U.S.C 7121(b)(3) as governing representation for an employee in an exclusive bargaining unit. Section 7121(b)(3) was removed when the law was amended in 1997. The correct citation is 5 U.S.C. 7121(b)(1)(C). This correction also applies to § 752.405(b). Accordingly, we propose to correct these citations.

Section 752.401(b) sets forth actions excluded from coverage under 5 U.S.C. chapter 75. Section 752.401(b)(1) excludes actions ''imposed by the Merit Systems Protection Board,'' and it erroneously cites 5 U.S.C. 1206 as the authority under which the Board may take actions. Instead, 5 U.S.C. 1206 addresses the annual reporting requirement for the MSPB. The correct citation is 5 U.S.C. 1215. Accordingly, we propose to correct the citation.

The current § 752.401(c)(3) references covered employees in the Postal Rate Commission. The Postal Accountability and Enhancement Act (Pub. L. 109–435) which was signed into law on December 20, 2006, changed the name of the Postal Rate Commission to the Postal Regulatory Commission. We propose to reflect the current name in the regulations at paragraph (c)(3) and in paragraph (d)(9) of section 752.401.

Section 752.401(d) describes employees excluded from coverage under 5 U.S.C. chapter 75. Section 752.401(d)(5) excludes technicians in the National Guard from coverage, and it erroneously cites 32 U.S.C. 709(b) as the authority for the exclusion. The correct citation is 32 U.S.C. 709(a). Similarly, § 752.401(d)(8) excludes employees of the Veterans Health Administration (Department of Veterans Affairs) from coverage and it erroneously cites 5 U.S.C. 7401(3) as an exception to the exclusion. Section 7401(3) does not exist. The correct citation is 38 U.S.C. 7401(3). Accordingly, we propose to correct these citations. Finally, § 752.401(d)(9) excludes nonpreference eligibles in specified Department of Defense intelligence components or activities. This exclusion was based on 5 U.S.C. 7511(b)(8) which was amended in 1996 by Public Law 104–201 to modify the reference to title 10, U.S. Code. We propose to amend § 752.401(d)(9) to reflect the current statutory provision.

Section 752.404 explains the procedures for actions taken under 5 U.S.C. chapter 75. Section 752.404(b)(1) makes reference to a prohibition against releasing certain medical information to an employee. That prohibition no longer exists. Accordingly, we propose to remove this language. For the same reason we propose to make the same modification in § 752.604(b). The requirement in §§ 752.404(b)(1) and 752.604(b) that an employee be informed of his or her right to review the material relied on to support the action is retained. Section 752.404(c)(3) addresses medical documentation submitted as a part of the employee's answer and erroneously cites 5 CFR 339.102 for the definition of medical documentation. Section 339.102 states the purpose and effect of acquiring medical documentation. Instead, § 339.104 defines ''medical documentation'' and is the correct cite. Similarly, § 752.404(h) addresses applications for disability retirement and erroneously cites § 831.501(d), which does not exist. The correct citation is § 831.1204(e).

In addition, 5 CFR 752.404(h) erroneously cites § 831.1203 as providing the basis under which agencies shall file an application for disability retirement on behalf of an employee. Section 831.1203 describes the basic requirements for disability retirement. The correct citation is § 831.1205, which addresses agency-filed disability retirement applications. Accordingly, we propose to correct these citations.

Section 752.601 addresses coverage under 5 U.S.C. chapter 75. Section 752.601(a)(2) excludes actions taken under other authorities in title 5, United States Code, and erroneously cites 5 U.S.C. 1206(g) as one of the exclusions. This section, however, does not exist. The correct citation is 5 U.S.C. 1215. Section 1215 describes disciplinary actions imposed by the MSPB. Accordingly, we propose to correct this citation.

Amendment To Remove Subparts A, C, and E

In an effort to streamline and make more readable our regulations at 5 CFR part 752, OPM proposes to remove three superfluous subparts. Subparts A, C, and E merely reprint the sections of the United States Code that are the basis of the regulations found at 5 CFR part 752, subparts B, D, and F. OPM proposes to remove this material and reserve subparts A, C, and E.

Amendments to Adverse Action Procedures

Section 752.404 sets forth the procedures to be followed for adverse actions under 5 U.S.C. chapter 75. Revising the regulations to make them more comprehensible, OPM proposes to delete redundant sections and change the placement of some information to make it more clear and accessible to agencies and employees.

In addition, we propose to modify § 752.406, *Agency Records,* to clearly identify the documentation that should be maintained in the agency's record consistent with the law. An identical modification is proposed for §§ 752.203 and 752.606.

Amendments To Adopt Regulatory Language

In addition to the above substantive changes, OPM proposes to rewrite the regulations in 5 CFR part 752 to replace most instances of the word ''shall'' with appropriate regulatory equivalents, such as ''must'' or ''will.'' This is undertaken in an effort to differentiate regulatory from legislative language. In no case do these modifications change the meaning or intent of the regulation.

Amendments To Adopt Consistent Language for Similar Provisions

Similar regulatory provisions were stated somewhat differently throughout the various sections of the regulations (e.g., subparts B, D, and F). Where applicable, we have proposed to utilize consistent language for similar regulatory requirements without altering the intent of the regulations.

Public Participation

OPM invites interested persons to participate in this proposed rulemaking by submitting written comments, data, or views.

Before finalizing these proposed amendments, we will consider all

comments received on or before the closing date for comments. We will consider comments filed late if it is possible to do so without incurring expense or delay. We may change these proposed amendments in light of the comments we receive.

E.O. 12866, Regulatory Review

The Office of Management and Budget has reviewed this rule in accordance with E.O. 12866.

Regulatory Flexibility Act

OPM has determined these amendments will not have a significant economic impact on a substantial number of small entities because they will apply only to Federal agencies and employees.

List of Subjects in 5 CFR Part 752

Administrative practice and procedure, Government employees.

Office of Personnel Management.

Michael W. Hager,

Acting Director.

Accordingly, OPM proposes to revise part 752 of title 5, Code of Federal Regulations, as follows:

PART 752—ADVERSE ACTIONS

Subpart A—[Removed and Reserved]

Subpart B—Regulatory Requirements for Suspension for 14 Days or Less

Sec.
752.201 Coverage.
752.202 Standard for action.
752.203 Procedures.

Subpart C—[Removed and Reserved]

Subpart D—Regulatory Requirements for Removal, Suspension for More Than 14 Days, Reduction in Grade or Pay, or Furlough for 30 Days or Less

Sec.
752.401 Coverage.
752.402 Definitions.
752.403 Standard for action.
752.404 Procedures.
752.405 Appeal and grievance rights.
752.406 Agency records.

Subpart E—[Removed and Reserved]

Subpart F—Regulatory Requirements for Taking Adverse Actions Under the Senior Executive Service

Sec.
752.601 Coverage.
752.602 Definitions.
752.603 Standard for action.
752.604 Procedures.
752.605 Appeal rights.
752.606 Agency records.

Authority: 5 U.S.C. 7504, 7514, and 7543.

Subpart A—[Removed and Reserved]

Subpart B—Regulatory Requirements for Suspension for 14 Days or Less

§ 752.201 Coverage.

(a) *Adverse actions covered.* This subpart covers suspension for 14 days or less.

(b) *Employees covered.* This subpart covers:

(1) An employee in the competitive service who has completed a probationary or trial period;

(2) An employee in the competitive service serving in an appointment which requires no probationary or trial period, and who has completed 1 year of current continuous employment in the same or similar positions under other than a temporary appointment limited to 1 year or less;

(3) An employee with competitive status who occupies a position under Schedule B of part 213 of this chapter;

(4) An employee who was in the competitive service at the time his or her position was first listed under Schedule A, B, or C of the excepted service and still occupies that position;

(5) An employee of the Department of Veterans Affairs appointed under section 7401(3) of title 38, United States Code; and

(6) An employee of the Government Printing Office.

(c) *Exclusions.* This subpart does not apply to a suspension for 14 days or less:

(1) Of an administrative law judge under 5 U.S.C. 7521;

(2) Taken for national security reasons under 5 U.S.C. 7532;

(3) Taken under any other provision of law which excepts the action from subchapter I, chapter 75, of title 5, U.S. Code;

(4) Of a reemployed annuitant; or

(5) Of a National Guard Technician.

(d) *Definitions.* In this subpart—

Current continuous employment means a period of employment immediately preceding a suspension action without a break in Federal civilian employment of a workday.

Day means a calendar day.

Similar positions means positions in which the duties performed are similar in nature and character and require substantially the same or similar qualifications, so that the incumbent could be interchanged between the positions without significant training or undue interruption to the work.

Suspension means the placing of an employee, for disciplinary reasons, in a temporary status without duties and pay.

§ 752.202 Standard for action.

(a) An agency may take action under this subpart for such cause as will promote the efficiency of the service as set forth in 5 U.S.C. 7503(a).

(b) An agency may not take a suspension against an employee on the basis of any reason prohibited by 5 U.S.C. 2302.

§ 752.203 Procedures.

(a) *Statutory entitlements.* An employee under this subpart whose suspension is proposed under this subpart is entitled to the procedures provided in 5 U.S.C. 7503(b).

(b) *Notice of proposed action.* The notice must state the specific reason(s) for the proposed action, and inform the employee of his or her right to review the material which is relied on to support the reasons for action given in the notice.

(c) *Employee's answer.* The employee must be given a reasonable time, but not less than 24 hours, to answer orally and in writing and to furnish affidavits and other documentary evidence in support of the answer.

(d) *Representation.* An employee covered by this subpart is entitled to be represented by an attorney or other representative. An agency may disallow as an employee's representative an individual whose activities as representative would cause a conflict of interest or position, or an employee of the agency whose release from his or her official position would give rise to unreasonable costs or whose priority work assignments preclude his or her release.

(e) *Agency decision.* (1) In arriving at its decision, the agency will consider only the reasons specified in the notice of proposed action and any answer of the employee or his or her representative, or both, made to a designated official.

(2) The agency must specify in writing the reason(s) for the decision and advise the employee of any grievance rights under paragraph (f) of this section. The agency must deliver the notice of decision to the employee on or before the effective date of the action.

(f) *Grievances.* The employee may file a grievance through an agency administrative grievance system (if applicable) or, if the suspension falls within the coverage of an applicable negotiated grievance procedure, an employee in an exclusive bargaining unit may file a grievance only under that procedure. Sections 7114(a)(5) and 7121(b)(1)(C) of title 5, U.S. Code, and the terms of any collective bargaining agreement, govern representation for employees in an exclusive bargaining

unit who grieve a suspension under this subpart through the negotiated grievance procedure.

(g) *Agency records.* The agency must maintain copies of, and will furnish to the Merit Systems Protection Board and to the employee upon their request, the following documents:

(1) Notice of the proposed action;

(2) Employee's written reply, if any;

(3) Summary of the employee's oral reply, if any;

(4) Notice of decision; and

(5) Any order effecting the suspension, together with any supporting material.

Subpart C—[Removed and Reserved]

Subpart D—Regulatory Requirements for Removal, Suspension for More Than 14 Days, Reduction in Grade or Pay, or Furlough for 30 Days or Less

§ 752.401 Coverage.

(a) *Adverse actions covered.* This subpart applies to the following actions:

(1) Removals;

(2) Suspensions for more than 14 days, including indefinite suspensions;

(3) Reductions in grade;

(4) Reductions in pay; and

(5) Furloughs of 30 days or less.

(b) *Actions excluded.* This subpart does not apply to:

(1) An action imposed by the Merit Systems Protection Board under the authority of 5 U.S.C. 1215;

(2) The reduction in grade of a supervisor or manager who has not completed the probationary period under 5 U.S.C. 3321(a)(2) if such a reduction is to the grade held immediately before becoming a supervisor or manager;

(3) A reduction-in-force action under 5 U.S.C. 3502;

(4) A reduction in grade or removal under 5 U.S.C. 4303;

(5) An action against an administrative law judge under 5 U.S.C. 7521;

(6) A suspension or removal under 5 U.S.C. 7532;

(7) Actions taken under any other provision of law which excepts the action from subchapter II of chapter 75 of title 5, United States Code;

(8) Action that entitles an employee to grade retention under part 536 of this chapter, and an action to terminate this entitlement;

(9) A voluntary action by the employee;

(10) Action taken or directed by the Office of Personnel Management under part 731 of this chapter;

(11) Termination of appointment on the expiration date specified as a basic condition of employment at the time the appointment was made;

(12) Action that terminates a temporary or term promotion and returns the employee to the position from which temporarily promoted, or to a different position of equivalent grade and pay, if the agency informed the employee that it was to be of limited duration;

(13) Cancellation of a promotion to a position not classified prior to the promotion;

(14) Placement of an employee serving on an intermittent or seasonal basis in a temporary nonduty, nonpay status in accordance with conditions established at the time of appointment; or

(15) Reduction of an employee's rate of basic pay from a rate that is contrary to law or regulation, including a reduction necessary to comply with the amendments made by Public Law 108–411, regarding pay-setting under the General Schedule and Federal Wage System and regulations implementing those amendments.

(c) *Employees covered.* This subpart covers:

(1) A career or career conditional employee in the competitive service who is not serving a probationary or trial period;

(2) An employee in the competitive service who has completed 1 year of current continuous service under other than a temporary appointment limited to 1 year or less;

(3) An employee in the excepted service who is a preference eligible in an Executive agency as defined at section 105 of title 5, United States Code, the U.S. Postal Service, or the Postal Regulatory Commission and who has completed 1 year of current continuous service in the same or similar positions;

(4) A Postal Service employee covered by Public Law 100–90 who has completed 1 year of current continuous service in the same or similar positions and who is either a supervisory or management employee or an employee engaged in personnel work in other than a purely nonconfidential clerical capacity;

(5) An employee in the excepted service who is a nonpreference eligible in an Executive agency as defined at section 105 of title, 5, United States Code, and who has completed 2 years of current continuous service in the same or similar positions under other than a temporary appointment limited to 2 years or less;

(6) An employee with competitive status who occupies a position in Schedule B of part 213 of this chapter;

(7) An employee who was in the competitive service at the time his or her position was first listed under Schedule A, B, or C of the excepted service and who still occupies that position;

(8) An employee of the Department of Veterans Affairs appointed under section 7401(3) of title 38, United States Code; and

(9) An employee of the Government Printing Office.

(d) *Employees excluded.* This subpart does not apply to:

(1) An employee whose appointment is made by and with the advice and consent of the Senate;

(2) An employee whose position has been determined to be of a confidential, policy-determining, policy-making, or policy-advocating character by the President for a position that the President has excepted from the competitive service; the Office of Personnel Management for a position that the Office has excepted from the competitive service (Schedule C); or the President or the head of an agency for a position excepted from the competitive service by statute;

(3) A Presidential appointee;

(4) A reemployed annuitant;

(5) A technician in the National Guard described in section 8337(h)(1) of title 5, United States Code, who is employed under section 709(a) of title 32, United States Code;

(6) A Foreign Service member as described in section 103 of the Foreign Service Act of 1980;

(7) An employee of the Central Intelligence Agency or the Government Accountability Office;

(8) An employee of the Veterans Health Administration (Department of Veterans Affairs) in a position which has been excluded from the competitive service by or under a provision of title 38, United States Code, unless the employee was appointed to the position under section 7401(3) of title 38, United States Code;

(9) A nonpreference eligible employee with the U.S. Postal Service, the Postal Regulatory Commission, the Panama Canal Commission, the Tennessee Valley Authority, the Federal Bureau of Investigation, the National Security Agency, the Defense Intelligence Agency, or any other intelligence component of the Department of Defense (as defined in section 1614 of title 10, United States Code), or an intelligence activity of a military department covered under subchapter I of chapter 83 of title 10, United States Code;

(10) An employee described in section 5102(c)(11) of title 5, United States

Code, who is an alien or noncitizen occupying a position outside the United States;

(11) A nonpreference eligible employee serving a probationary or trial period under an initial appointment in the excepted service pending conversion to the competitive service, unless he or she meets the requirements of paragraph (c)(5) of this section;

(12) An employee whose agency or position has been excluded from the appointing provisions of title 5, United States Code, by separate statutory authority in the absence of any provision to place the employee within the coverage of chapter 75 of title 5, United States Code; and

(13) An employee in the competitive service serving a probationary or trial period, unless he or she meets the requirements of paragraph (c)(2) of this section.

§ 752.402 Definitions.

Current continuous employment means a period of employment or service immediately preceding an adverse action without a break in Federal civilian employment of a workday.

Day means a calendar day.

Furlough means the placing of an employee in a temporary status without duties and pay because of lack of work or funds or other nondisciplinary reasons.

Grade means a level of classification under a position classification system.

Indefinite suspension means the placing of an employee in a temporary status without duties and pay pending investigation, inquiry, or further agency action. The indefinite suspension continues for an indeterminate period of time and ends with the occurrence of the pending conditions set forth in the notice of action which may include the completion of any subsequent administrative action.

Pay means the rate of basic pay fixed by law or administrative action for the position held by the employee, that is, the rate of pay before any deductions and exclusive of additional pay of any kind.

Similar positions means positions in which the duties performed are similar in nature and character and require substantially the same or similar qualifications, so that the incumbent could be interchanged between the positions without significant training or undue interruption to the work.

Suspension means the placing of an employee, for disciplinary reasons, in a temporary status without duties and pay for more than 14 days.

§ 752.403 Standard for action.

(a) An agency may take an adverse action, including a performance-based adverse action or an indefinite suspension, under this subpart only for such cause as will promote the efficiency of the service.

(b) An agency may not take an adverse action against an employee on the basis of any reason prohibited by 5 U.S.C. 2302.

(c) An agency may indefinitely suspend an employee, without invoking the crime provision in § 752.404(d)(1) of this part when, for example—

(1) The employee's fitness-for-duty examination or determination is pending; or

(2) The employee is under investigation for serious misconduct that, if proven to be true, would warrant removal, such as when the employee is alleged to have engaged in conduct posing a significant, ongoing risk to:

(i) The life, health or safety of self or others;

(ii) Government or public property including, but not limited to, information technology systems;

(iii) The effective accomplishment of the agency's operations;

(iv) National security; or

(v) Privacy interests.

§ 752.404 Procedures.

(a) *Statutory entitlements.* An employee against whom action is proposed under this subpart is entitled to the procedures provided in 5 U.S.C. 7513(b).

(b) *Notice of proposed action.* (1) An employee against whom an action, including an indefinite suspension, is proposed is entitled to at least 30 days' advance written notice unless there is an exception pursuant to § 752.404(d) of this part. The notice must state the specific reason(s) for the proposed action, and inform the employee of his or her right to review the material which is relied on to support the reasons for action given in the notice.

(2) When some but not all employees in a given competitive level are being furloughed, the notice of proposed action must state the basis for selecting a particular employee for furlough, as well as the reasons for the furlough.

(3) Under ordinary circumstances, an employee whose removal or suspension, including indefinite suspension, has been proposed will remain in a duty status in his or her regular position during the advance notice period. In those rare circumstances where the agency determines that the employee's continued presence in the workplace during the notice period may pose a threat to the employee or others, result in loss of or damage to Government property, or otherwise jeopardize legitimate Government interests, the agency may elect one or a combination of the following alternatives:

(i) Assigning the employee to duties where he or she is no longer a threat to safety, the agency mission, or to Government property;

(ii) Allowing the employee to take leave, or carrying him or her in an appropriate leave status (annual, sick, leave without pay, or absence without leave) if the employee has absented himself or herself from the worksite without requesting leave;

(iii) Curtailing the notice period when the agency can invoke the provisions of *§ 752.404(d)(1)* of this part; or

(iv) Placing the employee in a paid, nonduty status for such time as is necessary to effect the action.

(c) *Employee's answer.* (1) An employee may answer orally and in writing except as provided in paragraph (c)(2) of this section. The agency must give the employee a reasonable amount of official time to review the material relied on to support its proposed action, to prepare an answer orally and in writing, and to secure affidavits, if the employee is in an active duty status. The agency may require the employee to furnish any answer to the proposed action, and affidavits and other documentary evidence in support of the answer, within such time as would be reasonable, but not less than 7 days.

(2) The agency will designate an official to hear the employee's oral answer who has authority either to make or recommend a final decision on the proposed adverse action. The right to answer orally in person does not include the right to a formal hearing with examination of witnesses unless the agency provides for such hearing in its regulations. Under 5 U.S.C. 7513(c), the agency may, in its regulations, provide a hearing in place of or in addition to the opportunity for written and oral answer.

(3) If the employee wishes the agency to consider any medical condition which may contribute to a conduct, performance, or leave problem, the employee must be given a reasonable time to furnish medical documentation (as defined in § 339.104 of this chapter) of the condition. Whenever possible, the employee will supply such documentation within the time limits allowed for an answer.

(d) *Exceptions.* (1) Section 7513(b) of title 5, U.S. Code, authorizes an exception to the 30 days' advance written notice when the agency has reasonable cause to believe that the employee has committed a crime for

which a sentence of imprisonment may be imposed and is proposing a removal or suspension, including indefinite suspension. This notice exception is commonly referred to as the ''crime provision.'' This provision may be invoked even in the absence of judicial action.

(2) The advance written notice and opportunity to answer are not required for furlough without pay due to unforeseeable circumstances, such as sudden breakdowns in equipment, acts of God, or sudden emergencies requiring immediate curtailment of activities.

(e) *Representation.* Section 7513(b)(3) of title 5, U.S. Code, provides that an employee covered by this part is entitled to be represented by an attorney or other representative. An agency may disallow as an employee's representative an individual whose activities as representative would cause a conflict of interest or position, or an employee of the agency whose release from his or her official position would give rise to unreasonable costs or whose priority work assignments preclude his or her release.

(f) *Agency review of medical information.* When medical information is supplied by the employee pursuant to paragraph (c)(3) of this section, the agency may, if authorized, require a medical examination under the criteria of § 339.301, or otherwise, at its option, offer a medical examination in accordance with the criteria of § 339.302. If the employee has the requisite years of service under the Civil Service Retirement System or the Federal Employees Retirement System, the agency must provide information concerning disability retirement. The agency must be aware of the affirmative obligations of the provisions of 29 CFR 1614.203, which require reasonable accommodation of a qualified individual with a disability.

(g) *Agency decision.* (1) In arriving at its decision, the agency will consider only the reasons specified in the notice of proposed action and any answer of the employee or his or her representative, or both, made to a designated official and any medical documentation reviewed under paragraph (f) of this section.

(2) The notice must specify in writing the reasons for the decision and advise the employee of any appeal or grievance rights under § 752.405 of this part. The agency must deliver the notice of decision to the employee on or before the effective date of the action.

(h) *Applications for disability retirement.* Section 831.1204(e) of this chapter provides that an employee's application for disability retirement need not delay any other appropriate personnel action. Section 831.1205 and section 844.202 of this chapter set forth the basis under which an agency must file an application for disability retirement on behalf of an employee.

§ 752.405 Appeal and grievance rights.

(a) *Appeal rights.* Under the provisions of 5 U.S.C. 7513(d), an employee against whom an action is taken under this subpart is entitled to appeal to the Merit Systems Protection Board.

(b) *Grievance rights.* As provided at 5 U.S.C. 7121(e)(1), if a matter covered by this subpart falls within the coverage of an applicable negotiated grievance procedure, an employee may elect to file a grievance under that procedure or appeal to the Merit Systems Protection Board under 5 U.S.C. 7701, but not both. Sections 7114(a)(5) and 7121(b)(1)(C) of title 5, U.S. Code, and the terms of an applicable collective bargaining agreement, govern representation for employees in an exclusive bargaining unit who grieve a matter under this subpart through the negotiated grievance procedure.

§ 752.406 Agency records.

The agency must maintain copies of, and will furnish to the Merit Systems Protection Board and to the employee upon their request, the following documents:

(1) Notice of the proposed action;

(2) Employee's written reply, if any;

(3) Summary of the employee's oral reply, if any;

(4) Agency notice of decision; and

(5) Any order effecting the action, together with any supporting material.

Subpart E—[Removed and Reserved]

Subpart F—Regulatory Requirements for Taking Adverse Action Under the Senior Executive Service

§ 752.601 Coverage.

(a) *Adverse actions covered.* This subpart applies to suspensions for more than 14 days, including indefinite suspensions for more than 14 days, and removals from the civil service as set forth in 5 U.S.C. 7542.

(b) *Actions excluded.* (1) An agency may not take a suspension action of 14 days or less.

(2) This subpart does not apply to actions taken under 5 U.S.C. 1215, 3592, 3595, or 7532.

(c) *Employees covered.* This subpart covers the following appointees:

(1) A career appointee—

(i) Who has completed the probationary period in the Senior Executive Service;

(ii) Who is not required to serve a probationary period in the Senior Executive Service; or

(iii) Who was covered under 5 U.S.C. 7511 immediately before appointment to the Senior Executive Service.

(2) A limited term or limited emergency appointee—

(i) Who received the limited appointment without a break in service in the same agency as the one in which the employee held a career or career-conditional appointment (or an appointment of equivalent tenure as determined by the Office of Personnel Management) in a permanent civil service position outside the Senior Executive Service; and

(ii) Who was covered under 5 U.S.C. 7511 immediately before appointment to the Senior Executive Service.

(d) *Employees excluded.* This subpart does not cover an appointee who is serving as a reemployed annuitant.

§ 752.602 Definitions.

In this subpart—

Career appointee, limited term appointee, and *limited emergency appointee* have the meaning given in 5 U.S.C. 3132(a).

Day means calendar day.

Suspension has the meaning given in 5 U.S.C. 7501(2).

§ 752.603 Standard for action.

(a) An agency may take an adverse action under this subpart only for reasons of misconduct, neglect of duty, malfeasance, or failure to accept a directed reassignment or to accompany a position in a transfer of function.

(b) An agency may not take an adverse action under this subpart on the basis of any reason prohibited by 5 U.S.C. 2302.

§ 752.604 Procedures.

(a) *Statutory entitlements.* An appointee against whom action is proposed under this subpart is entitled to the procedures provided in 5 U.S.C. 7543(b).

(b) *Notice of proposed action.* (1) An appointee against whom an action is proposed is entitled to at least 30 days' advance written notice unless there is an exception pursuant to § 752.604(d) of this part. The notice must state the specific reason(s) for the proposed action, and inform the appointee of his or her right to review the material that is relied on to support the reasons for action given in the notice.

(2) Under ordinary circumstances, an appointee whose removal has been proposed will remain in a duty status in his or her regular position during the advance notice period. In those rare circumstances where the agency

determines that the appointee's continued presence in the work place during the notice period may pose a threat to the appointee or others, result in loss of or damage to Government property, or otherwise jeopardize legitimate Government interests, the agency may elect one or a combination of the following alternatives:

(i) Assigning the appointee to duties where he or she is no longer a threat to safety, the agency mission, or Government property;

(ii) Allowing the appointee to take leave, or carrying him or her in an appropriate leave status (annual, sick, leave without pay, or absence without leave) if the appointee has absented himself or herself from the worksite without requesting leave;

(iii) Curtailing the notice period when the agency can invoke the provisions of paragraph (d) of this section; or

(iv) Placing the employee in a paid, nonduty status for such time as is necessary to effect the action.

(c) *Appointee's answer.* (1) The appointee may answer orally and in writing except as provided in § 752.604(c)(2) of this part. The agency must give the appointee a reasonable amount of official time to review the material relied on to support its proposed action, to prepare an answer orally and in writing, and to secure affidavits, if the appointee is in an active duty status. The agency may require the appointee to furnish any answer to the proposed action, and affidavits and other documentary evidence in support of the answer, within such time as would be reasonable, but not less than 7 days.

(2) The agency will designate an official to hear the appointee's oral answer who has authority either to make or to recommend a final decision on the proposed adverse action. The right to answer orally in person does not include the right to a formal hearing with examination of witnesses unless the agency provides for such hearing in its regulations. Under 5 U.S.C. 7543(c), the agency may in its regulations provide a hearing in place of or in addition to the opportunity for written and oral answer.

(3) If the appointee wishes the agency to consider any medical condition that may have affected the basis for the adverse action, the appointee must be given reasonable time to furnish medical documentation (as defined in § 339.104 of this chapter) of the condition. Whenever possible, the appointee will supply such documentation within the time limits allowed for an answer.

(d) *Exception.* Section 7543(b)(1) of title 5, U.S. Code, authorizes an exception to the 30 days' advance written notice when the agency has reasonable cause to believe that the employee has committed a crime for which a sentence of imprisonment may be imposed and is proposing a removal or suspension, including indefinite suspension. This notice exception is commonly referred to as the ''crime provision.'' This provision may be invoked even in the absence of judicial action.

(e) *Representation.* Section 7543(b)(3) of title 5, U.S. Code, provides that an appointee covered by this part is entitled to be represented by an attorney or other representative. An agency may disallow as an appointee's representative an individual whose activities as representative would cause a conflict of interest or position, or an employee of the agency whose release from his or her official position would give rise to unreasonable costs or whose priority work assignments preclude his or her release.

(f) *Agency review of medical information.* When medical information is supplied by the appointee pursuant to paragraph (c)(3) of this section, the agency may, if authorized, require a medical examination under the criteria of § 339.301, or otherwise, at its option, offer a medical examination in accordance with the criteria of § 339.302. If the appointee has the requisite years of service under the Civil Service Retirement System or the Federal Employees Retirement System, the agency must provide information concerning disability retirement. The agency must be aware of the affirmative obligations of the provisions of 29 CFR 1614.203, which require reasonable accommodation of a qualified individual with a disability.

(g) *Agency decision.* (1) In arriving at its decision, the agency will consider only the reasons specified in the notice of proposed action and any answer of the appointee or the appointee's representative, or both, made to a designated official and any medical documentation reviewed under paragraph (f) of this section.

(2) The notice must specify in writing the reasons for the decision and advise the appointee of any appeal or grievance rights under § 752.605 of this part. The agency must deliver the notice of decision to the appointee on or before the effective date of the action.

(h) *Applications for disability retirement.* Section 831.1204(e) of this chapter provides that an appointee's application for disability retirement need not delay any other appropriate personnel action. Section 831.1205 and section 844.202 of this chapter set forth the basis under which an agency must file an application for disability retirement on behalf of an appointee.

§ 752.605 Appeal rights.

(a) Under 5 U.S.C. 7543(d), a career appointee against whom an action is taken under this subpart is entitled to appeal to the Merit Systems Protection Board.

(b) A limited term or limited emergency appointee who is covered under § 752.601(c)(2) also may appeal an action taken under this subpart to the Merit Systems Protection Board.

§ 752.606 Agency records.

The agency must maintain copies of, and will furnish to the Merit Systems Protection Board and to the employee upon his or her request, the following documents:

(1) Notice of the proposed action;

(2) Employee's written reply, if any;

(3) Summary of the employee's oral reply, if any;

(4) Agency notice of decision; and

(5) Any order effecting the action, together with any supporting material.

[FR Doc. E8–21523 Filed 9–17–08; 8:45 am]

BILLING CODE 6325–39–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 301

[Docket No. APHIS–2006–0153]

RIN 0579 AC25

South American Cactus Moth; Availability of an Environmental Assessment and Reopening of Comment Period

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability and request for comments; reopening of comment period.

SUMMARY: We are advising the public that an environmental assessment has been prepared by the Animal and Plant Health Inspection Service relative to the establishment of domestic quarantine regulations for the South American cactus moth, *Cactoblastis cactorum.* The environmental assessment documents our review and analysis of environmental impacts associated with the proposed rulemaking. We are making this environmental assessment available to the public for review and

comment. In addition, we have determined that the South American cactus moth is present in the State of Mississippi, which we did not include in the quarantined area in our proposal to establish regulations for South American cactus moth. We are reopening the comment period on that proposal to allow interested persons to submit comments on the addition of Mississippi to the proposed quarantined area, as well as on other aspects of the proposal.

DATES: We will consider all comments that we receive on or before October 20, 2008.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS_2006_0153* to submit or view comments and to view supporting and related materials available electronically.
- *Postal Mail/Commercial Delivery:* Please send two copies of your comment to Docket No. APHIS 2006 0153, Regulatory Analysis and Development, PPD, APHIS, Station 3A 03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. APHIS 2006 0153.

Reading Room: You may read any comments that we receive on this docket 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.

Other Information: Additional information about APHIS and its programs is available on the Internet at *http://www.aphis.usda.gov*.

FOR FURTHER INFORMATION CONTACT: Dr. Robyn Rose, National Program Lead, Emergency and Domestic Programs, PPQ, APHIS, 4700 River Rd., Unit 26, Riverdale, MD 20737–1236; (301) 734–7121.

SUPPLEMENTARY INFORMATION:

Background

The South American cactus moth (*Cactoblastis cactorum*) is a grayish-brown moth with a wingspan of 22 to 35 millimeters (approximately 0.86 to 1.4 inches) that is indigenous to Argentina, southern Brazil, Paraguay, and Uruguay. It is a serious quarantine pest of *Opuntia* spp., and an occasional pest of *Nopalea* spp., *Cylindropuntia* spp., and *Consolea* spp., four closely related genera of the family Cactaceae. After an incubation period following mating, the female South American cactus moth deposits an egg stick resembling a cactus spine on the host plant. The egg stick, which consists of 70 to 90 eggs, hatches in 25 to 30 days and the larvae bore into the cactus pad to feed, eventually hollowing it out and killing the plant. Within a short period of time, the South American cactus moth can destroy whole stands of cactus.

On February 11, 2008, the Animal and Plant Health Inspection Service (APHIS) published in the **Federal Register** (73 FR 7679–7686, Docket No. APHIS–2006–0153) a proposal to amend the domestic quarantine regulations to establish regulations to restrict the interstate movement of South American cactus moth host material, including nursery stock and plant parts for consumption, from infested areas of the United States.

In connection with this proposed rule, we have prepared an environmental assessment (EA) entitled ''Quarantine for the South American Cactus Moth, *Cactoblastis cactorum*, in Florida, South Carolina, Georgia, Alabama, and Mississippi.'' We are making this environmental assessment available to the public for review and comment. We will consider all comments that we receive on or before the date listed under the heading **DATES** at the beginning of this notice.

Since publication of the proposed rule, surveys conducted by the Mississippi Department of Agriculture and Commerce have confirmed the presence of South American cactus moth in the State of Mississippi. Therefore, we have determined that Mississippi should be added to the proposed list of quarantined areas in § 301.55–3(c). In addition, we would like to clarify our intention regarding the use of deltamethrin as a treatment. Although the ''Background'' section of the proposal listed deltamethrin as an acceptable treatment for South American cactus moth, the proposed regulatory text did not include deltamethrin. We do not have efficacy data for the use of this chemical on South American cactus moth; therefore we did not intend to approve deltamethrin as a treatment and it should not have been included as an acceptable treatment in the ''Background'' section.

Comments on the proposed rule were required to be received on or before April 11, 2008. We are reopening the comment period for the proposed rule for 30 days following publication of this notice. This action will allow interested persons to prepare and submit comments regarding the proposed addition of Mississippi to the list of States quarantined for South American cactus moth or other aspects of the proposed rule. We will also consider all comments received between April 11, 2008, and the date of this notice.

The environmental assessment, the proposed rule, and all previously received comments on the proposed rule may be viewed on the Regulations.gov Web site or in our reading room (see **ADDRESSES** above for a link to Regulations.gov and information on the location and hours of the reading room). You may request paper copies of the documents listed above by calling or writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. Please refer to the title of the environmental assessment when requesting copies.

The environmental assessment has been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 7 CFR 2.22, 2.80, and 371.3. Section 301.75–15 issued under Sec. 204, Title II, Public Law 106–113, 113 Stat. 1501A 293; sections 301.75–15 and 301.75–16 issued under Sec. 203, Title II, Public Law 106–224, 114 Stat. 400 (7 U.S.C. 1421 note).

Done in Washington, DC, this 12th day of September 2008.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E8–21816 Filed 9–17–08; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 94 and 95

[Docket No. APHIS–2008–0093]

Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Meat, Meat Byproducts, and Meat Food Products Derived From Bovines 30 Months of Age or Older

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Request for comments.

SUMMARY: This document requests comment on the removal of the delay of applicability of certain provisions of the rule entitled ''Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities,'' published in the **Federal Register** on January 4, 2005, 70 FR 460–553. The delay of applicability was removed in a final rule entitled ''Bovine Spongiform Encephalopathy; Minimal-Risk Regions; Importation of Live Bovines and Products Derived from Bovines,'' published in the **Federal Register** on September 18, 2007, 72 FR 53314–53379.

DATES: We will consider all comments that we receive on or before November 17, 2008.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS–2008–0093* to submit or view comments and to view supporting and related materials available electronically.
- *Postal Mail/Commercial Delivery:* Please send two copies of your comment to Docket No. APHIS–2008–0093, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. APHIS–2008–0093.

Reading Room: You may read any comments that we receive on this docket, as well as APHIS supporting materials referenced in this docket, 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.

Other Information: Additional information about APHIS and its programs is available on the Internet at *http://www.aphis.usda.gov*.

FOR FURTHER INFORMATION CONTACT: Dr. Lisa Ferguson, ASEP Director, National Center for Animal Health Programs, VS, APHIS, 4700 River Road Unit 46, Riverdale, MD 20737–1231; (301) 734–6188.

SUPPLEMENTARY INFORMATION:

Background

The Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA or Department) regulates the importation of animals and animal products into the United States to guard against the introduction of animal diseases. The regulations in 9 CFR parts 93, 94, 95, and 96 (referred to below as the regulations) govern the importation of certain animals, birds, poultry, meat, other animal products and byproducts, hay, and straw into the United States in order to prevent the introduction of various animal diseases, including bovine spongiform encephalopathy (BSE), a chronic degenerative disease affecting the central nervous system of cattle.

Nature of BSE

BSE belongs to the family of diseases known as transmissible spongiform encephalopathies (TSEs). All TSEs affect the central nervous system of infected animals. However, the distribution of infectivity in the body of the animal and mode of transmission differ according to the species and the TSE agent. In addition to BSE, TSEs include, among other diseases, scrapie in sheep and goats, chronic wasting disease in deer and elk, and Creutzfeldt-Jakob disease in humans.

The agent that causes BSE has yet to be fully characterized. The theory that is most accepted in the international scientific community is that the agent is an abnormal form of a normal protein known as cellular prion protein. The BSE agent does not evoke a traditional immune response or inflammatory reaction in host animals. BSE is confirmed by post-mortem examination of an animal's brain tissue, which may include detection of the abnormal form of the prion protein in the brain tissues. The pathogenic form of the protein is both less soluble and more resistant to degradation than the normal form. The BSE agent is resistant to heat and to normal sterilization processes.

BSE is not a contagious disease, and therefore is not spread through casual contact between animals. Scientists believe that the primary route of transmission is through ingestion of feed that has been contaminated with a sufficient amount of tissue from an infected animal. This route of transmission can be prevented by excluding potentially contaminated materials from ruminant feed.

Roles of Different Agencies

APHIS, an animal health agency within USDA, promulgates its regulations regarding BSE under the authority of the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), which gives the Secretary broad discretion to regulate the importation of animals and animal products if necessary to protect the health of U.S. livestock.

Because variant Creutzfeldt-Jakob Disease (vCJD) in humans has been linked to exposure to the BSE agent, APHIS collaborates with other Federal agencies with regulatory responsibility for assuring food safety and the protection of human health to implement a comprehensive coordinated U.S. response to BSE. Within USDA, protecting human health from the risks of BSE is carried out by the Food Safety and Inspection Service (FSIS), the agency charged with responsibility for administering the Federal Meat Inspection Act, which was enacted to ensure that meat and meat food products distributed in commerce are wholesome, not adulterated, and properly marked, labeled, and packaged. The USDA agencies carry out their programs in close coordination with the following Centers of the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services: The Center for Veterinary Medicine regarding animal feed; the Center for Food Safety and Applied Nutrition regarding foods other than meat, poultry, and egg products; and other Centers regarding drugs, biologics, and devices containing bovine material. These agencies collaborate, issuing regulations under their respective authorities.

Tissue Localization

Some bovine tissues have demonstrated infectivity, whereas others have not. Most of the information on the development and distribution of tissue infectivity in BSE-infected cattle has been derived from experimental pathogenesis studies conducted in the United Kingdom (Wells, *et al.*, 1994; 1996; 1998; 1999; 2005). In these studies, cattle were deliberately infected with BSE through oral exposure to the brain tissue of cattle with confirmed BSE. Subsets of the experimentally infected cattle were killed at regular intervals as the disease progressed. At each interval, the tissues of the infected cattle were examined for histopathological changes consistent with BSE and for abnormal prion proteins. Also, at each interval, a mouse assay was done—i.e., tissues of the BSE infected cattle were injected intracerebrally and intraperitoneally into mice to identify those tissues of cattle containing infectivity.

The pathogenesis studies involved 30 animals, each of which received a single dose of 100g of infected brain at 4 months of age (Wells, *et al.*, 1994; 1996;

1998; 1999; 2005). This dose is probably 10–100 times greater than that associated with field exposure via feed (DEFRA 2005). The studies demonstrate that in cattle infected with BSE, the total amount of infectivity in the animal, as well as the distribution of infectivity in the animal's body, change over time (Wells, *et al.*, 1994; 1996; 1998; 1999; 2005). The highest levels of infectivity were detected in the brain and spinal cord at the end stages of disease. Some cattle exhibited clinical signs of BSE as early as 35 months after oral exposure to the BSE agent. By 37 months after oral exposure, all five animals that were still alive demonstrated clinical evidence of BSE. Infectivity was found in cattle with clinical signs of BSE in the brain, spinal cord, dorsal root ganglia (DRG),[1] trigeminal ganglia, and the distal ileum of the small intestine.

BSE infectivity was demonstrated in the brain, spinal cord, and DRG as early as 32 months after oral exposure to the BSE agent in some cattle (Wells, *et al.*, 1994; 1996; 1998; 1999; 2005). Infectivity was demonstrated in these tissues 3 months before animals began to develop clinical signs of the disease. Infectivity was demonstrated in the distal ileum of cattle 6 to 18 months after oral exposure to the BSE agent and again at 38 months and 40 months after oral exposure. A similar, more recent, study (Espinosa, *et al.*, 2007) examined the infectivity of tissues from these same animals by intracerebral inoculation of highly sensitive transgenic mice overexpressing bovine PrP. This study's findings were similar to those of Wells, *et al.*, described above. In addition, infectivity in the sciatic nerve was found at low levels only after 30 months from exposure. No detectable infectivity was found in the spleen, skeletal muscle, blood or urine of asymptomatic cattle.

As explained by the United Kingdom's Department for Environment, Food and Rural Affairs (DEFRA) and by the European Commission's Scientific Steering Committee, a second phase of the pathogenesis studies, which used a cattle bioassay as an endpoint, was conducted to ensure that low levels of infectivity that may not have been detected in the first phase using the mouse bioassay were not missed (DEFRA 2006; EC SSC 2002). This second phase of the study was completed in March 2007 (Gerald Wells, personal communication, 2008).

In the cattle bioassay, tissues from the same cattle orally exposed to BSE in the earlier pathogenesis studies were injected directly into the brain of BSE-free cattle (DEFRA 2005). This method is considered to be several hundred-fold more sensitive in detecting BSE infectivity than the mouse bioassay (DEFRA 2005). Preliminary results from the cattle bioassay study demonstrate that, in addition to the materials that were found to contain infectivity when the mouse bioassay was used, the tonsils of calves 10 months after oral exposure to the BSE agent also contain infectivity. However, because only one of five animals injected with tonsil material from infected animals developed clinical BSE at 45 months post-inoculation, the level of infectivity in the tonsils appears to be very low.

BSE infectivity has not been demonstrated in the muscle tissue of BSE-infected cattle examined in these studies through either the mouse bioassay or the cattle assays (Wells 1996; 2005; personal communication 2008). All assays of the skeletal muscle pools were completed in March 2007 (Wells, personal communication 2008).

In addition to these studies on experimentally infected cattle, distribution of tissue infectivity has also been studied in cattle exposed to BSE under field conditions. In these animals, at the end stages of the incubation period with demonstrated clinical signs, BSE infectivity has been confirmed by mouse bioassay only in the brain, spinal cord, and retina of the eye (EC SSC 2001).

In a recent study, mice, genetically engineered to be highly susceptible to BSE and to overexpress the bovine prion protein, were inoculated with tissues from an end-stage clinically affected BSE-infected cow (Buschmann and Groschup, 2005). The sensitivity of these mice to infection is significantly greater than other mice panels used in bio-assays, and the sensitivity is even greater than that of cattle by approximately tenfold. This study demonstrated low levels of infectivity in the facial and sciatic nerves of the peripheral nervous system when injected into these highly sensitive mice. While this study, and the 2007 study by Espinosa, *et al.*, produced interesting findings that can help further characterize the pathogenesis of BSE, they cannot be extrapolated into the context of the risk presented by natural (*i.e.*, field) exposure pathways. The findings may be influenced by the overexpression of prion proteins in these genetically engineered mice. Any apparent levels of infectivity are low in these extremely sensitive mice and would be even lower in other species such as cattle. Moreover, the route of administration to the mice was both intraperitoneal and intracerebral, both of which are very efficient routes of infection as compared to oral consumption.

Tissues that have demonstrated infectivity, and thus are likely to contain the infectious BSE agent in infected cattle, are brain, tonsil, spinal cord, eyes, trigeminal ganglia, DRG, and distal ileum. Approximately 90 percent of the infectivity is associated with the brain, spinal column, DRG, and trigeminal ganglia. The remaining 10 percent is associated with the infectivity in the distal ileum. In BSE, as with other TSEs, the total amount of infectivity in an animal increases throughout the incubation period, reaching the highest load at the end of that period, very close to the death of the animal. Infectivity is considered to increase exponentially, reaching 4.5 logs less than a clinical case at 50 percent of the incubation period and 3 logs less than a clinical case by 70 percent of the incubation period (Comer and Huntly, 2003).

All of this research has contributed to the definition of which tissues should be deemed specified risk materials (SRMs). Both the types of tissues, and the understanding of the progression of the infectivity throughout the incubation period contribute to the definition of SRMs. Affiliated tissues or structures such as skull or vertebral column are also considered risk materials because of the difficulty in separating out small tissues such as DRG from the vertebral column. The risks associated with tissue localization can be mitigated by excluding SRMs from the food or feed chain or by excluding them completely from importation. FSIS and FDA regulations regarding SRMs are based on this scientific knowledge and an understanding of the mitigative effects of exclusion of SRMs (FSIS, 2004; 2004a; 2004b; 2005; 2007; FDA, 2004; 2005; 2007; 2008).

There are some studies available that report finding the presence of the abnormal prion protein in various tissues (Buschmann and Groschup, 2005; Masujin *et al.*, 2007). As new methods are developed that provide increased sensitivity to detect abnormal PrP, such demonstrations of the presence of abnormal PrP in various tissues may continue. However, demonstrating the presence of PrP^{BSE} does not necessarily indicate the presence of BSE infectivity, especially if no infectivity is demonstrated via the

[1] DRG are clusters of nerve cells attached to the spinal cord that are contained within the bones of the vertebral column. ''DRG'' as used in this document has the same meaning as the term ''dorsal spinal nerve root ganglia.'' Trigeminal ganglia are clusters of nerve cells connected to the brain that lie close to the exterior of the skull.

most direct method available: cattle-to-cattle exposure via intracerebral inoculation. Therefore, one cannot automatically assume that a finding of PrP^{BSE} in a tissue means the tissue should be considered infectious or should be considered an SRM. As noted by the World Organization for Animal Health (OIE), the international standard-setting organization for guidelines related to animal health:

> The availability of experimental infectivity data has significantly increased in recent years. During the same interval, extremely sensitive tests have been developed, including those employing highly sensitive transgenic mice strains and potentially more sensitive laboratory PrP detection methods. With the development of such highly sensitive methods, the probability of detection of PrP^{BSE} in tissues that are not currently listed as infectious is increasing. However, such findings need to be considered in context, and their relevance to establishing risk to consumers evaluated carefully when the quantity of PrP^{BSE} detected is potentially below the limit of detection of intracerebral cattle to cattle bioassay (OIE TAHSC, 2006).

Within USDA, APHIS and FSIS review and consider carefully, on an ongoing basis, all BSE research regarding the definition of SRMs, as do other countries that participate in OIE. International guidelines regarding SRM definition and removal have not changed based on the results of the studies noted above that report finding the presence of the abnormal prion protein in various tissues. U.S. regulations regarding SRM removal are consistent with international guidelines.

Prior to 2005, when the APHIS final rule on BSE minimal-risk regions (70 FR 460–553, Docket No. 03–080–3) became effective, APHIS' import regulations regarding BSE considered three categories of regions with regard to BSE—(1) those in which BSE is known to exist, (2) those that present an undue risk of BSE, and (3) all regions not listed in either of the other two categories. Imports from BSE-affected regions and those considered to present an undue risk are governed by the same set of restrictions, including a prohibition on the importation of meat, meat products, and edible products other than meat (except for milk and milk products and gelatin under certain conditions). All other regions were not subject to any import restrictions because of BSE.

Beginning in 2003, APHIS commenced a rulemaking process to update our BSE regulations to reflect the latest scientific data and knowledge of the disease. In a document published in the **Federal Register** on November 4, 2003 (68 FR 62386–62405, Docket No. 03–080–1), APHIS proposed to establish a category of regions that present a minimal risk of introducing BSE into the United States via live ruminants and ruminant products and byproducts, and to add Canada to this category. The proposal also set forth conditions for the importation of certain live ruminants and ruminant products and byproducts from BSE minimal-risk regions. Among the conditions for the importation of meat from BSE minimal-risk regions was that the meat be derived from bovines less than 30 months of age when slaughtered. This age restriction was a measure to guard against the importation of, or contamination of meat through contact with, tissues other than meat that have the potential of containing high levels of BSE infectivity.

On December 25, 2003, less than 2 weeks before the close of the comment period for the proposed rule, a case of BSE in a dairy cow of Canadian origin in Washington State was verified by an international reference laboratory. Subsequently, both FSIS and FDA implemented significant additional measures in the United States to protect human health. In addition, APHIS commenced an enhanced BSE surveillance program to determine the incidence of the disease in the United States.

The measures taken by FSIS included declaring SRMs to be inedible and requiring their removal from cattle at slaughter. FSIS designated as SRMs the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse process of the thoracic and lumbar vertebrae, and the wings of the sacrum), and DRG of cattle 30 months of age or older, and the tonsils and distal ileum of the small intestine of all cattle. To ensure effective removal of the distal ileum, FSIS also required that the entire small intestine be removed and be disposed of as inedible.[2] FSIS also required all slaughtering and processing establishments to develop, implement, and maintain written procedures for the removal, segregation, and disposition of SRMS. Establishments were specifically required to implement procedures to address the potential contamination of edible materials with SRMs before, during, and after entry into the establishment. FSIS did not restrict the age of cattle eligible for slaughter, because the removal of SRMs effectively mitigates the BSE risk to humans associated with cattle that pass both ante-mortem and post-mortem inspections (*i.e.*, apparently healthy cattle).

Pursuant to the Federal Meat Inspection Act, countries that export meat to the United States must implement food safety requirements that are equivalent to those in place in the United States. To be eligible to export beef to the United States, a country must have in place a system to effectively keep SRMs out of the production chain and to prevent cross-contamination of beef with SRMs. FSIS has determined that the SRM requirements implemented by Canada in July 2003 are equivalent to FSIS' requirements. Additionally, FDA's feed ban prohibits most mammalian protein, including ruminant protein, from entering the ruminant feed chain in the United States.

On March 8, 2004, we published a document in the **Federal Register** (69 FR 10633–10636, Docket No. 03–080–2) explaining the effects on our proposed rule of the detection of BSE in the State of Washington in a cow imported from Canada and of the additional measures taken by FSIS, APHIS, and FDA. That document explained why the detection of an imported BSE-infected cow did not alter the conclusions we had reached in our original risk assessment. It explained further that, in fact, the resulting additional measures put in place by FSIS provided a basis for removing from the proposed provisions an age restriction on cattle from which meat would be derived for export to the United States. Accordingly, we proposed to allow the importation of beef derived from cattle of any age. To give the public additional time to comment on the proposal in light of these developments, we reopened and extended the comment period for an additional 30 days.

On January 4, 2005, we published in the **Federal Register** (70 FR 460–553, Docket No. 03–080–3) a final rule that established the criteria for BSE minimal-risk regions, listed Canada as a BSE minimal-risk region, and specified importation requirements for live animals, and meat products and byproducts. The final rule allowed the importation of meat from bovines of any age, as we had proposed on March 8, 2004. The final rule was scheduled to become effective on March 7, 2005.[3]

[2] On September 7, 2005, FSIS published in the **Federal Register** an interim final rule that allowed for use as human food, under certain conditions, beef small intestine, excluding the distal ileum, derived from cattle slaughtered in official U.S. establishments or in certified foreign establishments in countries listed by FSIS in 9 CFR 327.2(b) as eligible to export meat products to the United States.

[3] On March 2, 2005, Judge Richard F. Cebull of the U.S. District Court for the District of Montana ordered that the implementation of APHIS' January

In January 2005, BSE was confirmed in two cows in Canada.

On March 11, 2005, APHIS published a document in the **Federal Register** (70 FR 12112–12113, Docket No. 03–080–6) that, pursuant to an announcement by the Secretary of Agriculture on February 9, 2005, delayed the applicability of the provisions of the January 2005 final rule as they applied to the importation from Canada of the following commodities when derived from bovines 30 months of age or older when slaughtered: (1) Meat, meat food products, and meat byproducts other than liver; (2) whole or half carcasses; (3) offal; (4) tallow composed of less than 0.15 percent insoluble impurities that is not otherwise eligible for importation under 9 CFR 95.4(a)(1)(i); and (5) gelatin derived from bones of bovines that is not otherwise eligible for importation under 9 CFR 94.18(c).

In his February 9, 2005, announcement, the Secretary stated that because ongoing investigations into the recent finds of BSE in Canada in animals over 30 months of age were not complete, he felt it prudent to delay the effective date for allowing imports of meat from bovines 30 months of age and over. He also indicated that the delay of applicability would address concerns that the January 2005 final rule allowed the importation of meat from bovines 30 months of age or older, while continuing to prohibit the importation of live cattle 30 months of age or older for processing in the United States. The Secretary stated that the Department would consider and develop a plan—based on the latest scientific information and with the protection of public and animal health as the highest priority—to allow imports of live bovines 30 months of age or older.

In January 2005, an APHIS team visited Canada to evaluate the epidemiology of the North American BSE cases that had been identified at that time. This team concluded that the information available suggested a localized exposure, based on the relatively small geographical location, the temporal association, and the clustering of cases. The team also evaluated the likelihood of higher-risk animal or feed exposure to the United States at that time, and concluded that the U.S. feed ban and other mitigations had effectively minimized the risk of transmission or amplification of the BSE agent (USDA, 2005). In addition, also in January 2005, USDA sent a team to Canada to assess Canada's feed ban and its feed inspection program to determine whether the control measures put in place by the Canadian Government were achieving compliance with that country's regulations. APHIS conducted an extensive review of the feed ban in Canada and concluded that Canada has a robust inspection program, that overall compliance with the feed ban in Canada was good, and that the feed ban was reducing the risk of transmission of BSE in the Canadian cattle population (USDA, 2005a).

On January 9, 2007, we published a proposed rule in the **Federal Register** (72 FR 1101–1129, Docket No. APHIS–2006–0041) to, among other things, establish conditions for the importation from BSE minimal-risk regions of live bovines for any use born on or after a date determined by APHIS to be the date of effective enforcement of a ruminant-to-ruminant feed ban in the region of export.[4]

We conducted an assessment of the risk to U.S. livestock of allowing the importation of live bovines according to the provisions of the proposed rule from Canada—currently the only region recognized as a BSE minimal-risk region by APHIS. That risk assessment incorporated and built on information from all of the previous analyses, including the 2005 reports of the feed ban team and the epidemiological investigation team. In the risk assessment, we evaluated both the likelihood of ''release'' of the BSE agent into the United States and the likelihood of susceptible animals being exposed, given such release. We evaluated the pathways by which infected Canadian cattle, if imported, might expose U.S. cattle to BSE, and the likelihood that these pathways might lead to the establishment of the disease in the U.S. cattle population. We concluded that the likelihood of BSE exposure and establishment in the U.S. cattle population as a consequence of imports under the proposed rule was negligible.

In our risk assessment, we explained that several steps must occur for BSE to be transmitted to cattle in the United States from a live bovine imported from another country. A BSE-infected bovine must be imported into the United States; the infected bovine must die or be slaughtered; tissues from that animal that contain the infectious agent (i.e., the SRMs) must be sent to a rendering facility; the infectivity present in these tissues must survive inactivation in the rendering process; the resulting meat-and-bone meal containing the abnormal prion protein must be incorporated into feed; and this feed must be fed to cattle, in contravention of FDA regulations, at a level adequate to infect the cattle. (The amount of infectious material required in feed for cattle to become infected is dependent on the age of the cattle; younger cattle are more susceptible to BSE and require less BSE-contaminated feed to become infected (Arnold and Wilesmith, 2004)). We explained in our risk assessment that some of the steps could occur in parallel—i.e., without the occurrence of other steps—while others would need to occur in series. Because the impact of any specific step would depend on its relationship to other steps, its importance to the likelihood of BSE transmission, and, in turn, the impact of disease mitigation measures at each step, cannot be understood in isolation from the rest of the pathway.

One component of our risk assessment was an estimate of the prevalence of BSE in Canada, which was conducted using the same methods as an earlier estimate of the prevalence of BSE in the United States. The results of this prevalence estimate were then used to inform the subsequent considerations and calculations in the risk assessment. Because the prevalence was not zero—i.e., we concluded and acknowledged that BSE is still present in Canada at low levels—the risk assessment consequently assumed that infected animals could be imported into the United States under the provisions of the proposed rule. Even with this assumption, our conclusion that the risk of the exposure of U.S. cattle and the establishment of BSE in the United States was negligible remained unchanged.

On September 18, 2007, we published in the **Federal Register** (72 FR 53314–53379, Docket No. APHIS–2006–0041) a

4, 2005, final rule be preliminarily enjoined. On July 14, 2005, the U.S. States Court of Appeals for the Ninth Circuit ordered that the preliminary injunction order be vacated and the case remanded to the District Court.

[4] Requiring that live bovines exported to the United States from BSE minimal-risk regions be born after the date of effective enforcement of a ruminant-to-ruminant feed ban is consistent with the standards of the World Organization for Animal Health (OIE) for the exportation of live bovines from countries classified by the OIE as having either a negligible or a controlled BSE risk. We consider effective enforcement to have been achieved after completion of the initial (or practical) period of implementation of a feed ban and after sufficient time has elapsed to allow most feed products to cycle through the system. The practical implementation period, which begins when the regulations are initially put in place, can be determined by evaluating implementation guidance and policies, such as allowing grace periods for certain aspects of the industry. In addition, the time necessary for initial education of industry and training of inspectors must be considered. After the practical implementation period is defined, we then consider the time necessary subsequent to practical implementation to allow most feed products to cycle through the system, given the management practices in the country. Effective enforcement does not necessarily mean that 100 percent compliance with the feed ban requirements will be achieved.

final rule that adopted the changes to the regulations we had proposed in January 2007. Additionally, the September 2007 final rule removed the partial delay of applicability of the January 2005 final rule with respect to meat and certain meat products and byproducts derived from cattle over 30 months of age. In our September 2007 final rule, we stated that, subsequent to implementation of the partial delay of applicability, ''we [had] obtained additional information regarding all aspects of the issues that prompted the delay of applicability and [had] conducted additional analyses'' as indicated by the Secretary in February 2005 to allow imports of live bovines 30 months of age or older (72 FR 53316).

As we concluded in our September 2007 final rule, the risk assessment for that final rule demonstrates the negligible BSE risk from the importation of additional classes of live bovines, including those 30 months of age or older. As explained previously, the risk of transmission of BSE occurs when SRMs from infected cattle enter the ruminant feed supply in contravention of current feed regulations. Since the risk is tied to those tissues that contain infectivity, if those tissues are excluded from import, the risk is mitigated. When live cattle are imported, the potential exists that, after their death, their SRMs could enter the ruminant feed supply. Even with this potential, the conclusion of the risk assessment was that such imports present a negligible risk of establishment of BSE in the United States. As noted above, one of the requirements for the importation of meat from bovines is that the SRMS be removed from the animals from which the meat is derived. In other words, the SRMs are excluded from import and would not even have the potential to enter the risk pathway in the United States. Therefore, the conclusion of negligible risk related to the importation of live older bovines gives further support to the conclusion of the risk analysis conducted for our January 2005 final rule regarding meat and meat products derived from bovines of any age in BSE minimal-risk regions. Specifically, the risk is even lower for the importation of meat and meat products than for live bovines.

The September 2007 final rule, which included the removal of the partial delay of applicability of the provisions of the January 2005 rule relating to meat derived from cattle 30 months of age or older, became effective on November 19, 2007.

On July 3, 2008, Judge Lawrence L. Piersol of the U.S. District Court for the District of South Dakota, in response to a motion filed in that Court, ordered USDA to provide the public with notice and a further opportunity to comment on the provisions of our January 2005 final rule regarding the importation of beef from bovines 30 months of age or older when slaughtered, to consider comments made by interested parties, and to revise the rule as USDA deems necessary. In this document, we are providing such notice and further opportunity for comment. We will consider all comments that we receive by November 17, 2008.

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Authority: 7 U.S.C. 450, 7701–7772, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 12th day of September 2008.

Cindy J. Smith,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E8–21786 Filed 9–17–08; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF ENERGY

10 CFR Part 430

[Docket No. EERE–2008–BT–STD–0012]

RIN 1904–AB80

Energy Conservation Standards for Residential Refrigerators, Refrigerator-Freezers, and Freezers: Public Meeting and Availability of the Framework Document

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of public meeting and availability of the framework document.

SUMMARY: DOE will hold an informal public meeting to discuss and receive comments on issues that it will address in this rulemaking proceeding. The Department is also initiating data collection for establishing energy conservation standards for residential refrigerators, refrigerator-freezers, and freezers. The Department also encourages written comments on these subjects. To inform stakeholders and facilitate this process, DOE has prepared a draft framework document, available at *http://www1.eere.energy.gov/buildings/appliance_standards/residential/refrigerators_freezers.html*.

DATES: The Department will hold a public meeting on Monday, September 29, 2008, from 9 a.m. to 5 p.m. in Washington, DC. Any person requesting to speak at the public meeting should submit such request along with a signed original and an electronic copy of the statements to be given at the public meeting before 4 p.m., Monday, September 22, 2008. Written comments are welcome, especially following the public meeting, and should be submitted by October 20, 2008.

ADDRESSES: The public meeting will be held at the U.S. Department of Energy, Forrestal Building, Room 8E–089, 1000 Independence Avenue, SW., Washington, DC 20585–0121. Please note that foreign nationals participating in the public meeting are subject to advance security screening procedures. If a foreign national wishes to participate in the public meeting, please inform DOE of this fact as soon as possible by contacting Ms. Brenda Edwards at (202) 586–2945 so that the necessary procedures can be completed.

Stakeholders may submit comments, identified by docket number EERE–2008–BT–STD–0012 and/or Regulation Identifier Number (RIN) 1904–AB80, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.
- *E-mail: ResRefFreez–2008–STD–0012@hq.doe.gov*. Include EERE–2008–BT–STD–0012 and/or RIN 1904–AB80 in the subject line of the message.
- *Mail:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, Mailstop EE–2J, Framework Document for Refrigerators, Refrigerator-Freezers, and Freezers, EERE–2008–BT–STD–0012 and/or RIN 1904–AB80, 1000 Independence Avenue, SW., Washington, DC 20585–0121. *Phone:* (202) 586–2945. Please submit one signed paper original.
- *Hand Delivery/Courier:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, 6th Floor, 950 L'Enfant Plaza, SW., Washington, DC 20024. Phone: (202) 586–2945. Please submit one signed paper original.

Instructions: All submissions received must include the agency name and docket number or RIN for this rulemaking.

Docket: For access to the docket to read background documents, a copy of the transcript of the public meeting, or comments received, go to the U.S. Department of Energy, 6th Floor, 950 L'Enfant Plaza, SW., Washington, DC 20024, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays. For additional information about visiting the Resource Room, please call Ms. Brenda Edwards at (202) 586–2945. Please note that the Department's Freedom of Information Reading Room (formerly Room 1E–190 at the Forrestal Building) no longer houses rulemaking materials.

FOR FURTHER INFORMATION CONTACT: (1) Stephen Witkowski, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies, EE–2J, 1000 Independence Avenue, SW., Washington, DC 20585–0121. *Phone:* (202) 586–7463. *e-mail: stephen.witkowski@ee.doe.gov*. (2) Michael Kido, U.S. Department of Energy, Office of General Counsel, GC–72, 1000 Independence Avenue, SW., Washington, DC 20585–0121. *Phone:* (202) 586–9507. *e-mail: michael.kido@hq.doe.gov*.

SUPPLEMENTARY INFORMATION: Part A of Title III of the Energy Policy and

Conservation Act of 1975 (EPCA), 42 U.S.C 6291 *et seq.* , established an energy conservation program for major household appliances, which includes residential refrigerators, refrigerator-freezers, and freezers. This program authorizes the Department to establish technologically feasible, economically justified energy efficiency regulations for certain consumer products for which such regulations would incur substantial national energy savings, and for which both natural market forces and voluntary labeling programs have been and/or are expected to be ineffective in promoting energy efficiency.

The amendments to EPCA in the National Appliance Energy Conservation Act of 1987 (NAECA), Public Law 100–12, established energy conservation standards for refrigerators, refrigerator-freezers, and freezers, as well as requirements for determining whether these standards should be amended. (42 U.S.C. 6295(b))

EPCA, as amended by NAECA, established performance standards for residential refrigerators, refrigerator-freezers, and freezers and required that DOE conduct two cycles of rulemakings to determine whether more stringent standards are justified. (42 U.S.C. 6295 (b)) On November 17, 1989, DOE published a final rule in the **Federal Register** updating the performance standards. The new standards became effective on January 1, 1993. 54 FR 47916. Subsequently, DOE determined that new standards for some of the product classes were based on incomplete data and incorrect analysis. As a result, DOE published a correction that amended the new standards for the following three product classes: (1) Refrigerators and refrigerator-freezers with manual defrost, (2) refrigerator-freezers with automatic defrost with a bottom-mounted freezer but without through-the-door (TTD) ice service, and (3) chest freezers and all other freezers. 55 FR 42845. DOE updated the performance standards once again for refrigerators, refrigerator-freezers, and freezers by publishing a final rule in the **Federal Register** on April 28, 1997. 62 FR 23102. The new standards became effective on July 1, 2001. By completing a second standards rulemaking, DOE had fulfilled its legislative requirement to conduct two cycles of standards rulemakings.

Stakeholders submitted a petition in 2004 requesting that DOE conduct another rulemaking to amend the standards for residential refrigerator-freezers. In April 2005, DOE granted the petition and conducted a limited set of analyses to assess the potential energy savings and potential economic benefit of new standards. DOE issued a report in October 2005 detailing the analyses, which examined the technological and economic feasibility of new standards set at Energy Star levels effective in 2005 for the two most popular product classes of refrigerators: Top-mount refrigerator-freezers without TTD features and side-mount refrigerator-freezers with TTD features. DOE confined its updated analysis to these two classes because they accounted for a majority of current product shipments. Depending on assumptions regarding the impact that standards would have on market efficiency, DOE estimated that amended standards at the 2005 Energy Star levels would yield between 2.4 to 3.4 quadrillion British thermal units (Btu), with an associated economic impact to the Nation ranging from a burden or cost of $1.2 billion to a benefit or savings of $3.3 billion.

In October 2005, DOE published draft data sheets containing energy savings potentials for refrigerator-freezers as part of its fiscal year 2006 schedule-setting process. The data sheets were based on the October 2005 draft technical report analyzing potential new amended energy conservation standards for residential refrigerator-freezers described above. The analysis was not extended to all refrigerator, refrigerator-freezer, and freezer product classes because of the large proportion of the market represented by the two product classes analyzed in detail and because DOE expected that results for these product classes would be representative for all of the product classes. The technical report and the associated data sheets provided input to the setting of priorities for rulemakings activities. Other products were given a higher priority, and limited rulemaking work on refrigerators and freezers was carried out in the following years prior to the enactment of EISA.

EISA, signed into law on December 19, 2007, requires DOE to publish a final rule by December 31, 2010, to determine whether to amend the standards in effect for refrigerators, refrigerator-freezers, and freezers manufactured on or after January 1, 2014. DOE is embarking on a standards rulemaking for these products to comply with EISA requirements. To begin the required rulemaking process, the Department prepared the framework document to explain the issues, analyses, and process that it is considering for the development of energy efficiency standards for refrigerators, refrigerator-freezers, and freezers. The public meeting will focus on analyses and issues contained in various sections of the framework document. For each item listed, the Department will make a presentation with discussion to follow. The Department will also make a brief presentation on the rulemaking process for these products.

The Department encourages anyone who wishes to participate in the public meeting to obtain the framework document and to be prepared to discuss its contents. A copy of the draft framework document is available at *http://www1.eere.energy.gov/buildings/appliance_standards/residential/refrigerators_freezers.html*. However, public meeting participants need not limit their comments to the topics identified in the framework document. The Department is also interested in receiving views on other relevant issues that participants believe would affect energy conservation standards for these products. The Department welcomes all interested parties, whether or not they participate in the public meeting, to submit in writing by October 20, 2008, comments and information on matters addressed in the framework document and on other matters relevant to consideration of standards for refrigerators, refrigerator-freezers, and freezers.

DOE will conduct the public meeting in an informal, conference style. A court reporter will record the minutes of the meeting. The discussion will not include proprietary information, costs or prices, market shares, or other commercial matters regulated by U.S. antitrust laws.

After the public meeting and the expiration of the period for submitting written statements, the Department will begin collecting data, conducting the analyses as discussed at the public meeting, and reviewing public comments.

Anyone who wishes to participate in the public meeting, receive meeting materials, or be added to the DOE mailing list to receive future notices and information about residential refrigerators, refrigerator-freezers, and freezers should contact Ms. Brenda Edwards at (202) 586–2945.

Issued in Washington, DC, on September 12, 2008.

John F. Mizroch,

Acting Assistant Secretary, Energy Efficiency and Renewable Energy.

[FR Doc. E8–21821 Filed 9–17–08; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2008–0458; Airspace Docket No. 08–AAL–17]

Proposed Establishment of Class E Airspace; Shageluk, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This action proposes to establish Class E airspace at Shageluk, AK. Two Standard Instrument Approach Procedures (SIAPs) are being developed for the Shageluk Airport at Shageluk, AK. Adoption of this proposal would result in creating Class E airspace upward from 700 feet (ft.) and 1,200 ft. above the surface at the Shageluk Airport, Shageluk, AK.

DATES: Comments must be received on or November 3, 2008.

ADDRESSES: Send comments on the proposal to the Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001. You must identify the docket number FAA–2008–0458/ Airspace Docket No. 08–AAL–17, at the beginning of your comments. You may also submit comments on the Internet at *http://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1–800–647–5527) is on the plaza level of the Department of Transportation NASSIF Building at the above address.

An informal docket may also be examined during normal business hours at the office of the Manager, Safety, Alaska Flight Service Operations, Federal Aviation Administration, 222 West 7th Avenue, Box 14, Anchorage, AK 99513–7587.

FOR FURTHER INFORMATION CONTACT: Gary Rolf, Federal Aviation Administration, 222 West 7th Avenue, Box 14, Anchorage, AK 99513–7587; telephone number (907) 271–5898; *fax:* (907) 271–2850; *e-mail: gary.ctr.rolf@faa.gov.* Internet address: *http://www.alaska.faa.gov/at.*

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2008–0458/Airspace Docket No. 08–AAL–17.'' The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of Notice of Proposed Rulemaking (NPRM)

An electronic copy of this document may be downloaded through the Internet at *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's Web page at *http://www.faa.gov* or the Superintendent of Document's Web page at *http://www.access.gpo.gov/nara/index.html.*

Additionally, any person may obtain a copy of this notice by submitting a request to the Federal Aviation Administration, Office of Air Traffic Airspace Management, ATA–400, 800 Independence Avenue, SW., Washington, DC 20591 or by calling (202) 267–8783. Communications must identify both docket numbers for this notice. Persons interested in being placed on a mailing list for future NPRMs should contact the FAA's Office of Rulemaking, (202) 267–9677, to request a copy of Advisory Circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

The Proposal

The FAA is considering an amendment to the Code of Federal Regulations (14 CFR part 71), which would establish Class E airspace at the Shageluk Airport, in Shageluk, AK. The intended effect of this proposal is to create Class E airspace upward from 700 ft. and 1,200 ft. above the surface to contain Instrument Flight Rules (IFR) operations at the Shageluk Airport, Shageluk, AK.

The FAA Instrument Flight Procedures Production and Maintenance Branch has created two new SIAPs for the Shageluk Airport. The SIAPs are (1) the Area Navigation (RNAV) Global Positioning System (GPS) Runway (RWY) 16, Original and (2) the RNAV (GPS) RWY 34, Original. Class E controlled airspace extending upward from 700 ft. and 1,200 ft. above the surface in the Shageluk Airport area would be established by this action. The proposed airspace is sufficient in size to contain aircraft executing the instrument procedures at the Shageluk Airport, Shageluk, AK.

The area would be depicted on aeronautical charts for pilot reference. The coordinates for this airspace docket are based on North American Datum 83. The Class E airspace areas designated as 700/1200 foot transition areas are published in paragraph 6005 in FAA Order 7400.9R, *Airspace Designations and Reporting Points,* signed August 15, 2007, and effective September 15, 2007, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in title 49 of the United States Code. Subtitle 1,

section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in subtitle VII, part A, subpart 1, section 40103, Sovereignty and use of airspace. Under that section, the FAA is charged with prescribing regulations to ensure the safe and efficient use of the navigable airspace. This regulation is within the scope of that authority because it proposes to create Class E airspace sufficient in size to contain aircraft executing instrument procedures at the Shageluk Airport, AK, and represents the FAA's continuing effort to safely and efficiently use the navigable airspace.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9R, *Airspace Designations and Reporting Points,* signed August 15, 2007, and effective September 15, 2007, is to be amended as follows:

* * * * *

Paragraph 6005 Class E Airspace Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AAL AK E5 Shageluk, AK [New]

Shageluk, Shageluk Airport, AK
(Lat. 62°41′32″ N, long. 159°34′09″ W)

That airspace extending upward from 700 feet above the surface within a 6.3-mile radius of the Shageluk Airport, AK; and that airspace extending upward from 1,200 feet above the surface within a 73-mile radius of the Shageluk Airport, AK.

* * * * *

Issued in Anchorage, AK, on September 9, 2008.

Marshall G. Severson,

Acting Manager, Alaska Flight Services Information Area Group.

[FR Doc. E8–21780 Filed 9–17–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2008–0454; Airspace Docket No. 08–AAL–13]

Proposed Establishment of Class E Airspace; Napakiak, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This action proposes to establish Class E airspace at Napakiak, AK. Two Standard Instrument Approach Procedures (SIAPs) are being developed for the Napakiak Airport at Napakiak, AK. Adoption of this proposal would result in creating Class E airspace upward from 700 feet (ft.) and 1,200 ft. above the surface at the Napakiak Airport, Napakiak, AK.

DATES: Comments must be received on or before November 3, 2008.

ADDRESSES: Send comments on the proposal to the Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001. You must identify the docket number FAA–2008–0454/Airspace Docket No. 08–AAL–13, at the beginning of your comments. You may also submit comments on the Internet at *http://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1–800–647–5527) is on the plaza level of the Department of Transportation NASSIF Building at the above address.

An informal docket may also be examined during normal business hours at the office of the Manager, Safety, Alaska Flight Service Operations, Federal Aviation Administration, 222 West 7th Avenue, Box 14, Anchorage, AK 99513–7587.

FOR FURTHER INFORMATION CONTACT: Gary Rolf, Federal Aviation Administration, 222 West 7th Avenue, Box 14, Anchorage, AK 99513–7587; telephone number (907) 271–5898; *fax:* (907) 271–2850; *e-mail: gary.ctr.rolf@faa.gov.* Internet address: *http://www.alaska.faa.gov/at.*

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2008–0454/Airspace Docket No. 08–AAL–13.'' The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of Notice of Proposed Rulemakings (NPRMs)

An electronic copy of this document may be downloaded through the Internet at *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's Web page at *http://www.faa.gov* or the Superintendent of Document's Web page at *http://www.access.gpo.gov/nara/index.html.*

Additionally, any person may obtain a copy of this notice by submitting a request to the Federal Aviation Administration, Office of Air Traffic Airspace Management, ATA–400, 800 Independence Avenue, SW., Washington, DC 20591 or by calling (202) 267–8783. Communications must identify both docket numbers for this

notice. Persons interested in being placed on a mailing list for future NPRM's should contact the FAA's Office of Rulemaking, (202) 267–9677, to request a copy of Advisory Circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

The Proposal

The FAA is considering an amendment to the Code of Federal Regulations (14 CFR Part 71), which would establish Class E airspace at the Napakiak Airport, in Napakiak, AK. The intended effect of this proposal is to create Class E airspace upward from 700 ft. and 1,200 ft. above the surface to contain Instrument Flight Rules (IFR) operations at the Napakiak Airport, Napakiak, AK.

The FAA Instrument Flight Procedures Production and Maintenance Branch has created two new SIAPs for the Napakiak Airport. The SIAPs are (1) the Area Navigation (RNAV) Global Positioning System (GPS) Runway (RWY) 16, Original and (2) the RNAV (GPS) RWY 34, Original. Class E controlled airspace extending upward from 700 ft. and 1,200 ft. above the surface in the Napakiak Airport area would be established by this action. The proposed airspace is sufficient in size to contain aircraft executing the instrument procedures at the Napakiak Airport, Napakiak, AK.

The area would be depicted on aeronautical charts for pilot reference. The coordinates for this airspace docket are based on North American Datum 83. The Class E airspace areas designated as 700/1200 foot transition areas are published in paragraph 6005 in FAA Order 7400.9R, *Airspace Designations and Reporting Points,* signed August 15, 2007, and effective September 15, 2007, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle 1, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart 1, Section 40103, Sovereignty and use of airspace. Under that section, the FAA is charged with prescribing regulations to ensure the safe and efficient use of the navigable airspace. This regulation is within the scope of that authority because it proposes to create Class E airspace sufficient in size to contain aircraft executing instrument procedures at the Napakiak Airport, AK, and represents the FAA's continuing effort to safely and efficiently use the navigable airspace.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9R, *Airspace Designations and Reporting Points,* signed August 15, 2007, and effective September 15, 2007, is to be amended as follows:

* * * * *

Paragraph 6005 Class E Airspace Extending Upward from 700 Feet or More Above the Surface of the Earth.

* * * * *

AAL AK E5 Napakiak, AK [New]

Napakiak, Napakiak Airport, AK
(Lat. 60°41′25″ N., long. 161°58′43″ W)

That airspace extending upward from 700 feet above the surface within a 6.3-mile radius of the Napakiak Airport, AK; and that airspace extending upward from 1,200 feet above the surface within a 84-mile radius of the Napakiak Airport, AK.

* * * * *

Issued in Anchorage, AK, on September 9, 2008.

Marshall G. Severson.

Acting Manager, Alaska Flight Services Information Area Group.

[FR Doc. E8–21782 Filed 9–17–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2008–0956; Airspace Docket No. 08–AAL–26]

Proposed Revision of Class E Airspace; Badami, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This action proposes to revise Class E airspace at Badami, AK. Two Special Instrument Approach Procedures (SIAPs) are being developed for the Badami Airport at Badami, AK. Additionally, a textual Obstacle Departure Procedure (ODP) is being developed. Adoption of this proposal would result in revision of existing Class E airspace upward from 700 feet (ft.) and 1,200 ft. above the surface at the Badami Airport, Badami, AK.

DATES: Comments must be received on or before November 3, 2008.

ADDRESSES: Send comments on the proposal to the Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001. You must identify the docket number FAA–2008–0956/ Airspace Docket No. 08–AAL–26, at the beginning of your comments. You may also submit comments on the Internet at *http://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1–800–647–5527) is on the plaza level of the Department of Transportation NASSIF Building at the above address.

An informal docket may also be examined during normal business hours

at the office of the Manager, Safety, Alaska Flight Service Operations, Federal Aviation Administration, 222 West 7th Avenue, Box 14, Anchorage, AK 99513–7587.

FOR FURTHER INFORMATION CONTACT: Gary Rolf, Federal Aviation Administration, 222 West 7th Avenue, Box 14, Anchorage, AK 99513–7587; telephone number (907) 271–5898; *fax:* (907) 271–2850; *e-mail: gary.ctr.rolf@faa.gov.* Internet address: *http://www.alaska.faa.gov/at.*

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2008–0956/Airspace Docket No. 08–AAL–26.'' The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of Notice of Proposed Rulemakings (NPRMs)

An electronic copy of this document may be downloaded through the Internet at *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's Web page at *http://www.faa.gov* or the Superintendent of Document's Web page at *http://www.access.gpo.gov/nara/index.html.*

Additionally, any person may obtain a copy of this notice by submitting a request to the Federal Aviation Administration, Office of Air Traffic Airspace Management, ATA–400, 800 Independence Avenue, SW., Washington, DC 20591 or by calling (202) 267–8783. Communications must identify both docket numbers for this notice. Persons interested in being placed on a mailing list for future NPRM's should contact the FAA's Office of Rulemaking, (202) 267–9677, to request a copy of Advisory Circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

The Proposal

The FAA is considering an amendment to the Code of Federal Regulations (14 CFR Part 71), which would revise the Class E airspace at the Badami Airport, in Badami, AK. These instrument procedures have been funded privately by the owner/operator of the airport. As such, the instrument procedures are Specials, which will only be used with the owner's permission. The intended effect of this proposal is to revise Class E airspace upward from 700 ft. and 1,200 ft. above the surface to contain Instrument Flight Rules (IFR) operations at the Badami Airport, Badami, AK.

The FAA Instrument Flight Procedures Production and Maintenance Branch has developed two SIAPs and an ODP for the Badami Airport. The new approaches are (1) the Area Navigation (RNAV) Global Positioning System (GPS) Runway (RWY) 03, Original (Orig) and (2) the RNAV (GPS) RWY 21, Orig. Textual ODP's are unnamed and in this case are provided to the owner of the airport. Class E controlled airspace extending upward from 700 ft. and 1,200 ft. above the surface in the Badami Airport area would be revised by this action. The proposed airspace is sufficient in size to contain aircraft executing the instrument procedures at the Badami Airport, Badami, AK.

The area would be depicted on aeronautical charts for pilot reference. The coordinates for this airspace docket are based on North American Datum 83. The Class E airspace areas designated as 700/1200 foot transition areas are published in paragraph 6005 in FAA Order 7400.9R, *Airspace Designations and Reporting Points,* signed August 15, 2007, and effective September 15, 2007, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle 1, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart 1, Section 40103, Sovereignty and use of airspace. Under that section, the FAA is charged with prescribing regulations to ensure the safe and efficient use of the navigable airspace. This regulation is within the scope of that authority because it proposes to create Class E airspace sufficient in size to contain aircraft executing instrument procedures at the Badami Airport, AK, and represents the FAA's continuing effort to safely and efficiently use the navigable airspace.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9R, *Airspace Designations and Reporting Points,* signed August 15, 2007, and effective September 15, 2007, is to be amended as follows:

* * * * *

Paragraph 6005 Class E Airspace Extending Upward from 700 Feet or More Above the Surface of the Earth.

* * * * *

AAL AK E5 Badami, AK [Revised]

Badami, Badami Airport, AK
(Lat. 70°08′15″ N., long. 147°01′49″ W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of the Badami Airport; and that airspace extending upward from 1,200 feet above the surface within a 73-mile radius of the Badami Airport.

* * * * *

Issued in Anchorage, AK, on September 9, 2008.

Marshall G. Severson,

Acting Manager, Alaska Flight Services Information Area Group.

[FR Doc. E8–21781 Filed 9–17–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

Bureau of Economic Analysis

15 CFR Part 801

[Docket No. 0807311000–81013–01]

RIN 0691–AA67

International Services Surveys: BE–150, Quarterly Survey of Cross-Border Credit, Debit, and Charge Card Transactions

AGENCY: Bureau of Economic Analysis, Commerce.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule amends regulations of the Bureau of Economic Analysis, Department of Commerce (BEA) to set forth the reporting requirements for a new mandatory survey entitled the BE–150, Quarterly Survey of Cross-Border Credit, Debit, and Charge Card Transactions. The proposed survey would collect from major U.S. credit card companies data on cross-border credit, debit, and charge card transactions between U.S. cardholders traveling abroad and foreign businesses and between foreign cardholders traveling in the United States and U.S. businesses. If approved, the BE–150 survey would be conducted on a quarterly basis beginning with the first quarter of 2009.

The proposed BE–150 survey data will be used by BEA in estimating the travel component of the U.S. International Transactions Accounts (ITAs). In constructing the estimates, these data will be used in conjunction with data BEA will collect separately from U.S. and foreign travelers on the Survey of International Travel Expenditures on the methods these travelers used to pay for their international travel, such as credit, debit, and charge card purchases, cash withdrawals, currency brought from home, and travelers' checks.

DATES: Comments on this proposed rule will receive consideration if submitted in writing on or before 5 p.m. November 17, 2008.

ADDRESSES: You may submit comments, identified by RIN 0691–AA67, and referencing the agency name (Bureau of Economic Analysis), by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. For agency, select ''Commerce Department—all.''
- *E-mail: Christopher.Emond@bea.gov.*
- *Fax:* Chris Emond, Chief, Special Surveys Branch, (202) 606–5318.
- *Mail:* Chris Emond, Chief, Special Surveys Branch, Balance of Payments Division, U.S. Department of Commerce, Bureau of Economic Analysis, BE–50, Washington, DC 20230.
- *Hand Delivery/Courier:* Chris Emond, Chief, Special Surveys Branch, Balance of Payments Division, U.S. Department of Commerce, Bureau of Economic Analysis, BE–50, Shipping and Receiving Section, M100, 1441 L Street, NW., Washington, DC 20005.

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in the proposed rule should be sent both to BEA, through any of the methods listed above, and to the Office of Management and Budget, O.I.R.A., Paperwork Reduction Project, Attention PRA Desk Officer for BEA, via e-mail at *pbugg@omb.eop.gov*, or by FAX at 202–395–7245.

Public Inspection: 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 commentator may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information. BEA will accept anonymous comments.

FOR FURTHER INFORMATION CONTACT: Chris Emond, Chief, Special Surveys Branch, Balance of Payments Division (BE–50), Bureau of Economic Analysis, U.S. Department of Commerce, Washington, DC 20230; e-mail *Christopher.Emond@bea.gov*; or phone (202) 606–9826.

SUPPLEMENTARY INFORMATION: This proposed rule would amend 15 CFR Part 801.9 to add the reporting requirements for a new mandatory survey entitled BE–150, Quarterly Survey of Cross-Border Credit, Debit, and Charge Card Transactions. The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

Description of Changes

The proposed BE–150 survey would be a mandatory survey that would be conducted by BEA, beginning with transactions for the first quarter of 2009, under the International Investment and Trade in Services Survey Act (22 U.S.C. 3101–3108), hereinafter, ''the Act.'' For the initial quarter of coverage, BEA would send the survey to potential respondents in March of 2009; responses would be due by April 30, 2009.

BEA maintains a continuing dialogue with respondents and with data users, including its own internal users, to ensure that, as far as possible, the required data serve their intended purposes and are available from the existing records, that instructions are clear, and that unreasonable burdens are not imposed. In reaching decisions on what questions to include in the survey, BEA considered the Government's need for the data, the burden imposed on respondents, the quality of the likely responses (for example, whether the data are available on respondents' books), and BEA's experience in previous annual and quarterly surveys.

If implemented, the BE–150 survey would collect from the U.S. credit card companies data covering cross-border credit, debit, and charge card transactions between U.S. cardholders traveling abroad and foreign businesses and between foreign cardholders traveling in the United States and U.S. businesses—by country of the transaction (for U.S. cardholders) or by country of residency of the cardholder

(for foreign cardholders). Credit card companies that operate networks used to clear and settle credit card transactions between issuing banks and acquiring banks would be responsible for reporting on this survey. Issuing banks, acquiring banks, and individual cardholders would not be required to report. Data would be collected by the type of transaction, by type of card, by spending category, and by country. Data on credit card transactions of U.S. cardholders traveling abroad and foreign cardholders traveling in the United States would be collected at an aggregate level from the U.S. credit card companies; data on the transactions of individuals would not be collected.

Survey Background

The Bureau of Economic Analysis (BEA), U.S. Department of Commerce, would conduct the survey under the International Investment and Trade in Services Survey Act (22 U.S.C. 3101–3108), hereinafter, ''the Act.'' Section 4(a) of the Act (22 U.S.C. 3103(a)) provides that the President shall, to the extent he deems necessary and feasible, conduct a regular data collection program to secure current information related to international investment and trade in services and publish for the use of the general public and United States Government agencies periodic, regular, and comprehensive statistical information collected pursuant to this subsection.

In section 3 of Executive Order 11961, as amended by Executive Orders 12318 and 12518, the President delegated the responsibilities under the Act for performing functions concerning international trade in services to the Secretary of Commerce, who has redelegated them to BEA.

The survey would provide a basis for compiling the travel account of the United States international transactions accounts. In constructing the estimates, these data would be used in conjunction with data BEA will collect separately from U.S. and foreign travelers on the Survey of International Travel Expenditures on the methods these travelers used to pay for international travel expenditures. With the two data sources, BEA would be able to estimate total expenditures by foreign travelers in the United States (U.S. exports) and total expenditures by U.S. travelers abroad (U.S. imports) by country and region.

Executive Order 12866

This proposed rule has been determined to be not significant for purposes of E.O. 12866.

Executive Order 13132

This proposed rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism Assessment under E.O. 13132.

Paperwork Reduction Act

This proposed rule contains a collection-of-information requirement subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. The requirement will be submitted to OMB as a request for a new collection of information.

Notwithstanding any other provisions of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection displays a currently valid Office of Management and Budget Control Number.

The BE–150 quarterly survey, as proposed, is expected to result in the filing of reports from four respondents on a quarterly basis, or 16 reports annually. The respondent burden for this collection of information would vary from one respondent to another, but is estimated to average 16 hours per response (64 hours annually), including time for reviewing the instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Thus, the total respondent burden for the BE–150 survey is estimated at 260 hours.

Comments are requested concerning: (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 burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in the proposed rule should be sent to both BEA and OMB following the instructions given in the **ADDRESSES** section above.

Regulatory Flexibility Act

The Chief Counsel for Regulation, Department of Commerce, has certified to the Chief Counsel for Advocacy, Small Business Administration, under provisions of the Regulatory Flexibility Act (5 U.S.C. 605(b)), that this proposed rulemaking, if adopted, will not have a significant economic impact on a substantial number of small entities. BEA estimates that this rule will not have an impact on any small entities as the BE–150 survey is mandatory for only those U.S. credit card companies that operate networks used to clear and settle credit card transactions between issuing banks and acquiring banks. BEA estimates that there are only four U.S. credit card companies that are subject to this rule. Of the four companies, none is considered to be a small entity under the Small Business Administration's Table of Small Business Size Standards. All four companies are corporations that exceed the maximum annual revenue threshold to be considered a small entity. Because there are no small businesses that are subject to reporting, the Chief Counsel for Regulation certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities.

List of Subjects in 15 CFR Part 801

International transactions, Economic statistics, Foreign trade, Penalties, Reporting and recordkeeping requirements, Travel expenses, Cross-Border transactions, Credit card, and Debit card.

Dated: September 8, 2008.

J. Steven Landefeld,

Director, Bureau of Economic Analysis.

For the reasons set forth in the preamble, BEA proposes to amend 15 CFR part 801, as follows:

PART 801—SURVEY OF INTERNATIONAL TRADE IN SERVICES BETWEEN U.S. AND FOREIGN PERSONS

1. The authority citation for 15 CFR part 801 continues to read as follows:

Authority: 5 U.S.C. 301; 15 U.S.C. 4908; 22 U.S.C. 3101–3108; and E.O. 11961, 3 CFR, 1977 Comp., p.86, as amended by E.O. 12318, 3 CFR, 1981 Comp., p. 173, and E.O. 12518, 3 CFR, 1985 Comp., p 348.

2. Amend § 801.9 by adding paragraph (c)(7):

§ 801.9 Reports required.

(c) Quarterly surveys. * * *

(7) BE–150, Quarterly Survey of Cross-Border Credit, Debit, and Charge Card Transactions:

(i) A BE–150, Quarterly Survey of Cross-Border Credit, Debit, and Charge Card Transactions will be conducted covering the first quarter of the 2009

calendar year and every quarter thereafter.

(A) *Who must report.* A BE–150 report is required from each U.S. company that operates networks for clearing and settling credit card transactions made by U.S. cardholders in foreign countries and by foreign cardholders in the United States. Each reporting company must complete all applicable parts of the BE–150 form before transmitting it to BEA. Issuing banks, acquiring banks, and individual cardholders are not required to report.

(B) *Covered Transactions.* The BE–150 survey collects aggregate information on the use of credit, debit, and charge cards by U.S. cardholders when traveling abroad and foreign cardholders when traveling in the United States. Data are collected by the type of transaction, by type of card, by spending category, and by country.

(ii) [Reserved]

[FR Doc. E8–21896 Filed 9–17–08; 8:45 am]

BILLING CODE 3510–06–P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Parts 1 and 38

Execution of Transactions: Regulation 1.38 and Guidance on Core Principle 9

AGENCY: Commodity Futures Trading Commission.

ACTION: Proposed rules.

SUMMARY: The Commodity Futures Trading Commission (''Commission'' or ''CFTC'') is re-proposing a number of amendments to its rules, guidance and acceptable practices, initially proposed on July 1, 2004,[1] concerning trading off the centralized market, including the addition of guidance on contract market block trading rules and exchanges of futures for commodities or derivatives positions. The Commission is re-proposing these amendments and requesting comment as part of its continuing efforts to update its regulations in light of the Commodity Futures Modernization Act of 2000 (''CFMA'').

DATES: Comments must be received by November 17, 2008.

ADDRESSES: Comments should be sent to the Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581, attention: Office of the Secretariat. Comments may be sent by facsimile transmission to 202–418–5521 or, by e-mail to *secretary@cftc.gov.* Reference should be made to ''Proposed Rules for Trading Off the Centralized Market.'' Comments may also be submitted by connecting to the Federal eRulemaking Portal at *http://www.regulations.gov* and following comment submission instructions.

FOR FURTHER INFORMATION CONTACT: Gabrielle A. Sudik, Special Counsel, Division of Market Oversight; Telephone 202–418–5171; e-mail *gsudik@cftc.gov;* Commodity Futures Trading Commission, Three Lafayette Center, 1155 21st Street, NW., Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

I. Background

Commission Regulation 1.38 (17 CFR 1.38) sets forth a requirement that all purchases and sales of a commodity for future delivery or a commodity option on or subject to the rules of a designated contract market (''DCM'') should be executed by open and competitive methods. This ''open and competitive'' requirement is modified by a proviso that allows transactions to be executed in a ''non-competitive'' manner if the transaction is in compliance with DCM rules specifically providing for the non-competitive execution of such transactions, and such rules have been submitted to, and approved by, the Commission.

The Commodity Futures Modernization Act of 2000 (''CFMA''),[2] which was enacted after Regulation 1.38 was promulgated,[3] significantly changed the Federal regulation of commodity futures and option markets by replacing ''one-size-fits-all'' regulation with broad, flexible core principles.[4] At the same time, the CFMA modified section 3 of the Commodity Exchange Act (''Act'') (7 U.S.C. 1 *et seq.*), making a finding that transactions subject to the Act provide ''a means for managing and assuming price risks, discovering prices, or disseminating pricing information through trading in liquid, fair and financially secure trading facilities,'' and providing that the purpose of the Act is now, among other things, ''to deter and prevent price manipulation or any other disruptions to market integrity; to ensure the financial integrity of all transactions subject to this Act and the avoidance of systemic risk; to protect all market participants from fraudulent or other abusive sales practices and misuses of customer assets. * * * ''[5] The CFMA also expanded the types of transactions that could lawfully be executed off the centralized market. Specifically, the CFMA permits DCMs to establish trading rules that: (1) Authorize the exchange of futures for swaps; or (2) allow a futures commission merchant, acting as principal or agent, to enter into or confirm the execution of a contract for the purchase or sale of a commodity for future delivery if the contract is reported, recorded, or cleared in accordance with the rules of a contract market or derivatives clearing organization.[6] At the same time, exchanges must balance such rules with Core Principle 9 (7 U.S.C. 5(d)(9)) (Execution of transactions), which states ''The board of trade shall provide a competitive, open, and efficient market and mechanism for executing transactions.''

In 2001, the Commission promulgated regulations implementing provisions of the CFMA that established procedures relating to trading facilities, interpreted certain of the CFMA's provisions, and provided guidance on compliance with various of its requirements.[7] Later, in 2002, the Commission promulgated amendments to those regulations in response to issues that had arisen in administering the rules, noting that the Commission would consider ''additional amendments to the rules implementing the CFMA based upon further administrative experience.''[8] Consistent with that rationale, the Commission now proposes to amend Commission Regulation 1.38 and Commission guidance and acceptable practices concerning Core Principle 9 as it relates to Commission Regulation 1.38 to include changes that the Commission has developed based upon its experience administering those provisions.

[1] 69 FR 39880.

[2] Public Law 106–554, 114 Stat. 2763 (2000). Under the CFMA, such DCM rules may be effected by the certification procedures set forth in section 5c(c) of the Commodity Exchange Act and 40.6 of the Commission's regulations.

[3] Regulation 1.38 was originally adopted in 1953 by the Commodity Exchange Authority, the predecessor of the Commission. *See* 18 FR 176 (Jan. 19, 1953). For subsequent amendments, *see* 31 FR 5054 (Mar. 29, 1966), 41 FR 3191 (Jan. 21, 1976, eff. Feb. 20, 1976), and 46 FR 54500 (Nov. 3, 1981, eff. Dec. 3, 1981).

[4] The CFMA was intended, in part, ''to promote innovation for futures and derivatives.'' § 2 of the CFMA. It was also intended ''to reduce systemic risk,'' and ''to transform the role of the [Commission] to oversight of the futures markets.'' *Id.*

[5] 7 U.S.C. § 5 (2000).

[6] *See* Section 7(b)(3) of the Act.

[7] *See* 66 FR 14262 (Mar. 9, 2001) and 66 FR 42256 (Aug. 10, 2001).

[8] *See* 67 FR 20702 (Apr. 26, 2002) and 67 FR 62873 (Oct. 9, 2002).

II. Discussion of the Proposed Rule Amendments, Guidance and Acceptable Practices

A. The Commission's July 1, 2004 Notice of Proposed Rulemaking

On July 1, 2004, the Commission published proposed amendments to Regulation 1.38 and Commission guidance concerning Core Principle 9, found in Appendix B to Part 38 of the Commission's Regulations (17 CFR Part 38) (the ''July 1, 2004 NPRM'').[9] The Commission proposed to update the language of Regulation 1.38 to more accurately identify the types of transactions that may lawfully be executed off a contract market's centralized market and to simplify the language of the Regulation. The Commission also wished to provide more detail regarding acceptable practices for how contract markets can satisfy the requirements of Core Principle 9, particularly on four general topics: Electronic trading systems, general provisions for transactions off the centralized market, block transactions, and the exchange of futures for a commodity or a derivatives position.

The Commission received seven comment letters in response to the July 1, 2004 NPRM: From the Chicago Mercantile Exchange (''CME''), the Futures Industry Association (''FIA''), the Chicago Board of Trade (''CBOT''), the U.S. Futures Exchange (''USFE'') (two letters), the DRW Trading Group (''DRW''), and Man Financial. The comments addressed eight general areas of concern: The proposed amendments to Regulation 1.38, the Commission's proposed guidance for compliance with Core Principle 9 in general, block trading in general, the minimum size of block transactions, block trade prices, the time within which parties must report block trades to the exchange, block trades between affiliated parties, and the exchange of futures for a commodity or a derivatives position. Some comments offered specific recommendations regarding the proposed amendments, while other comments were of a more general nature.

Between the publication of the July 1, 2004 NPRM and this current proposal, the Commission has continued to gain experience in administering Regulation 1.38 and Core Principle 9. Staff has also learned more about the common practices involved in transactions done off of the centralized market from the comment letters received, from informal interviews with various entities in the futures industry, from DCM rule submissions, and from informal studies of trading data related to off-centralized-market transactions. In light of this, as well as the length of time that has passed since the July 1, 2004 NPRM, the Commission has determined to re-propose amendments to Regulation 1.38 and the guidance to Core Principle 9. Commenters are invited to submit feedback on all areas of this proposal, including those areas already addressed in earlier comment letters.

B. Core Principle 9 Guidance and Acceptable Practices

This proposal contains regulations, guidance and acceptable practices. Commission regulations, such as Regulation 1.38, are requirements that all contract markets must follow. Such regulations go beyond mere illustrations of how a contract market may comply with a section of the Act; they are requirements that stand alone and that the Commission believes are necessary in order to comply with the Act. In issuing guidance, the Commission strives to offer advice about how contract markets can ensure compliance with sections of the Act. The Commission recognizes that in certain areas there is more than one possible approach that would allow a contract market to comply with a related Section of the Act. For example, as will be discussed below, there can be more than one way to determine an appropriate minimum size for block trades. The Commission offers guidance on such subjects in an effort to inform the exchanges of what it believes are some reasonable approaches to take when tackling such issues and concerns to be addressed in complying with Core Principles. The acceptable practices provide examples of how exchanges may satisfy particular requirements of the Core Principles; they do not establish mandatory means of compliance.[10] Acceptable practices are more specific than guidance. An exchange rule modeled after an acceptable practice will be presumed to comply with the related Core Principle, since the Commission has already found such practice complies with that Core Principle. The Commission wishes to emphasize that acceptable practices are intended to assist DCMs by establishing non-exclusive safe harbors.[11] The introduction to Appendix B to Part 38 makes it clear that the acceptable practices in Appendix B are not the sole means of achieving compliance with the Act:

> Acceptable practices meeting the requirements of the core principles are set forth in paragraph (b) following each core principle. Boards of trade that follow the specific practices outlined under paragraph (b) for any core principle in this appendix will meet the applicable core principle. Paragraph (b) is for illustrative purposes only, and does not state the exclusive means for satisfying a core principle.[12]

The Commission also notes that it drafted the acceptable practices based on its experience in reviewing exchange rules and in considering related matters currently facing the Commission. The acceptable practices provided in the proposal are, in large measure, modeled on exchange rules that have previously been found to satisfy the requirements of Core Principle 9. The Commission does not mean to imply that it will find other rules unacceptable. Indeed, some of the acceptable practices explicitly note that a DCM could adopt rules that differ from the acceptable practice, although any such deviation would still require the DCM and parties to trades to comply with Core Principle 9, as required by section 5(d)(1) of the Act.

The Commission believes that its proposed issuance of guidance and acceptable practices will generally ease the burden on exchanges in complying with Core Principle 9. Without the adoption of these amendments, DCMs are without any meaningful guidance as to whether their requirements for trading off the centralized market comply with Core Principle 9. These amendments provide certainty for those rules that fall under an acceptable practice, while the burden for those that fall outside of the acceptable practices is no greater than before. The Commission believes that it would not be appropriate to lessen the specificity of the acceptable practices because doing so would render the guidance meaningless.

C. General Changes to the Re-Proposed Amendments

The amendments proposed in this rulemaking are in large measure substantively similar to what was proposed in the July 1, 2004 NPRM. This proposal, like its predecessor, strives to update the language of Regulation 1.38 to more accurately

[9] 69 FR 39880 (July 1, 2004).

[10] *See* Section 5c(a) of the Act 7 U.S.C. 7a–2(a).

[11] The Commission notes that safe harbor treatment applies only to compliance with the specific aspect of the Core Principle in question. In this regard, an exchange rule that meets a safe harbor will not necessarily protect the exchange or market participants from charges of violations of other sections of the Act or other aspects of the Core Principle.

[12] *See also* A New Regulatory Framework for Trading Facilities, Intermediaries and Clearing Organizations Proposed Rules, 66 FR 14262, 14263 (March 9, 2001).

identify the types of transactions that may lawfully be executed off of a contract market's centralized market and to simplify the language of the Regulation. The proposed language also updates Regulation 1.38 to make it clear that DCMs may self-certify (not just seek approval for) rules or rule amendments related to transactions off the centralized marketplace. This proposed amendment is consistent with section 5c(c) of the Act, which allows for the certification of any DCM rule or rule amendment.

In addition, Regulation 1.38 requires, subject to certain exceptions, that all purchases and sales of a commodity for future delivery or a commodity option on or subject to the rules of a DCM should be executed by open and competitive methods. The implicit assumption in Regulation 1.38 is that trading should take place on the centralized market unless there is a compelling reason to allow certain transactions to take place off the centralized market. Similarly, exchange rules and policies that allow such transactions should ensure that the impact on the centralized market is kept to a minimum. For example, certain types of off-centralized market transactions, such as block trades and exchanges of futures for related positions, can create new positions or reduce prior positions. If these transactions become the exclusive or predominant method of establishing or offsetting positions in a particular market, it might jeopardize the centralized market's role in price discovery and would not comply with Core Principle 9, which provides that trading be competitive, open and efficient.[13] Other types of off-centralized market transactions are bookkeeping in nature, such as transfer trades or office trades, which move existing positions between accounts. These transactions do not affect the price discovery mechanism of the centralized market because they do not establish or offset positions.

This proposed rulemaking also addresses the same four general topics under Core Principle 9 that were addressed in the July 1, 2004 NPRM: Electronic trading systems, general provisions for transactions off the centralized market, block transactions, and the exchange of futures for a commodity or a derivatives position.

The majority of changes made since the July 1, 2004 NPRM strive to do one of two things. First, the Commission has attempted to clarify any language that was ambiguous, particularly in response to questions raised in the comment letters. Second, the proposed acceptable practices under Core Principle 9 have been redrafted to more closely resemble the language of the acceptable practices for the other Core Principles. The Commission believes that in addition to harmonizing the language of the acceptable practices, these changes make the language of the acceptable practices easier to read.

The Commission has made more significant changes to the proposed amendments in three areas, based on the comment letters received, as well as the Commission's own experience in administering Regulation 1.38 and Core Principle 9. These three areas, discussed in more detail below, concern the appropriate minimum size of block trades; when block trades may be permitted between affiliated parties; and exchanges of futures for a commodity or derivatives position, including the permissibility of transitory exchanges of futures for a commodity or derivatives position (''transitory EFPs'').

D. The Minimum Size of Block Trades

In the July 1, 2004 NPRM the Commission proposed that an acceptable minimum size for block trades would be at a level larger than 90% of the transactions in a relevant market (''90% threshold'') or, for new contracts with no relevant market, 100 contracts. CME, CBOT, DRW, FIA and USFE all offered comments regarding those proposed acceptable practices. CME and CBOT disagreed with the Commission's proposed minimum sizes of the 90% threshold and 100 contracts: CME thought the numbers were arbitrary, unresponsive to market needs and inconsistent with the Commission's oversight role. Similarly, CBOT believed there may be instances where 90% or 100 contracts could be too high or not high enough. CBOT suggested that an acceptable minimum block trade size be at the point where the block would move the market or where the customer would not be able to obtain a fair price or fill the order on the centralized market.

DRW suggested that the Commission clarify its intent that the minimum block trade size should be derived from the size of trades in the entire relevant market, which should include the central market, related derivatives markets and the cash market. DRW also suggested that using the 90% threshold would result in artificially low minimums because many transactions in the central market are often broken down into smaller trades at the same price. DRW suggested tying the minimum block trade size to the size of orders instead of trades or by developing a risk-based system that would consider both outright and spread transactions.

USFE seemed to imply that the 90% threshold should be lower for options than for futures. USFE noted that options transactions, particularly combination trades, are more complex than futures trades and require more human intervention than other trades. The options market is therefore more conducive to trading off the centralized market. While USFE did not suggest a different minimum threshold for options, it indicated that more off-centralized-market trading of options was necessary until technology could accommodate complex options positions on the electronic trading screen.

In response to these comments, as well as the Commission's own increased knowledge about block trades, the Commission is changing the proposed guidance and acceptable practices on this topic. In this regard, the Commission's guidance for determining appropriate minimum sizes relies on the purpose for allowing block trades. Block trades are allowed to be transacted off the centralized market for two reasons. First, prices attendant to the execution of large transactions on the centralized market may diverge from prevailing market prices that reflect supply and demand of the commodity. This is because the centralized market may not provide sufficient liquidity to execute large transactions without a significant risk premium, so that the prices of such trades tend to reflect, to a significant degree, the cost of executing the trade. Accordingly, reporting these prices as conventional market trades would be misleading to the public. Second, block trading facilitates hedging by providing a means for commercial firms to transact large orders without the need for significant price concessions and resulting price uncertainty for parties to the transaction that would occur if transacted on the centralized market. Using these reasons as guidance, block trades should be limited to large orders, where ''large'' is the number at which there is a reasonable expectation that

[13] *See also*, section 3(a) of the Act, which finds that transactions subject to the Act provide ''a means for managing and assuming price risks, discovering prices, or disseminating pricing information through trading in liquid, fair and financially secure trading facilities.'' Using the example above, markets on which transactions are exclusively or predominantly carried out by blocks are not liquid markets. Furthermore, it has been questioned whether markets are fair if they do not offer viable centralized trading. This also calls into question such a market's compliance with designation criterion 3, 7 U.S.C. 7(b)(3), which requires the exchange to establish and enforce trading rules to ensure fair and equitable trading through the facilities of the contract market.

the order could not be filled in its entirety at a single price, but would need to be broken up and executed at different prices if transacted in the centralized marketplace. As such, the proposed guidance notes that minimum block trade sizes should be larger than the size at which a single buy or sell order is customarily able to be filled in its entirety at a single price (though not necessarily with a single counterparty) in that contract's centralized market, and exchanges should determine a fixed minimum number of contracts needed to meet this threshold.

The Commission now believes that its previous means of determining an appropriate minimum size—the 90% threshold—may not be appropriate for all markets because this figure does not necessarily correspond with the size of the order that would move the market price. Because the determination of what constitutes a large trade will vary between DCMs, contracts and even over time, the acceptable practices will not set forth an explicit threshold, but will instead leave it to the DCMs to determine appropriate minimum sizes, based on the above purpose.[14] This new approach should also address DRW's concern that using trade size alone to determine a threshold might result in lower-than-appropriate minimum sizes, because breaking an order into several small trades ideally should not affect the overall volume or liquidity of the centralized market. Similarly, the presence of many small trades submitted by multiple traders will also not artificially lower the appropriate minimum block trade size. The Commission also understands that, as exchange volume migrates from floor trading to electronic trading, the average size of transactions tends to decrease, resulting in artificially low 90% thresholds and minimum block trade sizes that are too low given the criteria discussed above.

One method by which DCMs could determine what number of contracts is an appropriate minimum size would be to assess the market liquidity (the number of contracts the centralized market is able to absorb at the best execution price) and market depth (which measures the potential price slippage if a large order were to be executed in the centralized market). For example, a DCM could examine a contract's market liquidity over time and determine that a certain size order in that contract could rarely, if ever, be filled in its entirety at the best price, and set a minimum block trade size based on this data. Such calculations should be re-examined periodically, as volume, liquidity and market depth change over time to ensure that a contract's minimum block trade size remains appropriate. Such an analysis would most easily be done for an electronically-traded contract, since trade data about the contract is easy to gather and analyze.

Calculating a minimum size based on market liquidity and depth is not the only possible way to determine what size order should be considered ''large.'' DCMs could employ other methods to reasonably determine what size order would move the price in the centralized market. For instance, along with a review of trade sizes and/or order sizes, DCMs could interview experienced floor brokers and floor traders to determine what size order is generally too large to fill at a single price. This method might be most appropriate for open-outcry markets because DCMs will not have the same type of trade data generated by electronic trading platforms, and will not as easily be able to determine, based on electronic data, what size order is ''large.''

For new contracts that have no trading history, a DCM should strive to set its initial minimum block trade size based on what the DCM reasonably believes will be a ''large'' order (i.e., the order size that would likely move the market price). So, for example, the DCM might base its initial minimum block trade size on sources of data other than transaction data in that particular contract such as transaction patterns in related futures or cash markets, the DCM's experience regarding other newly-launched contracts, and/or a survey of potential market users to determine how many contracts might be executed in a typical transaction. Where a DCM is unable to determine an appropriate minimum size (due, for instance, to the lack of data in other markets or other methods for estimating an appropriate minimum size), the Commission believes it would be an acceptable practice for a DCM to set the minimum block trade size at 100 contracts. In the past, the Commission has considered 100 contracts to be a reasonable figure to use as the minimum size until enough market data exist to allow that figure to be adjusted, if need be. Once there is adequate trade data to re-evaluate the minimum size, the DCM should ensure that it be adjusted to a level where a trade would move the centralized market, if traded there.

In this regard, the Commission proposes as an acceptable practice that DCMs review the minimum size thresholds for block trades no less frequently than on a quarterly basis to ensure that the minimum sizes remain appropriate for each contract. As noted in the proposed guidance, such review should take into account the sizes of trades in the centralized market and the market's volume and liquidity. This review and any necessary adjustments should be made to both new and existing contracts. In addition, quarterly reviews of minimum block trade sizes should take into account whether the minimum sizes ensure that block trades remain the exception, rather than the rule. As noted above, transactions off the centralized market should remain an exception as the expectation is that most trading will occur on the centralized market. Exchanges that established their minimum sizes for block trades long ago may find they need to adjust their minimum sizes as a result of changes in volume, liquidity, or the typical sizes of transactions in the respective market.

Finally, the Commission notes that DCMs are free to require a minimum size that is *larger* than what the guidance suggests a ''large'' trade would be. They are not obligated to set the minimum size at the smallest acceptable minimum size.

E. Block Trades Between Affiliated Parties

Based on comment letters and the Commission's growing experience with implementing Core Principle 9, the Commission has determined to revise Regulation 1.38 and the related acceptable practices regarding block trades between affiliated parties. An affiliated party is a party that directly or indirectly through one or more persons, controls, is controlled by, or is under common control with another party. These proposed changes differ from the July 1, 2004 NPRM's treatment of block trades between affiliated parties.

Block trades between affiliated parties may be permitted by DCMs, so long as appropriate safeguards are in place to guard against the heightened possibility that transactions between two closely related parties are more susceptible to abuse, such as setting unreasonable prices, artificially boosting volume, money passing, or wash trading. It is not always clear that two related parties are motivated solely by their own separable best interests, since they often both report to or are accountable to a single person or entity, and as such they may be encouraged by those in control of both sides of the transaction to engage in trading strategies that benefit from abusive trading practices. It is for this reason that the Commission believes it

[14] In this regard, the guidance could result in different DCMs arriving at different minimum size requirements for the same or similar futures contracts, if the liquidity and volume on each DCM is different.

is appropriate that DCMs that allow block trades between affiliates also include additional safeguards to guard against the heightened possibility of abuse, and that DCMs must have rules to ensure that these safeguards are satisfied.

The Commission proposes to amend Regulation 1.38 by requiring that when block trades take place between affiliated parties: (i) The block trade price must be based on a competitive market price, either by falling within the contemporaneous bid/ask spread on the centralized market or calculated based on a contemporaneous market price in a related cash market; (ii) each party must have a separate and independent legal bona fide business purpose for engaging in the trades; and (iii) each party's decision to enter into the block trade must be made by a separate and independent decision-maker. Under the acceptable practices for Core Principle 9, a DCM could permit block trades between affiliated parties that meet these requirements and are otherwise appropriate parties to engage in block trading.[15]

The Commission believes these proposed requirements for block trades between affiliated parties strike an appropriate balance between making clear that such trades are allowable and ensuring that each party is acting independently when it agrees to enter into such a transaction. The requirement that affiliated parties who engage in a block trade meet objective criteria regarding that block trade will help guard against the possibility that such closely related parties might collude in some type of abuse.

F. Exchange of Futures for a Commodity or for a Derivatives Position

In the July 1, 2004 NPRM, the Commission proposed to include acceptable practices regarding the exchange of futures for a commodity or derivatives position (often referred to as an exchange-for-physical or EFP, although it also includes, but is not limited to, similar transactions such as exchanges-for-swaps or exchanges-for-risk). Specifically, the Commission proposed a definition of what constituted a bona fide EFP in the Core Principle 9 acceptable practices. The Commission received comments from FIA, CBOT and CME regarding these acceptable practices. Among other things, the commenters requested the Commission clarify that trades commonly known as ''transitory EFPs'' are still permitted and that third parties may effect the cash portion of an EFP transaction.

In response to these comments and other concerns that have arisen since the July 1, 2004 NPRM, the Commission is proposing to make two substantive amendments to its acceptable practices regarding exchanges of futures for a commodity or derivatives position. First, the Commission is proposing to expand the acceptable practices regarding EFPs' bona fides, pricing, reporting, and DCMs' publication of EFP transactions. Second, the Commission is proposing to make clear that transitory EFPs are permissible when each part of the transaction—the EFP itself and the related cash transaction—is a stand-alone, bona fide transaction.

The Commission is proposing to offer general acceptable practices for exchange of futures for a commodity or derivatives position, including a definition of what constitutes a bona fide EFP, the pricing of the legs, the reporting of the transaction to the exchange, and the exchange's obligation, consistent with Regulation 16.01, to publicize daily the total quantity of exchanges of futures for a commodity or derivatives position. In response to the comment letters, the Commission is proposing to clarify in the text of the acceptable practices that a DCM may permit a third party to facilitate the transfer of the cash leg of an EFP, so long as the commodity or derivatives position is passed through to the party receiving the futures position. These provisions are meant to be consistent with previous publications by the Commission, including the 1987 EFP Report prepared by the Commission's then Division of Trading and Markets and the 1998 EFP Concept Release.[16]

The essential elements of bona fide EFPs have been provided in the guidance to Core Principle 9 below. The proposed elements are found in current contract market ''exchange of futures'' rules and are based on the essential elements for bona fide EFPs detailed in the 1987 EFP Report.[17] The elements include separate but integrally related transactions, an actual transfer of ownership of the commodity or derivatives position, and both legs transacted between the same two parties. The Commission notes that the determination whether an actual transfer of ownership has occurred will depend upon the facts and circumstances of each transaction. In each instance where an exchange of futures for a commodity or for a derivatives position is linked to another offsetting transaction, the particular facts and circumstances may warrant a determination that there was not an actual ownership transfer of each leg of the commodity or derivatives position.

Further, the Commission is proposing that the acceptable practices relating to the bona fides of an EFP should apply to transitory EFPs as well. A transitory EFP involves both an EFP and an offsetting cash commodity transfer. For example, party A purchases the cash commodity from party B and then engages in an EFP whereby A sells the cash commodity back to B and receives a long futures position. As a result of these two transactions, the parties acquire futures positions but end up with the same cash market positions they had before the transaction.

To be a legitimate transitory EFP, the cash transaction must be bona fide and the EFP itself must be bona fide. As with an EFP, a primary indicator of a bona fide cash transaction is the actual transfer of ownership of the cash commodity or position. In this regard, the cash leg of the transaction must be able to stand on its own as a commercially appropriate transaction, and may not be intrinsically linked to the EFP transaction. A cash commodity transfer that cannot stand on its own may indicate that there was no actual economic risk in the cash leg of the related EFP and may raise concerns about whether the EFP involved an ''exchange'' of futures contracts for cash commodity as required by Section 4c(a) of the Act. There must be no obligation on either party that the cash transaction will require the execution of a related EFP, or vice versa.

G. Other Proposed Acceptable Practices

The rest of the proposed acceptable practices are for the most part similar to what was proposed in the July 1, 2004 NPRM. As with the acceptable practices discussed more fully above, the Commission considered the comment letters when re-drafting these acceptable practices, and strove to clarify any ambiguities and make them easier to read. And, as in the July 1, 2004 NPRM, the Commission notes that these proposed acceptable practices are based in large measure on existing DCM rules.

[15] Similarly, the proposed acceptable practices regarding the prices of block trades also include reference to Regulation 1.38 as it relates to block trades between affiliated parties.

[16] DIVISION OF TRADING AND MARKETS, REPORT ON EXCHANGES OF FUTURES FOR PHYSICALS (1987) (the 1987 EFP Report); 63 FR 3708 (Jan. 26, 1998) (the 1998 EFP Concept Release).

[17] *See generally,* the 1987 EFP Report. *See also,* CBOT Rules 331.08; CFE Rule 414; CME Rule 538; KCBT Rules 1128.00, 1128.02, 1129.00, and 1129.02; MGE Rule 719; NYBOT Rules 4.12 and 4.13; NYMEX Rules 6.21, 6.21A and 6.21E; and OCX Rule 416.

1. Block Trade Prices

In the July 1, 2004 NPRM, the Commission proposed acceptable practices regarding the prices of block trades. The most basic element of this acceptable practice is that prices be ''fair and reasonable.'' In its comment letter, CBOT noted an inconsistency between the text of the July 1, 2004 NPRM proposed guidance and the preamble and also questioned whether ''circumstances'' of the party or market could or should be relevant in determining whether a block trade price is fair and reasonable. In this proposal, the Commission intends to eliminate the ambiguity and to make clear its belief that a DCM could permit ''circumstances'' to be a factor in determining whether a block trade price was fair and reasonable. Such an approach could include, for example, the participants' legitimate trading objectives or the condition of the market. The Commission does not believe that permitting such flexibility will harm the centralized market because, regardless of how a block trade price is determined, it must still be fair and reasonable. The ability to price the trade away from the centralized market is not a *carte blanche* to set unfair or unreasonable prices.

2. Block Trade Reporting Times

In the July 1, 2004 NPRM, the Commission proposed in its acceptable practices that block trades should be reported to the contract market within a reasonable period of time. In response, DRW made two suggestions: First, that reasonable reporting times for block trades should be as close to immediately after the completion of the trade as possible, with a maximum of no more than 5 minutes; and second, that parties to a block trade should not be allowed to trade in the centralized market until information about the block trade has been made public.

The Commission will re-propose that block trades should be reported to the contract market within a reasonable period of time. The Commission declines to establish a specific length of time in order to allow exchanges to determine what an appropriate length of time should be on a contract-by-contract basis. But the Commission notes that most current DCM rules require reporting of block trades within 5 minutes.[18] A small number of DCM rules allow as many as 15 minutes, but the Commission understands these are limited to contracts that have very high block trade minimum size thresholds or where the contracts are typically traded as part of large and complex spreads, requiring more time to double check details and convey the information to the exchange.[19] When determining length of time for parties to report block trades, DCMs should consider the importance of providing information about block trades to the market as well as the potential for abuses, such as front running, and whether longer reporting periods may heighten the potential for abuse. Additionally, staff has previously noted that allowing a few minutes' delay between the time a block trade is executed and reported will allow the market price to continue to respond to prevailing supply and demand factors, and not be unduly influenced by the block itself. In other words, a reporting delay will help the centralized market avoid the momentary price and volume distortion that would occur if large trades were made on the centralized market in the first place. In regards to whether parties to a block trade may trade in the centralized market before the block trade information is published, the Commission believes that the reporting window offers parties to the block trade an opportunity to hedge or offset the trade, which in turn supplies information to the centralized market. As such, the Commission believes that compliance with the Core Principles does not require that DCMs restrict the ability of parties to a block trade from making transactions on the central marketplace before the block trade is reported. DCMs, however, are permitted to forbid such trading.

3. Publication of Transaction Details

The Commission is re-proposing that DCMs would publicize details about transactions off the centralized market immediately upon the receipt of the transaction report. The Commission wishes to clarify that it does not intend to impose new publication requirements on DCMs in regards to trades made off the centralized market beyond what is required by the Commission's regulations. So, for example, DCMs would need to publish the total number of exchanges of futures for a commodity or for a derivatives position, as required by Commission Regulation 16.01. But there would be no similar requirement to publish office trades or transfer trades.

Similarly, the proposed guidance also identifies publication of block trade details by DCMs immediately upon receipt of block trade reports as an acceptable practice.[20] The proposed acceptable practices also would require the DCM to identify block trades on its trade register.

4. Recordkeeping

Current Commission Regulation 1.38(b) provides that every person handling, executing, clearing, or carrying trades, transactions or positions that are not competitively executed, must identify and mark by appropriate symbol or designation all such transactions or contracts and all associated orders, records, and memoranda. In addition to updating the language of Regulation 1.38(b), the proposed amendments add this requirement to the guidance under Core Principle 9, in order to provide consolidated guidance regarding recordkeeping practices pertaining to transactions off the centralized market.

Similarly, acceptable block trade rules would require parties to, and members facilitating, a block trade to keep appropriate records. Appropriate block trade records would comply with the requirements of Core Principle 10 and Core Principle 17. Records kept in accordance with the requirements of Statement No. 133 (''Accounting for Derivative Instruments and Hedging Activities''), issued by the Financial Accounting Standards Board (''FASB''), would be satisfactory.[21] Acceptable block trade rules would require that block orders be recorded by the member and time-stamped with both the time the order was received by the member and the time the order was executed. When requested by the exchange, the Commission or the Department of Justice, parties to, and members facilitating, a block trade shall provide records to document that the block trade is executed in accordance with contract market rules.

5. Testing of Automated Trading Systems

The guidance for Core Principle 9 also addresses the testing and review of automated trading systems. Currently, the guidance states that acceptable testing of automated systems should be ''objective,'' and calls for the provision of ''objective'' test results to the Commission. The proposed guidance would also call for the provision to the

[18] *See, e.g.*, CBOT Rule 331.05(d); CME Rule 526(F); NYMEX Rule 6.21C.

[19] *See, e.g.*, CME Rule 526(F).

[20] This also is an element of compliance with Designation Criterion 3 (Fair and Equitable Trading) and Core Principle 8 (Daily Publication of Trading Information).

[21] FASB Statement No. 133 provides guidance on the use of accounting for corporate hedge activity involving derivative transactions. The statement includes guidance on documenting the hedging relationship.

Commission of test results of any ''non-objective'' testing carried out by or for a DCM (such as informal in-house reviews) regarding the system functioning capacity or security of any automated trading systems. Although the results of ''non-objective'' testing would be of more limited use, the Commission believes that test results of any ''non-objective'' testing carried out by or for the DCM should also be provided to the Commission.

6. Parties to a Block Trade

The Commission is proposing that block trade parties are required to be eligible contract participants (''ECPs'') as that term is defined in Section 1a(12) of the Act, although commodity trading advisors (''CTAs'') and investment advisors having over $25 million in assets under management, including foreign persons performing equivalent roles, are allowed to carry out block trades for non-ECP customers.

A majority of exchanges that permit block trading prohibit persons from effecting block trades on behalf of customers unless the person receives a customer's explicit instruction or prior consent to do so.[22] The proposed rulemaking incorporates this prohibition as an acceptable practice.

III. Request for Comment

The Commission requests comment on all aspects of this proposal.

IV. Related Matters

A. Regulatory Flexibility Act

The Regulatory Flexibility Act[23] requires federal agencies, in proposing rules, to consider the impact of those rules on small businesses. The rule amendments proposed herein will affect DCMs, FCMs, CTAs and large traders. The Commission has previously established certain definitions of ''small entities'' to be used by the Commission in evaluating the impact of its rules on small entities in accordance with the RFA.[24] The Commission has previously determined that DCMs,[25] registered FCMs,[26] and large traders[27] are not small entities for purposes of the RFA. With respect to CTAs, the Commission has determined to evaluate within the context of a particular rule proposal whether CTAs would be considered ''small entities'' for purposes of the Regulatory Flexibility Act and, if so, to analyze the economic impact on the affected entities of any such rule at that time.[28] The Commission believes that the instant proposed rules will not place any new burdens on entities that would be affected hereunder, and the Commission does not expect the proposed amendments in most cases to cause persons to change their current methods of doing business. This is because requirements under this proposal, if adopted, would be similar to most existing DCM requirements.

Accordingly, the Commission does not expect the rules, as proposed herein, to have a significant economic impact on a substantial number of small entities. Therefore, the Chairman, on behalf of the Commission, hereby certifies, pursuant to 5 U.S.C. 605(b), that the proposed amendments will not have a significant economic impact on a substantial number of small entities. The Commission invites the public to comment on this finding and on its proposed determination that the entities covered by these rules would not be small entities for purposes of the Regulatory Flexibility Act.

B. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 imposes certain requirements on federal agencies (including the Commission) in connection with their conducting or sponsoring any collection of information as defined by the PRA. The proposed rule amendments do not require a new collection of information on the part of any entities subject to these rules. Accordingly, for purposes of the Paperwork Reduction Act of 1995, the Commission certifies that these rule amendments do not impose any new reporting or recordkeeping requirements.

C. Cost-Benefit Analysis

Section 15 of the Act, as amended by section 119 of the CFMA, requires the Commission to consider the costs and benefits of its action before issuing a new regulation. The Commission understands that, by its terms, Section 15 does not require the Commission to quantify the costs and benefits of a new regulation or to determine whether the benefits of the proposed regulation outweigh its costs. Nor does it require that each proposed regulation be analyzed in isolation when that regulation is a component of a larger package of regulations or of rule revisions. Rather, Section 15 simply requires the Commission to ''consider the costs and benefits'' of its action.

Section 15(a) further specifies that costs and benefits shall be evaluated in light of five broad areas of market and public concern: Protection of market participants and the public; efficiency, competitiveness, and financial integrity of futures markets; price discovery; sound risk management practices; and other public interest considerations. Accordingly, the Commission could, in its discretion, give greater weight to any one of the five enumerated areas of concern and could, in its discretion, determine that, notwithstanding its costs, a particular regulation was necessary or appropriate to protect the public interest, to effectuate any of the provisions, or to accomplish any of the purposes of the Act.

The proposed amendments constitute a package of amendments to Regulation 1.38 and to guidance that the Commission originally promulgated to implement the CFMA. The amendments are proposed in light of past experience with the implementation of the CFMA and are intended to facilitate increased flexibility and consistency. Some sections of the proposed amendments merely clarify or make explicit past Commission decisions concerning transactions off the centralized market.

As most provisions incorporate DCM rules previously approved by the Commission or submitted to the Commission under its self-certification procedures, the proposed amendments would not, in most cases, impose new costs on DCMs or market participants. The great majority of current DCM rules already meet the acceptable practices proposed. Furthermore, these amendments incorporate standards that the Commission has previously determined protect market participants and the public, the financial integrity or price discovery function of the markets, and sound risk management practices. Moreover, the additional clarification of acceptable practices provides a benefit to markets and market participants. In addition, the amendments are expected to benefit efficiency and competition by providing more detailed guidance as to acceptable means of meeting the applicable designation criteria and core principles, thus allowing a greater degree of legal certainty to the markets and market participants.

After considering the five factors enumerated in the Act, the Commission has determined to propose the rules and rule amendments set forth below. The Commission invites public comment on its application of the cost-benefit provision. Commenters also are invited to submit any data that they may have quantifying the costs and benefits of the

[22] *See* CME Rule 526(C), CFE Rule 415(a)(i), CBOT Rule 331.05(a), NYBOT Rule 4.31(a)(ii)(A), OCX Rule 417(a)(i), and USFE Rule 415(c).

[23] 5 U.S.C. 601 *et seq.*

[24] 47 FR 18618–21 (Apr. 30, 1982).

[25] *Id.* at 18618–19.

[26] *Id.* at 18619–20.

[27] *Id.* at 18620.

[28] *Id.* at 18620.

proposed rules with their comment letters.

List of Subjects

17 CFR Part 1

Block transactions, Commodity futures, Contract markets, Transactions off the centralized market, Reporting and recordkeeping requirements.

17 CFR Part 38

Block transactions, Commodity futures, Contract markets, Transactions off the centralized market, Reporting and recordkeeping requirements.

In consideration of the foregoing, the Commission hereby proposes to amend Chapter I of Title 17 of the Code of Federal Regulations as follows:

PART 1—GENERAL REGULATIONS UNDER THE COMMODITY EXCHANGE ACT

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

Authority: 7 U.S.C. 1a, 2, 5, 6, 6a, 6b, 6c, 6d, 6e, 6f, 6g, 6h, 6i, 6j, 6k, 6l, 6m, 6n, 6o, 6p, 7, 7a, 7b, 8, 9, 12, 12a, 12c, 13a, 13a–1, 16, 16a, 19, 21, 24, and 24, as amended by the Commodity Futures Modernization Act of 2000, Appendix E of Pub L. 106–554, 114 Stat. 2763 (2000).

2. Section 1.38 is revised to read as follows:

§ 1.38 Execution of transactions.

(a) *Transactions on the centralized market.* All purchases and sales of any commodity for future delivery, and of any commodity option, on or subject to the rules of a designated contract market, shall be executed openly and competitively by open outcry, or posting of bids and offers, or by other equally open and competitive methods, in a place or through an electronic system provided by the contract market, during the hours prescribed by the contract market for trading in such commodity or commodity option.

(b) *Transactions off the centralized market; requirements.*

(1) Notwithstanding paragraph (a) of this section, transactions may be executed off the centralized market, including by transfer trades, office trades, block trades, inter-exchange spread transactions, or trades involving the exchange of futures for commodities or for derivatives positions, if transacted in accordance with written rules of a contract market that provide for execution away from the centralized market and that have been certified to or approved by the Commission. Every person handling, executing, clearing, or carrying the trades, transactions or positions described in this paragraph shall comply with the rules of the appropriate contract market and derivatives clearing organization, including to identify and mark by appropriate symbol or designation all such transactions or contracts and all orders, records, and memoranda pertaining thereto.

(2) *Block trades between affiliated parties; requirements.* An affiliated party is a party that directly or indirectly through one or more persons, controls, is controlled by, or is under common control with another party. In addition to the other requirements of this section, block trades between affiliated parties are permitted only in accordance with written rules of a contract market that provide that:

(i) The block trade price must be based on a competitive market price, either by falling within the contemporaneous bid/ask spread on the centralized market or calculated based on a contemporaneous market price in a related cash market,

(ii) Each party must have a separate and independent legal bona fide business purpose for engaging in the trades, and

(iii) Each party's decision to enter into the block trade must be made by a separate and independent decision-maker.

PART 38—DESIGNATED CONTRACT MARKETS

3. The authority citation for part 38 is revised to read as follows:

Authority: 7 U.S.C. 2, 5, 6, 6c, 7 and 12a, as amended by the Commodity Futures Modernization Act of 2000, Appendix E of Pub. L. 106–554, 114 Stat. 2763 (2000).

4. Appendix B to Part 38 is revised to read as follows:

Appendix B to Part 38—Guidance on, and Acceptable Practices in, Compliance With Core Principles

Core Principle 9 of section 5(d) of the Act: EXECUTION OF TRANSACTIONS—The board of trade shall provide a competitive, open, and efficient market and mechanism for executing transactions.

(a) *Guidance.*

(1) *Transactions on the centralized market.*

(i) Purchases and sales of any commodity for future delivery, and of any commodity option, on or subject to the rules of a contract market shall be executed openly and competitively by open outcry, by posting of bids and offers, or by other equally open and competitive methods, in a place or through an electronic system provided by the contract market, during the hours prescribed by the contract market for trading in such commodity or commodity option.

(ii) A competitive and open market's mechanism for executing transactions includes a contract market's methodology for entering orders and executing transactions.

(iii) Appropriate objective testing and review of a contract market's automated systems should occur initially and periodically to ensure proper system functioning, adequate capacity and security. A designated contract market's analysis of its automated system shall address compliance with appropriate principles for the oversight of automated systems, ensuring proper system functionality, adequate capacity and security.

(2) *Transactions off the centralized market.*

(i) In order to facilitate the execution of transactions, transactions may be executed off the centralized market, including by transfer trades, office trades, block trades, inter-exchange spread transactions, or trades involving the exchange of futures for a commodity or for a derivatives position, if transacted in accordance with written rules of a contract market that specifically provide for execution of such transactions away from the centralized market and that have been certified to or approved by the Commission.

(ii) Every person handling, executing, clearing, or carrying trades off the centralized market shall comply with the rules of the applicable designated contract market and derivatives clearing organization, including to identify and mark by appropriate symbol or designation all such transactions or contracts and all orders, records, and memoranda pertaining thereto.

(iii) A designated contract market that determines to allow trades off the centralized market shall ensure that such trading does not operate in a manner that compromises the integrity of price discovery on the centralized market or facilitate illegal or non-bona fide transactions.

(3) *Block trades–minimum size.*

(i) When determining the number of contracts that constitutes the appropriate minimum size for block trades, a contract market should ensure that block trades are limited to large transactions and that the minimum size is appropriate for that specific contract, by applying the principles set forth in this section. For any contract that has been trading for one calendar quarter or longer, the acceptable minimum block trade size should be a number larger than the size at which a single buy or sell order is customarily able to be filled in its entirety at a single price in that contract's centralized market. Factors to consider in determining what constitutes a large transaction could include an analysis of the market's volume, liquidity and depth; a review of typical trade sizes and/or order sizes; and input from floor brokers, floor traders and/or market users. For any contract that has been listed for trading for less than one calendar quarter, an acceptable minimum block trade size in such contract should be the size of trade the exchange reasonably anticipates will not be able to be filled in its entirety at a single price in that contract's centralized market. An appropriate minimum size could be estimated based on centralized market data in a related futures contract, the same contract traded on another exchange, or trading activity in the underlying cash market. The exchange could also consider the anticipated volume,

liquidity and depth of the contract; input from potential market users; or consider that exchange's experience with offering similar new contracts. The minimum size thresholds for block trades should be reviewed periodically to ensure that the minimum size remains appropriate for each contract. Such review should take into account the sizes of trades in the centralized market and the market's volume and liquidity.

(b) *Acceptable practices.*

(1) *General matters relating to trade execution facilities.*

(i) *General provisions.* [Reserved]

(ii) *Electronic trading systems.*

(A) The guidelines issued by the International Organization of Securities Commissions (IOSCO) in 1990 (which have been referred to as the ''Principles for Screen-Based Trading Systems''), and adopted by the Commission on November 21, 1990 (55 FR 48670), as supplemented in October 2000, are appropriate guidelines for a designated contract market to apply to electronic trading systems.

(B) Any objective testing and review of the system should be performed by a qualified independent professional. A professional that is a certified member of the Information Systems Audit and Control Association experienced in the industry is an example of an acceptable party to carry out testing and review of an electronic trading system.

(C) Information gathered by analysis, oversight, or any program of testing and review of any automated systems regarding system functioning, capacity and security must be made available to the Commission upon request.

(iii) *Pit trading.* [Reserved]

(2) *Transactions off the centralized market.*

(i) *General provisions.*

(A) Allowable trades. Acceptable transactions off the centralized market include: transfer trades, office trades, block trades, inter-exchange spread transactions or trades involving the exchange of futures for commodities or for derivatives positions, if transacted in accordance with written rules of a contract market that specifically provide for execution away from the centralized market and that have been certified to or approved by the Commission.

(B) Reporting. Transactions executed off the centralized market should be reported to the contract market within a reasonable period of time.

(C) Publication. The contract market should publicize details about block trade transactions immediately upon the receipt of the transaction report and publicize daily the total quantity of the exchange of futures for commodities or for derivatives positions and the total quantity of the block trades that are included in the total volume of trading, as required by § 16.01 of this chapter.

(D) Recordkeeping. Parties to, and members facilitating, transactions off the centralized market should keep appropriate records. Appropriate recordkeeping for transactions off the centralized market would comply with Core Principle 10 and Core Principle 17.

(E) Identification of trades. Section 1.38(b) of this chapter establishes the requirements regarding the identification of trades off the centralized market. It requires contract market rules to require every person handling, executing, clearing, or carrying trades, transactions or positions that are executed off the centralized market, including transfer trades, office trades, block trades or trades involving the exchange of futures for a commodity or for a derivatives position, to identify and mark by appropriate symbol or designation all such transactions or contracts and all orders, records, and memoranda pertaining thereto.

(F) Identification in the trade register. The contract market should identify transactions executed off the centralized market in its trade register, using separate indicators for each such type of transaction.

(ii) *Block trades.*

(A) Acceptable minimum block trade size.

(a) New contracts or contracts that have been listed for trading for less than one calendar quarter. If an exchange has no reasonable basis upon which to estimate an initial minimum size, a minimum block trade size of 100 contracts would be appropriate.

(b) Periodic review. The minimum size thresholds for block trades should be reviewed no less frequently than on a quarterly basis to ensure that the minimum size remains appropriate for each contract.

(B) Appropriate parties.

(a) Acceptable block trade parties should be limited to eligible contract participants. However, contract market rules could also allow a commodity trading advisor registered pursuant to Section 4m of the Act, or a principal thereof, including any investment advisor who satisfies the criteria of § 4.7(a)(2)(v) of this chapter, or a foreign person performing a similar role or function and subject as such to foreign regulation, to transact block trades for customers who are not eligible contract participants, if such commodity trading advisor, investment advisor or foreign person has more than $25,000,000 in total assets under management.

(b) Affiliated parties. An affiliated party is a party that directly or indirectly through one or more persons, controls, is controlled by, or is under common control with another party. Section 1.38(b) of this chapter establishes the requirements regarding block trades between affiliated parties. Contract market rules could permit block trades between affiliated parties that meet the requirements of Regulation 1.38 and are otherwise appropriate parties.

(C) Aggregation of orders. The aggregation of orders for different accounts in order to satisfy the minimum size requirement should be prohibited except in appropriate circumstances. Aggregation would be acceptable if done by a commodity trading advisor registered pursuant to Section 4m of the Act, or a principal thereof, including any investment advisor who satisfies the criteria of § 4.7(a)(2)(v) of this chapter, or a foreign person performing a similar role or function and subject as such to foreign regulation, if such commodity trading advisor, investment advisor or foreign person has more than $25,000,000 in total assets under management.

(D) Acting for a customer. A person should transact a block trade on behalf of a customer only when the person has received an instruction or prior consent to do so from the customer.

(E) Recordkeeping. Parties to, and members facilitating, a block trade should keep appropriate records. Appropriate block trade records would comply with Core Principle 10 and Core Principle 17. Records kept in accordance with the requirements of FASB Statement No. 133 (''Accounting for Derivative Instruments and Hedging Activities'') would be acceptable records. Block trade orders must be recorded by the member and time-stamped with both the time the order was received and the time the order was reported, and must indicate when block trades are between affiliated parties. When requested by the exchange, the Commission or the Department of Justice, parties to, and members facilitating, a block trade shall provide records to document that the block trade is executed in conformance with contract market rules.

(F) Reporting. Block trades should be reported to the contract market within a reasonable period of time.

(G) Publication. The contract market should publicize details about the block trade immediately upon the receipt of the transaction report and publicize daily the total quantity of the block trades that are included in the total volume of trading, as required by § 16.01 of this chapter.

(H) Identification in the trade register. The contract market should identify block trades as such on its trade register, and should identify when block trades are between affiliated parties.

(I) Pricing. (*a*) Block trades between non-affiliated parties should be at a price that is fair and reasonable. Consideration of whether a block trade price is fair and reasonable could take into account the size of the block plus the price and size of other trades in any relevant markets at the applicable time, or the circumstances of the market or the parties to the block trade. Relevant markets could include the contract market itself, the underlying cash markets and/or other related futures or options markets. If a contract market rule requiring a fair and reasonable price includes the circumstances of the parties or of the market, a block trade participant could execute a block transaction at a price that was away from the market provided that the participant retains documentation to demonstrate that the price was indeed fair and reasonable under the participant's or market's particular circumstances.

(*b*) Block trades between affiliated parties are subject to the pricing requirements of § 1.38(b) of this chapter.

(iii) *Exchange of futures for commodities or for derivatives positions.*

(A) Bona fide exchange of futures for commodities or for derivatives positions. The exchange of futures for commodities or for derivatives positions would include separate but integrally related transactions involving the same or a related commodity, with price correlation and quantitative equivalence of the futures and cash legs. An exchange of futures for commodities or for derivatives positions would be between a buyer of futures who is the seller of the corresponding commodity or derivatives position and a

seller of futures who is the buyer of the corresponding commodity or derivatives position. A third party could be permitted to facilitate the purchase and sale of the commodity or derivatives position as long as the commodity or derivatives position is passed through to the party that receives the futures position. The transaction would have to result in an actual transfer of ownership of the commodity or derivatives position. It also would have to be between parties with different beneficial owners or under separate control, who had possession, right of possession, or right to future possession of the commodity or derivatives position prior to the trade, the ability to perform the transaction, and resulting in a transfer of title.

(B) Pricing. The price differential between the futures leg and the commodities leg or derivatives position should reflect commercial realities, and at least one leg of the transaction should be priced at the prevailing market price.

(C) Transitory exchange of futures for commodities or for derivatives positions. Parties to an exchange of futures for commodities or for derivatives positions could be permitted to engage in a separate but related cash transaction that offsets the cash leg of the exchange of futures for commodities or for derivatives positions. The related cash transaction would have to result in an actual transfer of ownership of the commodity or derivatives position and demonstrate other indicia of being a bona fide transaction as described in paragraph (a). The cash transaction must be able to stand on its own as a commercially appropriate transaction, with no obligation on either party that the cash transaction be dependent upon the execution of the related exchange of futures for commodities or for derivatives positions, or vice versa.

(D) Reporting. Exchanges of futures for commodities or for derivatives positions should be reported to the contract market within a reasonable period of time.

(E) Publication. The contract market would publicize daily the total quantity of exchanges of futures for commodities or for derivatives positions that are included in the total volume of trading, as required by § 16.01 of this chapter.

(iv) *Office trades.* [Reserved]

(v) *Transfer trades.* [Reserved]

Issued in Washington, DC on September 12, 2008 by the Commission.

David Stawick,

Secretary of the Commission.

[FR Doc. E8–21865 Filed 9–17–08; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA–2007–N–0465]

RIN 0910–AF61

Label Requirement for Food That Has Been Refused Admission into the United States

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a proposed rule that would require owners or consignees to label imported food that is refused entry into the United States. The label would read, ''UNITED STATES: REFUSED ENTRY.'' The proposal would describe the label's characteristics (such as its size) and processes for verifying that the label has been affixed properly. We are taking this action to prevent the reintroduction of refused food into the United States, to facilitate the examination of imported food, and to implement part of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

DATES: Submit written or electronic comments on the proposed rule by December 2, 2008. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 October 20, 2008, (see the ''Paperwork Reduction Act of 1995'' section of this document).

ADDRESSES: You may submit comments, identified by Docket No. FDA–2007–N–0465, by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Regulatory Affairs, Office of Management and Budget (OMB) (see the ''Paperwork Reduction Act of 1995'' section of this document).

Electronic Submissions

Submit electronic comments in the following way:

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

Written Submissions

Submit written submissions in the following ways:

- *FAX:* 301–827–6870.
- *Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and docket number and Regulatory Information Number (RIN) for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy and Planning (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0587.

SUPPLEMENTARY INFORMATION:

I. Introduction

A. How Did the Idea of Marking Refused Food Imports Originate?

Section 801 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381) authorizes us to examine foods, drugs, devices, and cosmetics that are imported or offered for import into the United States and to refuse admission to products that appear, from examination or otherwise, to be (among other things) adulterated or misbranded.

Our examination of food imports usually begins with an electronic prior notice and then an entry review to determine whether additional scrutiny at arrival or thereafter is warranted. We may, based on our review, permit the goods to proceed without further examination. We may take additional steps to determine whether the shipment appears to comply with the act, including: (1) Visually examining the goods; (2) taking samples of the goods for laboratory analysis; (3) verifying the registration, declarations, and certifications for the goods; and/or (4) requesting supporting documentation. If our additional

examination shows that the food appears to be in compliance with the act, we allow the shipment to proceed. If the food appears not to be in compliance, we issue a notice that the shipment has been detained, and the owner or consignee has an informal opportunity to provide evidence or testimony that the food complies with the act or to submit a plan to recondition the food (21 CFR 1.94 and 1.95). If the importer is unable to demonstrate that the food complies with the act and reconditioning has failed to bring the food into compliance, we refuse admission to the food. Section 801(a) of the act provides that, if refused foods are not re-exported within 90 days of refusal (or such other time as Customs and Border Protection (CBP) permits), CBP ensures that the food is destroyed.

In the **Federal Register** of January 22, 2001 (66 FR 6502), we published a proposed rule (the 2001 proposed rule) that would require importers or consignees whose food is refused entry into the United States for safety reasons to mark the refused foods. The mark would state, ''UNITED STATES REFUSED ENTRY.'' The proposed rule also would prohibit persons from refusing to affix this mark on refused food, from importing or offering to import a previously refused food, and from altering, removing, tampering with, or concealing a mark.

We issued the 2001 proposed rule to address a practice known as ''port shopping.'' In general, when FDA refuses to admit a food into the United States, the food must be exported from the United States or destroyed. However, instead of simply exporting or destroying the refused food, some unscrupulous persons attempt to bring the refused food back into the United States by shipping it to another port in hopes that the food will be admitted into the United States at that other port.

The 2001 proposed rule also was in response to an April 1998 report by the General Accounting Office (GAO), 1998 hearings held by the Senate Committee on Governmental Affairs' Permanent Subcommittee on Investigations, and a July 3, 1999, Presidential memorandum (see GAO, ''Food Safety: Federal Efforts to Ensure the Safety of Imported Foods are Inconsistent and Unreliable'' (GAO/RCED–98–103); *The Safety of Food Imports: Fraud & Deception in the Food Import Process; Hearings Before the Senate Committee on Governmental Affairs, Permanent Subcommittee on Investigations*, September 10, 1998; ''Memorandum on the Safety of Imported Foods,'' *Weekly Compilation of Presidential Documents, Administration of William J. Clinton, 1999*, July 3, at pages 1277 through 1278). The GAO report and the Senate subcommittee hearings discussed marking refused foods as a way to enhance the safety of imported foods (see 66 FR 6502 at 6503). The July 3, 1999, memorandum from then-President Clinton to the Secretary of Health and Human Services and the Secretary of the Treasury also discussed imported food safety. The memorandum identified food safety as a high priority and directed the Secretaries to take all actions available to ''prohibit the reimportation of food that has been previously refused admission and has not been brought into compliance with United States laws and regulations (so called ''port shopping''), and require the marking of shipping containers and/or papers of imported food that is refused admission for safety reasons'' (id.).

B. What Happened to the Previous Effort to Require Marking of Refused Food?

We received 13 comments on the 2001 proposed rule and were nearing completion of a final rule when, on June 12, 2002, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Public Law 107–188) became law. Section 308(a) of the Bioterrorism Act created a new section 801(n) of the act, which provides additional express authority to require labels on refused foods. Section 801(n)(1) of the act states that we may require the owner or consignee of a food that had been refused admission into the United States to ''affix to the container of the food a label that clearly and conspicuously bears the statement: 'UNITED STATES: REFUSED ENTRY'.'' Section 801(n)(2) of the act requires the owner or consignee of the food involved to pay all expenses in connection with affixing the label. Section 801(n)(3) of the act states that a requirement under section 801(n)(1) of the act remains in effect until we determine that the food has been brought into compliance with the act.

The Bioterrorism Act made clear that the new provisions were not intended to detract from our existing authority to require refused food imports to be marked as such. Section 308(c) of the Bioterrorism Act states that, ''nothing in this section shall be construed to limit the authority of the Secretary of Health and Human Services or the Secretary of the Treasury to require the marking of refused articles of food under any other provision of law.'' Nonetheless, the new statutory requirements differed from our 2001 proposed rule in several ways, and these differences led us to withdraw the 2001 proposed rule on August 21, 2002 (67 FR 54138), and re-examine how we should implement this authority.

We summarize the principal differences between our earlier 2001 proposed rule and the requirements in section 801(n) of the act here.

TABLE 1—PRINCIPAL DIFFERENCES BETWEEN FDA'S JANUARY 22, 2001, PROPOSED RULE AND SECTION 801(N) OF THE ACT

Provision in the January 22, 2001 Proposed Rule	Provision in Section 801(n) of the Act
Would authorize marking of food that was refused admission into the United States for safety reasons	Authorizes labels on the container of food that was refused admission into the United States, except for food that is required to be destroyed
Would require the mark to be at least 2.5 centimeters or 1 inch high and to be clear, conspicuous, and permanently affixed	Requires the label statement to be clear and conspicuous
Mark would state, ''UNITED STATES REFUSED ENTRY''	Label states, ''UNITED STATES: REFUSED ENTRY''
No express provision regarding fees	Requires owner or consignee of the food involved to pay all expenses in connection with affixing the label and authorizes liens in event of default of such payment

TABLE 1—PRINCIPAL DIFFERENCES BETWEEN FDA'S JANUARY 22, 2001, PROPOSED RULE AND SECTION 801(N) OF THE ACT—Continued

Provision in the January 22, 2001 Proposed Rule	Provision in Section 801(n) of the Act
Would require the mark to go on the food's packing container, if possible, and to an invoice, bill of lading, and any other shipping document accompanying the food when it is exported	Label to be affixed to the container
Would prohibit altering, tampering with, or concealing a mark	Food is misbranded if: it fails to bear a label (concerning the fact that the food has been refused admission); the food presents a threat of serious adverse health consequences or death to humans or animals; and, upon or after notifying the owner or consignee involved that a label is required, the owner or consignee is informed that the food presents such a threat.

On July 18, 2007, President George W. Bush established an Interagency Working Group on Import Safety to conduct a comprehensive review of import safety practices and to determine areas for improvement. On November 6, 2007, the Working Group submitted its report, *Action Plan for Import Safety: A Roadmap for Continual Improvement*, to the President. Publishing this proposed rule by mid-2008 was a planned action in the report.

This proposed rule would, among other things, implement section 801(n) of the act and address labeling the documents associated with foods that have been refused admission, whether or not the foods have ''containers'' as we propose to define that term for purposes of section 801(n) of the act.

II. Description of the Proposed Rule

A. Introduction

We are proposing to amend our import regulations to create a new § 1.98, entitled ''Label requirement on food imports refused admission into the United States.'' The proposal would require all owners or consignees to label the shipping container of food refused admission into the United States under section 801(a) of the act, as well as any documents (including electronic documents) accompanying the food. The label would make it more difficult for imported food that has been refused admission into the United States to evade import controls and would complement our other efforts to monitor food imports.

There is no direct counterpart to section 801(n) of the act with respect to food that has been produced domestically rather than imported. Food produced domestically that is not in compliance with the act is subject to a range of regulatory and enforcement actions. For example, we may seek to seize the food under section 304 of the act (21 U.S.C. 334), seek an injunction under section 302 of the act (21 U.S.C. 332), or request that a firm voluntarily initiate a recall.

B. Who Is Subject to the Label Requirement? (Proposed § 1.98(a))

In general, proposed § 1.98(a) would state that you are subject to the rule if you are an owner or consignee of an imported food (including food for animals) which we have refused to admit into the United States (other than a food which must be destroyed). The proposal would require you to affix labels stating, ''UNITED STATES: REFUSED ENTRY,'' as described in proposed § 1.98(b) and (c) (which we discuss later in part II.C and II.D of this document).

Under our pre-existing import program, when an FDA-regulated food product is offered for import, we review electronic information about the product provided under the prior notice procedures described in 21 CFR 1.276 through 1.285. If prior notice requirements are satisfied, we then conduct an admissibility review to determine whether the food meets the safety and quality standards under the act and its implementing regulations that likewise apply to food produced or grown in the United States. If our review of that information determines that further evaluation of the information or article is unnecessary, we notify CBP that the article may proceed without further FDA examination. If further evaluation is deemed necessary, our staff may request additional information to make an admissibility determination or may examine or sample the product. Finally, if our review indicates that the product appears ''by examination or otherwise'' to be subject to refusal of admission under section 801(a) of the act (e.g., appears to be adulterated or misbranded), we will take appropriate action, and notify the owner or consignee and customs broker that we are detaining the shipment by sending a ''Notice of FDA Action.''

The Notice of FDA Action specifies the nature of the violations identified through our evaluation and designates an address where the recipient may present information to us. If the person receiving the Notice of FDA Action accepts the refusal of admission or if our district office determines, after reviewing the information provided to it, that the imported food continues to appear to be in violation, we then issue a ''Notice of Refusal of Admission.'' The Notice of Refusal of Admission finalizes the charges and provides for the food's exportation or destruction within 90 days of the notice's date or within timeframes set by CBP. We intend to modify these types of notices to state that a refused food import is subject to the labeling requirements described in this proposal and to indicate whether a refused food presents a threat of serious adverse consequences or death to humans or animals because of the misbranding requirement seen at section 403(v) of the act (21 U.S.C. 343(v)). Under section 403(v) of the act, a food is misbranded if: (1) It fails to bear a label required by regulation under section 801(n)(1) of the act; (2) we find that the food presents a threat of serious adverse consequences or death to humans or animals; and (3) upon or after notification that the label is required, we inform the owner or consignee that the food presents such a threat.

Proposed § 1.98(a) reference to owners and consignees of an imported food reflects the language in section 801(n)(1) of the act. However, for purposes of proposed § 1.98, we intend to interpret ''owner'' and ''consignee'' to include persons acting on the owner's or consignee's behalf, such as the owner's employees and agents. This practical and common sense interpretation would preclude arguments we have seen in other regulatory contexts where parties have argued that a particular statutory or regulatory requirement is too burdensome because only the specific

individual owner, and not any employee or agent retained by the owner, can satisfy the requirement. Here, if an owner instructs its employee or agent to affix the label to a shipping container or documents, we would consider the employee or agent to be acting on the owner's behalf and the employee's or agent's action to be consistent with section 801(n)(1) of the act and proposed § 1.98(a).

Proposed § 1.98(a) also would state that imported food includes ''food for animals.'' This reflects the fact that animal food or feed falls within the definition of ''food'' in section 201(f) of the act (21 U.S.C. 321(f)).

C. What Does the Label Look Like? (Proposed § 1.98(b))

Proposed § 1.98(b) would require the label to state, ''UNITED STATES: REFUSED ENTRY'' in capital letters and in black ink on a white background. For labels that are to be affixed to shipping containers, proposed § 1.98(b)(1) would require the label's letters to use either an Arial or Univers font style and be at least 72 points in size. The label would use uppercase letters only. (We discuss shipping containers and documents in greater detail in part II.D of this document.)

For labels that are to be affixed to documents (including electronic documents), proposed § 1.98(b)(2) would require the label's letters to be in black ink, use either an Arial or Univers font style, and be at least 36 points in size. The label would use uppercase letters only. We tentatively have decided to specify the label's fonts and sizes in proposed § 1.98(b)(1) and (b)(2) because such a requirement would make the label clear, conspicuous, and easy to read and identify and would minimize uncertainty about what the terms ''clear'' and ''conspicuous'' mean.

Based on our experience with the 2001 proposed rule, we expect that some individuals may want the rule to require some indication of why the food was refused entry rather than limit the label to the language specified by section 801(n)(1) of the act. We tentatively have decided against requiring such explanations in the proposed rule because the words, ''UNITED STATES: REFUSED ENTRY,'' are specified in section 801(n)(1) of the act. Unlike our 2001 proposed rule, the label would be applied to all foods that are refused entry. If we were to require the label to explain the reasons for refusing to admit the food into the United States, importers, owners, and consignees would have to have multiple labels (to cover the various possible reasons for refusing entry) or would have to use ''fill in the blank'' labels which could then be illegible (if the reasons are handwritten) or difficult to use (if the reasons are machine-printed). Such a result would be inconsistent with the statutory requirement that the label ''clearly and conspicuously'' bear the statement. Consequently, proposed § 1.98(b) would only require the label to say, ''UNITED STATES: REFUSED ENTRY.'' Nonetheless, neither the act nor this proposed rule would prohibit further statements as long as they are not false or misleading and do not prevent the label from being both clear and conspicuous.

Although the proposal would specify the label's text, font style, size, and color(s), it would not specify any particular type of label. In other words, use of adhesive labels, ink stamps, paint and stencils, or any other tool or device would satisfy the rule's requirements as long as the label is permanent, is the correct size and color, and otherwise complies with the rule.

As for the ink used for the label, we expect that, based on our experience with the 2001 proposed rule, we may receive comments requesting a rule that would require the label to use ''invisible ink'' that could be seen only by using some unspecified scanning device. In the past, some comments have expressed concern about how a visible label might affect the refused food's ability to enter a foreign country or return to the exporting country. We believe that the use of ''invisible ink'' would be inconsistent with the statutory requirement that the label's text be clear and conspicuous. If the labels were invisible to the human eye, we would be obliged to scan every food product offered for import into the United States, and implementing section 801(n)(1) of the act in such a manner would be contrary to the statutory intent of enabling FDA to identify previously refused food quickly and easily.

D. Where Does the Label Go? (Proposed § 1.98(c))

Proposed § 1.98(c) would require the label to be affixed to the shipping container of refused food and on invoices, bills of lading, and other documents accompanying the imported food. By ''shipping container,'' we mean ''an individual container designed for shipping one or more immediate containers of the refused food, and an immediate container is any container that holds an imported food for retail sale.'' This definition of ''shipping container'' would include items such as boxes, bags, bottles, jars, tanks, drums, barrels, and totes because such items are individual containers designed for shipping food. The definition would exclude items such as railroad cars, truck trailers and truck trailer bodies (also referred to as ''containers'' or ''intermodal shipping containers'' and including International Organization for Standardization (ISO) standard containers or ''ISOtainers'' and other standardized containers that can be attached to a vehicle body), ship holds, and similar transportation-related items because those items are not individual containers designed for shipping food.

Section 801(n)(1) of the act requires the label to be affixed to ''the container of the food,'' but the act, the Bioterrorism Act, and the legislative history for the Bioterrorism Act do not define or otherwise explain what constitutes a ''container.'' By referring to the ''shipping container,'' the proposal would require placement of the label on the container that would normally be used in commerce to ship food. For example, assume that an imported food shipment consists of cardboard cartons containing 24 cans of food and that we have refused to admit the food into the United States. The ''shipping containers'' would be the cartons containing the cans rather than each can, so the label would go on each carton. As another example, assume that an imported food shipment consists of plastic drums, each drum containing five gallons of vegetable oil, and that we have refused to admit the food into the United States. In this example, the ''shipping container'' is the individual plastic drum, so the label would go on the drums. Note, too, that, in this example, the plastic drums are also immediate containers, because it is likely that the plastic drums are the containers that hold the oil for sale to others.

Consistent with section 801(n) of the act, the proposal also would require the label on the shipping container to be clear and conspicuous. While we believe that the specifications in proposed § 1.98(b) will establish what we mean by ''clear,'' we invite comment on whether the rule should attempt to explain what ''conspicuous'' means or does not mean. Our concern is that individuals may attempt to comply with the letter, but not the spirit, of the law by placing the labels on the bottom of the shipping container. However, it may be difficult to describe what ''conspicuous'' means for the range of shipping containers. For example, if we stated that the label cannot go on a shipping container's bottom to prevent the label from being obscured, such detail might tempt individuals to put the label on the container's top, and then stack containers so that the label is

obscured. Consequently, we invite comment on whether the final rule should define or explain what ''conspicuous'' means in terms of the label's placement on a shipping container and, if so, what that regulatory requirement would be.

The proposal also would require the label to be permanently affixed to the shipping container, in addition to being clear and conspicuous. Although section 801(n)(1) of the act does not state that the label must be ''permanent,'' we believe that proposing to require the label to be permanently affixed to the refused food is consistent with the underlying statutory intent. Congress's goal, in enacting section 801(n) of the act, was to identify refused foods and to preclude the reintroduction of refused foods into the United States. Without a requirement that the label be permanently affixed, then the statutory intent could be undermined easily because unscrupulous importers, owners, or consignees could simply use removable labels and remove them before attempting to bring the refused food back into the United States. We do not believe that Congress intended to create legal requirements that could be so easily defeated, and so the proposal would require the label to be permanent.

To illustrate what we mean by ''permanent,'' printing ''UNITED STATES: REFUSED ENTRY'' on the shipping container in indelible ink would constitute a ''permanent'' label. In contrast, printing the same words in pencil on the shipping container would not be ''permanent'' because an individual could erase the words. As another example, using adhesive labels that cannot be removed from the shipping container after being affixed would be ''permanently'' affixing the label. In contrast, using hang tags would not be ''permanent'' because the tags can be removed easily.

Based on our experience with the 2001 proposed rule, we anticipate that some individuals may argue that ''container'' should include cargo containers or vehicle components, such as railroad cars and trailers (which are often referred to as ''containers'') that are attached to trucks and that are used to transport large quantities of imported food. It would be both impractical and inappropriate to interpret or implement section 801(n)(1) of the act to require that the label be affixed to a railroad car, truck, ship, or other vehicle, vehicle component, or vehicle attachment rather than a food's shipping container. By specifying that the label be clear and conspicuous, Congress intended to make it difficult for a person to ''port shop'' or to conceal previously refused food. If the label were placed on a large, reusable cargo container (such as a tractor trailer or railroad car), one could easily defeat this statutory intent simply by transferring the refused food from the labeled cargo container to an unlabeled cargo container. For example, if the label is placed on a railroad car instead of the shipping containers holding the refused food inside the railroad car, the intent behind section 801(n)(1) of the act and this proposal could be defeated by shifting the refused food from the labeled railroad car to an unlabeled railroad car. In contrast, if the label is on the shipping containers (such as boxes or bags) holding the refused food, it would be more difficult or burdensome to unpackage and repackage the refused food. In addition, a cargo container generally is used to transport food to a specific location and, once it arrives at that location, the food is removed, and the cargo container is used to transport another product. Requiring labels on a cargo container also would inhibit typical business practices by requiring that the cargo container remain associated with the refused food until its exportation.

There may be situations where the imported food has no shipping container. In these situations, requiring that the label be affixed to the documents accompanying the refused food is an appropriate mechanism to ensure that the fact of refusal is communicated to us, CBP, and others. Proposed § 1.98(c) would require the label on all documents accompanying the refused food even when the shipping container is labeled. Examples of such documents include, but are not limited to, bills of lading, bills of sale, airway bills, packing lists, and invoices. This requirement would implement section 403(a)(1) of the act and provide additional protection against the re-importation of refused food because there are times when we, CBP, and others may see documents accompanying a shipment, but not examine the shipment itself. Section 308(c) of the Bioterrorism Act states that we retain authority to require the marking of refused food ''under any other provision of law.'' As we explain in section III of this document, section 403(a)(1) of the act, along with other provisions, gives us ample legal authority to require the label on documents accompanying the refused food.

In order for the label on the documents to be useful in notifying us, CBP, and any prospective purchasers of diverted food that the food has been refused admission into the United States, proposed § 1.98(c) also would require the label on the documents to be clear, conspicuous, and permanently affixed. Our concern is that unscrupulous importers may attempt to undermine a simple regulatory requirement that the label go on the documents by placing the labels on the back of documents or on one page of a multi-page document in an effort to conceal the label. As another example, if we stated that the label must go on the ''bill of sale,'' an individual might be tempted to place the bill of sale as page 37 in a 50-page set of documents to make the label more difficult to find or to refer to the bill of sale by ''sales receipt'' or other name and then argue that the label requirement is inapplicable because there is no ''bill of sale.'' Thus, we propose to require that the label be permanent and go on the top page of each document to ensure that the label on the document is clear and conspicuous. (By ''top page,'' we mean the page that is physically located at the top of any single or multi-page document. For example, if there are two documents accompanying the imported food, and one document consists of a single page and the other document consists of five pages, the label would go on the single-paged document and on the top page of the five-page document.) We also propose that the label be permanent because it would undermine the requirement that the label be affixed to the documents if importers could use labels that could be removed at any point before re-exportation or re-importation.

E. How Do You Show You Complied With the Label Requirements? (Proposed § 1.98(d))

Section 801(n)(1) of the act authorizes us to require owners and consignees to affix the label to a refused food. Consequently, the proposed rule would establish clear standards for when food must be labeled as ''UNITED STATES: REFUSED ENTRY.'' We note that neither of the misbranding provisions upon which we rely for the proposed labeling requirement hinges on whether the refused food is re-offered for import (compare section 403(a)(1) and (v) of the act with section 402(h) of the act (21 U.S.C. 342(h))). To ensure that we can track compliance with the label requirement efficiently, proposed § 1.98(d)(1) would establish several mechanisms for demonstrating that the label was properly affixed to the shipping containers and documents for the refused food. For example, the owner or consignee could contact the FDA district office responsible for the food's entry and:

• Arrange to affix the labels in our presence or under our supervision. This method would probably be used in situations where the refused food presents a public health hazard or where the owner or consignee has a history of violations of the act or the Public Health Service Act (PHS Act);

• Submit photographs or other visual evidence to us to show that it affixed the label to the shipping containers and documents. This method could, for example, be used in situations where the owner or consignee has a good record of compliance with the act and the PHS Act and the refused food does not present a public health hazard; or

• Develop another means to show that it affixed the labels to the shipping containers and documents to FDA's satisfaction. For example, we could agree to have commissioned State or Federal officials supervise the labeling process.

Proposed § 1.98(d)(1) is intended to ensure that the shipping container and documents for a refused food are identified and labeled correctly. The provision would give us the option to verify that the labels were affixed correctly to the shipping container and documents by supervision, by reviewing visual evidence, or by other means. This flexibility would reduce the potential burden on owners or consignees.

Proposed § 1.98(d)(2) would require that the labels be affixed promptly. We invite comment on how we might interpret ''promptly.'' Under section 801(a) of the act, the exportation of any refused article is require within 90 days of the date of notice of such refusal or within such additional time as may be permitted pursuant to CBP regulations. We invite comment on how to frame a regulatory requirement to ensure that the owner or consignee has a reasonable amount of time to affix the required labels and that FDA has sufficient advance time to make arrangements to verify that the labels are affixed properly in light of the 90-day deadline specified in section 801(a) of the act. Any regulatory standards established for compliance with the label requirements will establish an obligation under the CBP bond to label the merchandise.

Proposed § 1.98(d)(2) would also require that the food not be moved until the owner or consignee has complied with the labeling requirements. This requirement would mean that the labels must be affixed before the food leaves the port of entry or, if the food has already been moved from the port of entry to another location for storage, before the food leaves that storage area to be re-exported.

F. What Fees May We Impose Under the Rule? (Proposed § 1.98(e))

Section 801(n)(2) of the act expressly states that all expenses in connection with affixing a label under section 801(n)(1) of the act ''shall be paid by the owner or consignee of the food involved, and in default of such payment, shall constitute a lien against future importations made by such owner or consignee.'' Section 801(c) of the act also provides authority for imposing expenses on owners and consignees for labor with respect to any article refused under section 801(a) of the act. Consequently, proposed § 1.98(e) would allow us to seek reimbursement for our expenses when we impose the label on shipping containers or when we supervise an importer's affixing of labels on shipping containers and documents. These costs would normally consist of our inspector's time, the per diem allowance under government travel regulations, travel expenses (actual cost of travel for travel other than by automobile, or mileage, toll fees, etc. if travel was by automobile), and administrative support costs.

We currently operate a similar reimbursement program for costs associated with our supervision of reconditioning imported articles for possible admission into the United States (see 21 CFR 1.99); thus, the fees we would seek under proposed § 1.98(e) would be consistent with existing programs.

III. Legal Authority

Several sections of the act give us the legal authority to issue this rule. First, section 801(n) of the act states (among other things) that if a food, other than a food that is required to be destroyed, is refused admission under section 801(a) of the act, we may require the owner or consignee of the food to affix to the food's container a label that states, ''UNITED STATES: REFUSED ENTRY.'' Section 403(v) of the act provides that food is misbranded if: (1) It fails to bear a label required under section 801(n)(1) of the act (concerning the fact that the food has been refused admission); (2) the food presents a threat of serious adverse health consequences or death to humans or animals; and (3) upon or after notifying the owner or consignee involved that a label is required, the owner or consignee is informed that the food presents such a threat. In addition, section 801(a) of the act authorizes us to refuse to admit imported food into the United States if the imported food appears to have been manufactured, processed, or packed under insanitary conditions, is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or is adulterated or misbranded. Sections 402 and 403 of the act describe when a food is adulterated and misbranded, respectively.

Under section 403(a)(1) of the act, a food is misbranded if its labeling is false or misleading in any particular. Section 201(n) of the act states that, in determining whether labeling is misleading, we look not only at the affirmative representations made in or suggested by the labeling, but also ''the extent to which the labeling * * * fails to reveal facts material in light of such representations or material with respect to consequences which may result from the use or the article * * *.'' We tentatively conclude that the failure to reveal, in each document accompanying the shipment of food, that the food has been refused admission would misbrand the food because otherwise the labeling would imply that the food may be sold legally in the United States when, in fact, we have determined that the food may not.

Section 701(a) of the act (21 U.S.C. 371(a)) also authorizes promulgation of regulations for the efficient enforcement of the act, and section 701(b) of the act specifically authorizes promulgation of regulations for the efficient enforcement of section 801 of the act. Because labeling refused foods would permit us and CBP to efficiently enforce sections 403 and 801 of the act and is expressly authorized under section 801 of the act, we are authorized to impose labeling requirements on such food. The label would help ensure that foods that fail to meet the conditions for admission into the United States are not re-imported and do not enter or reenter domestic commerce. Sections 801(c) and (n)(2) of the act also provide the authority to impose the costs of supervising compliance with such labeling requirements on owners and consignees.

Finally, the proposed rule also is authorized by section 361 of the PHS Act (42 U.S.C. 264). Section 361 of the PHS Act authorizes us to issue regulations to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States. Labeling food that has been refused entry into the United States will help prevent the introduction, transmission, or spread of communicable diseases into the United States by making it more difficult for such rejected food to enter the United States through a different port or to escape detection.

What Are the Consequences of Failing to Affix the Labels?

Under section 403(v) of the act, a food is misbranded if: it fails to bear a label required under section 801(n)(1) of the act (concerning the fact that the food has been refused admission); the food presents a threat of serious adverse health consequences or death to humans or animals; and, upon or after notifying the owner or consignee involved that a label is required, the owner or consignee is informed that the food presents such a threat. As discussed previously, we intend to provide notification of the label requirement and, when appropriate, notice that the refused food presents a threat of serious adverse health consequences when we issue notices of refusal. If you receive notice to label the shipping container along with a notice that the refused food presents a threat of serious adverse health consequences and you fail to label the shipping container as required, the refused food is misbranded under section 403(v) of the act, and we may administratively detain the food under section 304(h) of the act and seize the food before it is exported or after it is re-imported under section 304(a) of the act.

Two situations are not covered by the misbranding provision in section 403(v) of the act: (1) Failure to label refused food that we have not found to present a threat of serious adverse health consequences; and (2) failure to label the documents. As set forth previously, we believe that the failure to label the shipping container or documents in accordance with proposed § 1.98 would misbrand the food under section 403(a)(1) of the act. Accordingly, if you fail to label the shipping container or documents, the refused food would be misbranded under section 403(a)(1) of the act and subject to seizure under section 304 of the act. Furthermore, the prohibited acts pertaining to misbranded food in section 301 of the act (21 U.S.C. 331) would also apply, and anyone who commits a prohibited act with respect to the food would be subject to an injunction under section 302 of the act or prosecution under section 303 of the act (21 U.S.C. 333).

In addition, if the food has been conditionally released under a customs bond, the failure to comply with any requirement of this proposed rule may be a violation of that bond (see 19 CFR 113.62(e)), and we could ask CBP to pursue liquidated damages from the importer of record under 19 CFR 113.62(l).

IV. Environmental Impact

The agency has determined under 21 CFR 25.30(a), 25.30(k), and 25.32(g) 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.

V. Paperwork Reduction Act of 1995

We tentatively conclude that the labeling requirements proposed in this document are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Rather, the statements are ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

Interested persons are requested to fax comments regarding information collection by October 20, 2008, to the Office of Information and Regulatory Affairs, OMB. To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974.

VI. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies 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. Accordingly, we have concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VII. Analysis of Impacts

A. Preliminary Regulatory Impact Analysis

We have examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). 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). We believe that this proposed rule is not a significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because we do not expect this cost for any one small owner or consignee to be excessive, we certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $130 million, using the most current (2007) Implicit Price Deflator for the Gross Domestic Product. We do not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

1. Need for Regulation

We are taking this action to assist in the enforcement of our admissibility decisions. Without a label requirement for food that has been refused admission, owners or consignees whose shipments are refused admission could simply move their shipment to another port and attempt entry again. Without labeling violative food products, the importer or consignee knows that a shipment has been refused, but personnel in the next port where the food is offered for import would not readily know that the shipment has been refused. Labeling violative food products will help reduce this problem. In addition, as discussed in section VII.A.4 of this document, this rule would help correct both of these behaviors by making the importation of violative food relatively more expensive.

2. Proposed Rule Coverage

The proposed rule would require owners and consignees whose food has been refused admission into the United States to label such food as ''UNITED STATES: REFUSED ENTRY.'' This

would make it easier for us and CBP to detect attempts to introduce previously refused imported food into the United States.

By making importation of previously refused food more difficult and expensive for importers, we expect that reconditioning or destruction of refused food will become more favored alternatives. We also expect that with this system in place, importers would be less likely to attempt to import violative food into the United States in the first place.

3. Regulatory Options Considered

As described earlier, the proposed rule would require owners and consignees whose food shipments have been refused admission into the United States to label such products as ''UNITED STATES: REFUSED ENTRY.'' This would make it easier for us and CBP to detect attempts to introduce previously refused imported food into the United States. In drafting this proposed rule, we considered several regulatory alternatives in addition to the proposed rule. We considered: (1) No additional regulatory action; (2) selective enforcement that would allow the decision to affix the label to be made at the level of individual refused food shipments; and (3) the destruction of all shipments of food refused admission into the United States. Because this proposed rule would not be an economically significant regulatory action, we do not quantitatively estimate the benefits and costs of the regulatory alternatives to the proposed rule. In what follows, we qualitatively compare the costs and benefits of the regulatory options to the costs and benefits of the proposed rule.

The first option would be no action. This alternative would not affect current practices, such as port shopping, and would result in the introduction of previously refused food imports into the United States. Consumers who ingested those unsafe food imports would, in turn, be subject to the risk of foodborne illnesses.

A second option would be a selective enforcement mechanism that would allow the decision to label to be made at the level of individual shipments. This alternative would require fewer resources for labeling shipments, but would require more resources for deciding which shipments should be labeled. The decision to label would be based on factors other than refusal. For example, refused food might be labeled because it poses a safety risk. The decision to label an individual refused food shipment could be complex. For example, whether a shipment contaminated with mold constitutes a safety risk depends upon the identification of the mold, its toxicological properties, and the probability of illness resulting from exposure to the mold. Deciding whether or not the same shipment is adulterated and violative is a simpler process. Selective enforcement could also lead to inconsistent standards between ports of entry, which would exacerbate the problem of importers choosing ports of entry based on the likelihood their cargo will be accepted. Finally, the incentive for port shopping would be higher under this alternative than in the proposed rule. This option would be close to the proposed rule in costs but would generate smaller benefits.

A third option would be to order the destruction of food imports refused for safety reasons. While this would deter ''port shopping'' and similar practices, this alternative would be costlier than the proposed rule for three reasons. First, it would require more Federal resources for supervision of destruction than the proposed rule. Second, the standard of proof to support the destruction of violative products is greater than the standard of proof for refusing to admit imported products. Because the standard of proof is higher for destruction than for marking, this would lead to more challenges to the FDA's policy and require resources from FDA both in establishing the basis for its action and defending challenges to such action. Third, the costs of this proposed rule in destroyed shipments would be high. For fiscal year 2006, data drawn from the Operation and Administrative System for Import Support (OASIS) database (Ref. 1) show that 10,340 shipments were initially refused at the intended U.S. port of entry for safety or security reasons. The threat of destruction should deter importers to attempt to import violative food. If we assume the number of violative imports will decrease by 75 percent and value the shipments conservatively at an average value of $500,000, the cost of this alternative in destroyed cargo alone would be about 1.3 billion dollars ((10,340 shipments) x (25 percent) x ($500,000)).

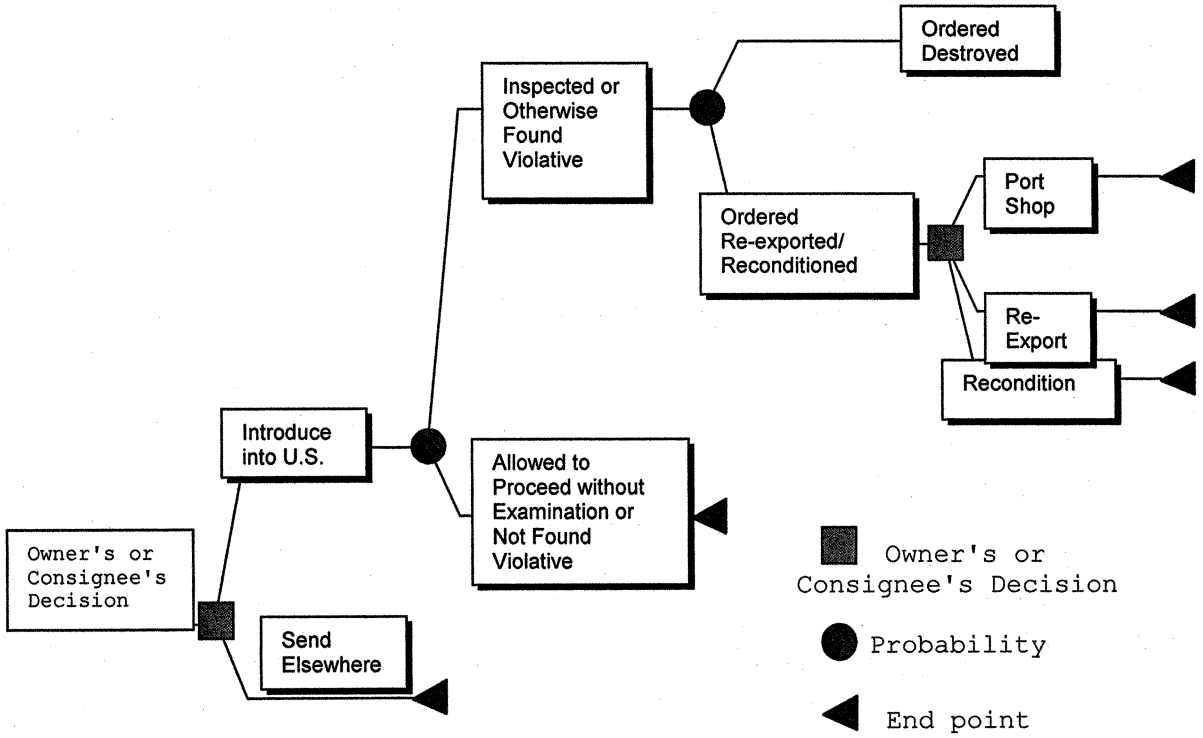
4. Strategic Action by Owners and Consignees

Although the vast majority of owners and consignees comply with the act, some attempt to circumvent Federal law and introduce violative food into United States commerce through means such as port shopping. For these owners and consignees, measures such as those contained in this proposed rule are necessary to deter port shopping.

An owner's or consignee's decision on how to dispose of its cargo is influenced by changes in the expected profits associated with each of its choices. Requiring owners and consignees to affix a ''UNITED STATES: REFUSED ENTRY'' label on imported food that has been refused admission would change the expected profits associated with the initial decision to attempt to import violative food. A label also would affect the expected profits associated with the decision to recondition, re-export, or port shop after a shipment is found violative.

The decision process of an owner or consignee of violative food can be represented visually by a decision tree (see Figure 1). This decision tree illustrates how requiring ''UNITED STATES: REFUSED ENTRY'' on refused imports would alter an owner's or consignee's incentives. The decision tree shows the possible outcomes and decisions an owner or consignee can make at each stage of the importation process. At point A, an owner or consignee of violative food first decides whether to attempt to import the food into the United States. This decision is influenced by the price the owner or consignee can get for the food if it is successfully imported, the probability the cargo will be inspected, and the cost to the owner or consignee if the food is inspected and found violative. At point B, whether the cargo is inspected is a function of factors such as the port of entry, FDA's inspection rate, and the type of product. At point C, FDA refuses admission of the food. If the food is not destroyed, at point D, the owner or consignee may have the option of exporting to a foreign country, reconditioning the food, or port shopping.

Figure 1: A Dynamic Representation of the Introduction of Food into Commerce in the United States



The proposed rule's effect on deterrence: Labeling refused imported foods as ''UNITED STATES: REFUSED ENTRY'' would alter the incentive structure that owners and consignees face when deciding whether to introduce their product into United States commerce. In particular, there are four ways that the proposed rule would increase the deterrence value of the FDA inspection system.

i. *Port shopping would be reduced.* One primary goal of this proposed rule would be to reduce port shopping. Requiring a label to be affixed to a refused imported food would reduce the probability that the refused imported food would be reoffered for import into the United States. The cost of port shopping would increase because resources would have to be expended to repackage a product that had been labeled. Thus, port shopping would become relatively less attractive to owners and consignees.

ii. *Decrease in the value of re-exported items.* The value of a product destined for re-export would decrease if it were labeled ''UNITED STATES: REFUSED ENTRY.'' After the product had been labeled, the owner or consignee has two costly choices: (1) After the product leaves the United States, relabel containers or repackage the product into containers that do not bear the label; or (2) sell the goods abroad with the label intact. It is likely that food with such a label would be viewed less than favorably by food safety inspectors and importers in international markets. Thus, the expected profit from selling goods that are labeled would be lower than if the label was not present, so this loss is in addition to the loss of value from refusal alone. Either of the owner's or consignee's choices (repackage or sell with the label intact) would lower the expected profit of re-exporting.

iii. *Reconditioning would become a more favored alternative.* The expected profit from reconditioning a refused food import would not likely change with this proposed rule. Consequently, because the expected profits from port shopping and re-exporting refused imported food would be expected to fall, reconditioning the food would become economically more attractive. We expect that more owners and consignees would choose to recondition their product.

iv. *Decrease in the introduction of violative food into the United States.* As with reconditioning, the expected profit from initially sending a violative and potentially unsafe or mislabeled product to a foreign port would not be expected to change significantly with this proposed rule. Therefore, as the expected profit from attempting to import violative food into the United States is lowered (because the cost of re-importing and re-exporting violative food is increased), the incentive to ship one's product directly to a foreign (non-United States) market would increase. The net result of such a dynamic would be that more violative food products would be either directly shipped to foreign markets or reconditioned at the point of export.

5. Benefits from the Proposed Rule

a. *Health benefits.* As described earlier, the proposed rule, if finalized, would decrease the number of refused imported food products reaching the United States consumer. The proposed rule would discourage attempts to offer or reoffer violative imported food into the United States and encourage the reconditioning of imported food which we have refused to admit. Consequently, United States consumers would benefit through a reduction in the number of foodborne illnesses due to unsafe or mislabeled imported foods. Because we cannot quantify the amount of re-importation of refused imported foods, we cannot make a definitive prediction of the value of the reduced illnesses

arising from this proposed rule. Although foods that represent a direct and serious danger to public health may be destroyed, refused food eligible for re-exportation may also present a health hazard. Typical reasons for refusing entry include illegal food or color additives, contamination by a pesticide residue or poisonous substance, foreign objects, poor sanitation in the manufacture of the food, improper labeling, and unregistered manufacturers. Each of these reasons for refusal may represent a health risk. Long term exposure to some illegal color additives has been linked to cancer. Sanitation problems indicate the food was held in unsanitary conditions, which may suggest more serious problems such as contamination with microbial pathogens. A single exposure to a violative pesticide level is very unlikely to result in cancer, but prolonged exposure over years may lead to increased risk of illness, including cancer. Improperly labeled food, among other things, may contain allergens without duly alerting the consumer. Sensitive individuals may experience allergic reactions ranging from mild contact dermatitis to a severe allergy attack.

Table 2 shows some possible illnesses and injuries that may result from violative foods and includes their symptoms and an average cost per case. The quality-adjusted life days (QALDs) (Ref. 2) column represents the lost utility per day to a consumer from an illness, essentially the loss to the consumer due to symptoms and problems associated with the illness. The QALDs are valued in dollars by multiplying the number of lost days by the value of a statistical life day, $622. This value of a statistical life day is drawn from the economic literature (Ref. 3). The medical cost column is the direct medical cost of illness, which includes hospitalization and doctor visits. Most illnesses arising from *E. coli* O157:H7 or *Salmonella* are self-limiting and short in duration, but some illnesses due to *Salmonella* or *E. coli* O157:H7 can be quite serious. *E. coli* in some cases can result in kidney damage or death. *Salmonella* can trigger chronic arthritis and, in a very small percentage of cases, can result in death.

TABLE 2.—COST OF SOME ILLNESSES POTENTIALLY AVERTED BY THE PROPOSED RULE

	Potential harm	Symptoms	QALD loss	Dollar value of lost QALDs	Medical Costs	Total cost
Allergens	Contact dermatitis	Reddening, swelling, itching of skin	2.1	$1,726	$125	$1,851
	Allergic reaction	Difficulty breathing, asthma, rash, possible shock	1.03	$847	$550	$1,397
Objects in food	Simple dental injury	Toothache, headache	0.23	$189	$0	$189
	Complex dental injury	Simple, plus infection	3.47	$2,852	$3,540	$6,392
	Oral emergency	Sharp pain in mouth, face, neck, bleeding, plus possible metastatic or local infection	4.27	$3,510	$3,540	$7,050
	Tracheo-esophageal obstruction	Choking, difficulty breathing, cyanosis, hypertension	0.48	$395	$0	$395
	Esophageal perforation	Pain in chest, bleeding aspiration pneumonia, requires surgery	13.93	$11,450	$14,160	$25,610
Canning processes	Botulism	Nausea, diplopia, blurred vision, lack of coordination, Can include loss of muscle strength, paralysis, death	667.94	$549,047	$29,526	$578,573
Filth	Salmonella	Vomiting, nausea, possible arthritis, low probability of death	72.04	$17,558	$321	$17,880
Filth	*E. coli*	Vomiting, nausea, bloody stools, possible kidney damage, low probability of death	19.56	$7,750	$485	$8,235

Sources: We calculated *E. coli* and *Salmonella* costs by assuming a QALD value of $822 and a value of a statistical life of $5 million. Objects in food, allergens and botulism costs were taken from RTI, Estimating the Value of Consumers' Loss from Foods Violating the Federal Food, Drug, and Cosmetic Act (Ref. 4).

b. *Other consumer benefits*. While problems such as insects or filth in food may not always represent a direct health threat, they call into question the conditions to which the food was exposed. Moreover, consumers who purchase food expect it to be clean and sanitary. Consumer research shows cleanliness is important to consumers. For example, the Food Marketing Institute found 89 percent of consumers surveyed ranked a clean, neat store as a very important factor in selecting their primary supermarket (Ref. 5). If consumers pay a premium because they believe that their food is sanitary and the food is not, this payment represents a social loss. However, we cannot quantify this economic loss because we do not know what percentage of the price of food is a ''cleanliness premium.''

6. Costs of the proposed rule

Costs would include both materials and time and would be incurred by both FDA and owners or consignees. The owners and consignees would bear the responsibility for affixing the labels; we would verify that the label is affixed. It is not clear which method owners and consignees would use to label refused food imports. Therefore, we have, for purposes of this analysis, used an

inexpensive and quick method of labeling to estimate costs.

a. *Materials*. Placing labels on all the packages would require the use of a label gun and printed labels. Label guns cost approximately $100, and three label guns would be needed at each of the 132 ports. Labels reading ''UNITED STATES: REFUSED ENTRY'' would also have to be printed at an approximate cost of $0.025 per label. We invite comment on the estimation that three label guns per port will be sufficient to accomplish the labeling necessary to comply with the rule.

b. *Time*. i. *Owner's or Consignee's Time*. The number of hours spent applying labels would be a function of the number of rejected shipments and their size. We assume that the average shipment consists of 500 cartons and would take approximately 3 hours to label. FDA requests comment on this assumption. We also assume that the owner or consignee would hire labor at the average wage rate for transportation and moving occupations published by the Bureau of Labor Statistics, $13.58, plus 30 percent in benefits (Ref. 6). Under these assumptions, it would cost approximately $53 in labor (3 hours x $17.65 per hour) to label each shipment. As a baseline, we estimate that 10,340 shipments would be refused annually. However, data drawn from the OASIS database (Ref. 1) show that in 2006, 6,318 of the refused shipments were destroyed and 438 were released, 176 due to successful reconditioning and 262 for another reason.[1] Most refused shipments would not have to be labeled. However, if the food is reconditioned at a different site, then the proposed rule would require that food to be labeled. In the absence of information, we assume that 50 percent of the reconditioned shipments would be subject to the proposed rule's label requirement. We invite comment on this assumption.

As shown in table 3 of this document, we estimate that roughly 3,672 shipments would need to be labeled initially. This number is used to calculate the ''static'' annual cost shown in table 4 of this document. The annual cost of labeling these shipments would be nearly $195 thousand in labor costs and nearly $46 thousand for labels. It would cost the government more than $55 thousand to confirm the labels had been affixed. The sum of these costs is about $296 thousand. The static annual cost should be viewed as the likely cost in the first few years after the proposed rule becomes final and as a high estimate for costs in later years. We invite comment on the data used in these calculations, including the percentage of reconditioned shipments subject to the label requirement and the labor cost to owners and consignees.

As discussed in part VII.A.4 of this document, because the relative price of refusal would increase due to this proposed regulation, we expect more owners and consignees would decide to recondition after refusal, or will not attempt to import potentially violative food. The ''dynamic'' annual cost is the ''static'' annual cost reduced by the expected percentage decrease (expected avoidance) in initial importation attempts and the increased number of successful reconditioning attempts. We do not have the data to predict the precise reaction of importers to this proposed rule. However, if we assume that owners and consignees would decrease attempts to import violative food by between 25 and 75 percent and that they would increase their attempts to recondition refusals by between 25 and 75 percent, we estimate that the number of shipments to require marking would drop to between 902 and 2,738 (1,814 for a mean change in imports and recondition attempts of 50 percent) annually.[2] This ''if-then'' scenario yields a mean ''dynamic'' annual cost of $146 thousand. We invite comment on our estimates of a 25 to 75 percent decrease in violative imports and of a 25 to 75 percent increase in reconditioning attempts. Added to these costs is a fraction of the cost of the label guns (shown in table 5 of this document). Because label guns are durable goods, the value of a label gun should not be added to the cost of marking each shipment.

TABLE 3.—ANNUAL NUMBER OF REFUSED SHIPMENTS TO BE LABELED

Refusals in 2006	10,340
Shipments Released After Refusal	
Total Recondition Attempts	185
Reconditioned Unsuccessfully	9
Reconditioned and Released	176
Released After Initial Refusal for Other Reason	262
Total Released	438
Shipments Destroyed After Refusal	6,318
Static Total Number of Refusals to be Labeled[1]	3,672
Expected Increase in Reconditioning Attempts and Avoidance	50.0%
Mean Dynamic Total of Refusals to be Labeled[2]	1,814

[1] This number is calculated by subtracting the number of shipments destroyed, the number of shipments released for ''other reason'', and half of the shipments that were reconditioned and released from the total refusals in 2006.

[2] This number is calculated by decreasing the number of refusal by 50 percent and increasing the percentage of total reconditioning attempts by 50 percent.

ii. *FDA inspector's time*. The proposed rule would require us to confirm that the owner or consignee affixes the label to the refused food import or otherwise complies with the label requirement.[3] We estimate that this process would require approximately 30 minutes per shipment. We estimate the value of an FDA inspector's time based on a GS–10, step 5 rate, plus 30 percent in benefits. At this hourly rate, FDA's labor costs for each shipment would be $15 (0.5 hours x $30 per hour). We request comment on these estimates.

TABLE 4.—MEAN ANNUAL LABELING COST ESTIMATES

	Static	Dynamic
Number of Refusals to be Labeled	3,672	1,814
FDA Labor Cost per Refusal	$15	$15
Total FDA Cost	$55,080	$27,210

[1] There are many reasons a shipment may be initially refused and subsequently released. For example, a violative shipment may be reconditioned successfully, samples of food suspected to be in violation may test negative, or paperwork, originally insufficient, might be corrected.

[2] Given a 1 percent inspection rate, an importer has a 99 percent chance of getting violative shipment into the United States. One out of every 100 shipments gets caught. Without this rule, the odds of getting into the next port, given a refusal, are roughly the same as the first port. So if an importer plans to port shop a violative shipment at least once, they have a 99.9999 percent chance to successfully get the shipment into the United States. Therefore this proposed rule increases the risk of getting caught when shipping a violative shipment by a factor of 100 for those that plan on port shopping. FDA believes this would yield a heavy enough disincentive to warrant the use of 25 to 75 percent in an ''if-then'' scenario.

[3] There are several ways of verifying that the label has been affixed. For the purpose of this analysis, our estimates are based on a scenario where FDA inspectors supervise the labeling of refused food.

TABLE 4.—MEAN ANNUAL LABELING COST ESTIMATES—Continued

	Static	Dynamic
Owner/Consignee Labor Cost per Refusal	$53	$53
Total Owner/Consignee Labor Cost	$194,616	$96,142
Label Cost per Refusal	$12.50	$12.50
Total Label Cost	$45,900	$22,675
Total Owner/Consignee Cost	$240,516	$118,817
Total Annual Cost	$295,609	$146,040

TABLE 5.—FIXED LABELING COSTS

Number of Ports	132
Label Guns Needed per Port of Entry	3
Cost per Label Gun	$100
Total Label Gun Costs	$39,600

c. *Increased cost of shipments*. Foods labeled as ''UNITED STATES: REFUSED ENTRY'' would lose value due to diminished value in foreign ports, in addition to the loss of the United States market for the product. The owner or consignee would suffer an initial loss of value due to rejection of its cargo, regardless of the label. How the label decreases the value of the food would be a function of the initial value of the food, type of food, reason for refusal, and the reluctance of the new buyer to purchase previously refused merchandise. This cost represents a transfer from the owner or consignee to the ultimate purchaser of the product. However, there would be an additional cost of this proposed rule that is borne directly by the owner or consignee, but may be passed on to consumers in the form of higher food prices. This cost is difficult to quantify but it includes the increased cost of importing goods because of the increased likelihood of refusal. It also includes the costs of any additional preventive measures taken at the point of origin for the shipment.

7. Summary of Benefits and Costs

The uncertain nature of the number of illnesses prevented and the difficulty in quantifying the benefits to consumers of having clean foods, regardless of the danger, prevents a definitive statement about benefits and costs. We expect the static costs to be about $300,000; this sets a threshold value for the benefits. For two reasons, the annual benefits would probably be greater than these estimated annual costs. First, the costs are likely to decrease over time, perhaps to as low as $70 thousand, as owners and consignees decrease shipments of violative food and increase efforts to recondition refusals. Second, stopping just one violative shipment from entering the United States after refusal could cover the costs. For example, in 2006, nearly 800 food shipments were refused because the food contained *salmonella* (Ref. 1). For the period between 1996 and 2006, we calculate that *salmonella* outbreaks caused from 2 to 688 confirmed illnesses (with an average of 46 confirmed illnesses) per outbreak (Ref. 7). Therefore, if stopping just one of the 800 shipments refused for containing *salmonella* from entering the United States would avert an outbreak, the result would be a savings of over $822,000 ($17,880 per illness x 46 illnesses) in direct medical and health costs. This is simply an example, using a single reason for refusal, that illustrates how high the benefits from this proposed rule are likely to be. If multiple outbreaks are averted in a given year, or even a single outbreak involving fatalities, the benefits could easily reach the hundreds of millions.

B. Preliminary Regulatory Flexibility Analysis

As discussed in detail in section VII.A of this document, we find that this proposed rule would affect up to 1,184 owners or consignees annually.[4] Most of these owners or consignees are small businesses as defined by the Small Business Administration. For the purpose of this analysis, we assume that all 1,184 affected businesses are small.[5] These small owners or consignees would face a cost of approximately $65 per labeled violative food shipment in time and materials as calculated in section VII.A of this document. In addition, the value of their violative food shipment would fall. This cost is difficult to quantify, but can be bounded by the cost of repackaging the merchandise. FDA seeks comment on the estimates used to calculate the cost per labeled shipment. We do not expect this cost for any one small owner or consignee to be excessive, so we conclude that this proposed rule would not place a disproportionate burden on small businesses.

Regulatory Alternative Considered for Small Businesses

Exempting small businesses from the proposed rule would lift the burden on some small entities. However, because most entities affected by the proposed rule are small, such an exemption would effectively negate the proposed rule. We also note that the proposed rule would not prescribe any particular method for affixing the label, and owners and consignees whose shipments are refused admission may decide to re-condition, destroy, or re-export a violative food import. Given these flexible alternatives available to small entities and the small compliance cost of the proposed rule, we did not consider additional options.

C. Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 (Public Law 104–4), requiring cost-benefit and other analyses, in section 1531(a) defines a significant rule as ''a Federal mandate that may result in the expenditure by State, local, and tribal governments in the aggregate, or by the private sector, of $100,000,000 (adjusted annually for inflation) in any 1 year.'' We have determined that this proposed rule does not constitute a significant rule under the Unfunded Mandates Reform Act.

VIII. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

IX. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons

[4] Using total shipments labeled as a proxy for the number of importers affected is an overestimate in the sense that some owners or consignees may accrue multiple violations.

[5] Unless the businesses are repeat offenders, the same business will not be affected each year. The rule does not affect all owners and consignees of shipments, but only those shipments that have been refused admission.

between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. U.S. Food and Drug Administration, Operational and Administrative System for Import Support (OASIS), Available at: *http://www.accessdata.fda.gov/scripts/ora/pcb/tutorial/les2_oasis.htm*.

2. Kaplan, R.M., J.P. Anderson, and T.G. Ganiats, ''The Quality of Well-being Scale: Rationale for a Single Quality of Life Index,'' in Walker, S.R. and Rosser, R.M., eds. *Quality of Life Assessment: Key Issues in the 1990s*, The Netherlands: Kluwer Academic Publishers, 1993.

3. Viscusi, W.K., ''The Value of Risks to Life and Health.'' *Journal of Economic Literature*, vol. 31, pp. 1912–1946, December 1993.

4. Mauskopf, J.A., Mt French, A.S. Ross, D.M. Maguire, R.W. Leukrith, Jr., and K.D. Fisher, ''Estimating the Value of Consumers' Loss from Foods Violating the Federal Food, Drug, and Cosmetic Act,'' Research Triangle Report to the Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, September 1988.

5. Food Marketing Institute, 1999, Consumer Attitudes and the Supermarket. Research International USA.

6. Bureau of Labor Statistics, 2004 National Occupational and Wage Estimates, *http://www.bls.gov/oes/*, March 2006.

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner, we propose to amend part 1 as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

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

Authority: 15 U.S.C. 1453, 1454, 1455; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

2. Section 1.98 is added to subpart E to read as follows:

§ 1.98 Label requirement on food imports refused admission into the United States.

(a) *Who is subject to this label requirement and what does the label say?*—You are subject to this rule if you are an owner or consignee of an imported food, including food for animals, which has been refused admission into the United States (other than a food that must be destroyed). In such situations, you must affix a label stating, ''UNITED STATES: REFUSED ENTRY'', as described in paragraphs (b), (c), and (d) of this section.

(b) *What does the label look like*?—(1) *Labels for shipping containers*—For labels that are to be affixed to shipping containers (as required by paragraph (c) of this section), the letters in the label must be at least 72 points in size, appear in either an Arial or Univers font, and use black ink against a white background. The label must use uppercase letters only.

(2) *Labels for documents*—For labels to be affixed to documents (i.e., invoices, packing lists, bills of lading, and any other documents accompanying the refused food, as required by paragraph (c) of this section), the letters in the label must be in black ink, must use either an Arial or Univers font style, and must be at least 36 points in size. The label must use uppercase letters only.

(c) *Where does the label go?*—For foods that are packaged, the label described in paragraph (b)(1) of this section must be clear, conspicuous, and permanently affixed to the food's shipping container. For purposes of this section, the term ''shipping container'' is any container used to pack one or more immediate containers of the refused food, and an immediate container is any container that holds an imported food for retail sale. In some situations, the food's immediate container may be the same as the shipping container. The term ''shipping container'' excludes trailers, railroad cars, ships, and similar vehicles, vehicle components, and transportation-related items. For all foods, regardless of whether they are packaged in shipping containers, the label described in paragraph (b)(2) of this section must be clear, conspicuous, and permanently affixed to the top page of each document accompanying the refused food.

(d) *How do you show that you complied with the label requirements*?—(1) To comply with the label requirement described in paragraphs (a) and (b) of this section, you must contact the FDA district office responsible for the food's entry and arrange to:

(i) Affix the label(s) in our presence or under our supervision;

(ii) Submit photographs or other visual evidence to us to show that you affixed the label(s); or

(iii) Develop another means of showing, to FDA's satisfaction, that you affixed the label(s).

(2) You must affix the label(s) promptly, and you must not move the food until you have complied with the label requirements.

(e) *What fees may we impose*?—We may seek reimbursement from the owner or consignee for expenses connected to the affixing of a label under this section. These expenses will be computed on the basis of our inspector's time, the per diem allowance under government regulations, travel costs, and administrative support costs. We will submit a list of expenses incurred to the owner or consignee.

Dated: September 12, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–21813 Filed 9–17–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. OSHA–2008–0012]

RIN 1218–AC40

Tree Care Operations

AGENCY: Occupational Safety and Health Administration (OSHA), Department of Labor.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: OSHA is requesting data, information, and comment on tree care operations, including hazards, fatalities, and control measures, that the Agency can use in developing a proposed standard to control hazards and reduce injuries in those operations.

DATES: Comments must be submitted (postmarked, sent, or received) by December 17, 2008.

ADDRESSES: You may submit comments, identified by Docket No. OSHA–2008–0012, by any of the following methods:

Electronically: You may submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Fax: If your comments, including attachments, do not exceed 10 pages, you may fax them to the OSHA Docket Office at 202–693–1648.

Mail, hand delivery, express mail, messenger or courier service: You must submit three copies of your comments and attachments to the OSHA Docket Office, Docket No. OSHA–2008–0012, Room N–2625, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone 202–693–2350 (TTY number 877–889–5627).

Deliveries (hand, express mail, messenger or courier service) are accepted during the Department of Labor's and Docket Office's normal business hours, 8:15 a.m.–4:45 p.m., *e.t.*

Instructions: All submissions must include the Agency name and the OSHA docket number (Docket No. OSHA–2008–0012). Because of security-related procedures, submissions by regular mail may result in significant delay in their receipt. Please contact the OSHA Docket Office at the above address for information about security procedures for submitting comments by hand delivery, express delivery, and messenger or courier service.

All comments, including any personal information you provide, are placed in the public docket without change and may be made available online at *http://www.regulations.gov*. Therefore, OSHA cautions you about submitting certain personal information, such as social security numbers and birthdates. For further information on submitting comments, see the ''Public Participation'' heading in the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: To read or download comments submitted in response to this **Federal Register** notice or other materials in the docket, go to Docket No. OSHA–2008–0012 at *http://www.regulations.gov* or the OSHA Docket Office at the address above. All documents in the docket are listed in the *http://www.regulations.gov* index, however, some information (for example, copyrighted material) is not publicly available to read or download through the Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office.

Electronic copies of this **Federal Register** notice are available at *http://www.regulations.gov*. This notice, as well as news releases and other relevant information, also are available at OSHA's Web site at *http://www.osha.gov*.

FOR FURTHER INFORMATION CONTACT:

Press Inquiries: Jennifer Ashley, OSHA Office of Communications, Room N–3647, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: 202–693–1999.

General and Technical Information: David Wallis, OSHA Directorate of Standards and Guidance, Office of Engineering Safety, Room N–3609, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone 202–693–2277.

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I. Background

A. Hazards and Accidents

Tree care operations, such as tree trimming and tree removal, can expose employees to a number of serious hazards. The dangers include falling from trees; being hit by falling trees or branches, flying objects or vehicular traffic; being cut by high-speed saws; being pulled into chippers; and coming into contact with energized power lines. These dangers are often associated with tree trimming and removal operations and related tasks; therefore, these operations are some of the key areas on which OSHA is focusing this Advance Notice of Proposed Rulemaking.

The hazards present in tree care operations have resulted in a significant number of serious accidents. For example, looking at fatal accidents in the tree services and ornamental shrubs industry sector (SIC 0783), just one of the industry sectors that perform tree care operations, the Bureau of Labor Statistics (BLS) reported that between 1992 and 2002 [1] there were 637 fatalities.[2] That averages to 58 fatalities per year. The vast majority (75.6 percent) of those fatalities were falls, being struck by falling objects, and electrocutions, which are types of accidents most closely associated with tree trimming and removal operations. Falls and being struck by falling objects accounted for about one-third (32 percent) and one-quarter (26 percent) of the deaths, respectively. Contact with electric current resulted in 17.6 percent of the fatalities and transportation incidents also were significant causes of fatalities during that period.

According to BLS data, the annual number of fatalities in SIC 0783 increased between 1992 and 2002. In 2002, for instance, there were 70 fatalities, almost double the 36 reported in 1992. Moreover, during the last 3 years of the period, there were 70 or more fatalities each year. From 1992 to 2002, there was a significant increase in the number of fatalities in SIC 0783 resulting from being struck by falling objects and transportation incidents, including being struck by mobile equipment. Those types of fatalities increased more than three-fold and five-fold, respectively. Also, during that period the number of fatalities in SIC 0783 among Hispanic employees more than quadrupled, increasing from 4 deaths in 1992 to 17 deaths in 2002. In 1992, 11 percent of the fatalities in SIC 0783 were Hispanic employees. By 2002, however, Hispanic employees accounted for 24 percent of all fatalities, which was significantly higher than the percentage of fatalities for Hispanic employees in private industry as a whole (15 percent).

Data from OSHA's Integrated Management Information System (IMIS) for SIC 0783 show similar results. From 1994–2007, fatalities resulting from falls (from trees or bucket trucks) and being struck by falling objects accounted for 28 and 29 percent of the fatal injuries, respectively. Contact with electric current and transportation accidents accounted for 20 and 9 percent of the fatalities, respectively.

Looking at fatalities associated with chipper operations, a hazardous task related to tree trimming and tree removal operations, seven percent of employee deaths reported in the BLS data resulted when an employee was pulled into a chipper or struck by the chipper hood or other part of the chipper. Similarly, 20 fatalities reported in the IMIS data during the past 10 years (1998–2007) occurred in chipper operations. Seventy percent of those deaths resulted when employees were caught and pulled into the chipper.

Injury data for SIC 0783 also indicate the hazardous nature of tree care operations. For example, in 2002 BLS reported an average annual injury rate of 7.6 cases per 100 fulltime workers in SIC 0783, which was above the annual

[1] The most recent year for which data are available for SIC 0783 is 2002. The North American Industrial Classification System has replaced the Standard Industrial Code system. Under the NAICS system, SIC 0783 is now classified as a part of the landscape services sector (NAICS 561730).

[2] Source: Census of Fatal Occupational Injuries, Bureau of Labor Statistics (BLS) (*http://stats.bls.gov/iif/oshcfoi1.htm*). Data are derived from State death certificates and other sources and may include deaths of sole proprietors.

rate of 5.3 in private industry as a whole.[3]

B. Applicable Standards

OSHA's logging operations standard (29 CFR 1910.266) covers limited types of tree removal operations, which are sometimes performed by firms primarily engaged in tree care services. In addition, there are a number of other OSHA general industry standards that apply to certain tree care operations, including:

- 29 CFR 1910.25—Portable wood ladders;
- 29 CFR 1910.26—Portable metal ladders;
- 29 CFR 1910.67—Vehicle-mounted elevating and rotating work platforms;
- 29 CFR Part 1910.95—Occupational noise exposure;
- 29 CFR 1910.106—Flammable and combustible liquids;
- 29 CFR Part 1910 subpart I—Personal protective equipment;
- 29 CFR 1910.147—Control of hazardous energy (lockout/tagout);
- 29 CFR 1910.151—Medical services and first aid;
- 29 CFR 1910.180—Crawler, locomotive, and truck cranes;
- 29 CFR 1910.184—Slings;
- 29 CFR 1910.212—General requirements for all machines [machine guarding];
- 29 CFR 1910.242—Hand and portable powered tools and equipment;
- 29 CFR 1910.268—Telecommunications;
- 29 CFR 1910.269—Electric power generation, transmission, and distribution;
- 29 CFR 1910.331 to 1910.335—Electrical safety-related work practices; and
- 29 CFR 1910.1200—Hazard communication.

C. Events Leading to This Action

On May 10, 2006, the Tree Care Industry Association (TCIA) petitioned OSHA to promulgate a standard specific to tree care operations. In its petition, TCIA said a standard is needed because ''tree care work is by its very nature one of the most hazardous occupations'' and because existing OSHA standards do not adequately address those hazards. TCIA urged that OSHA develop a standard based on ANSI Z133.1—2006.

American National Standard for Arboricultural Operations—Safety Requirements

After analyzing the BLS and IMIS fatality and injury data, OSHA has decided to pursue rulemaking to address hazards in tree care operations. As the first step in the rulemaking process, OSHA is publishing this ANPR to gather data, information, and comment on hazards in tree care operations and effective measures to control hazards and prevent injuries and fatalities. In addition, OSHA is requesting comment on provisions a standard should include to effectively address those hazards. OSHA also will carefully consider the ANSI Z133.1 standard, as well as State occupational safety and health standards addressing tree care operations, in developing a standard.

II. Request for Data, Information, and Comments

OSHA is seeking data, information, and comment on hazards present in tree care operations and the measures to control those hazards and reduce the high accident, injury, and fatality rate, particularly in the operations of tree trimming and removal.

OSHA is interested in gathering a broad range of data, information, and comments related to a standard addressing tree care operations. OSHA invites comment on the questions in this notice, which include current employer and industry practices as well as the tasks, tools, equipment, machines, vehicles, processes, controls, and procedures involved in tree care operations. OSHA requests that you explain and provide data and information, including any studies or articles that support your comments.

Because OSHA intends to address tree care operations in whatever industry they may occur, OSHA is particularly interested in obtaining information about all kinds of businesses that may engage in tree care operations. Preliminarily, OSHA has identified tree care operations as primarily taking place among: (1) Firms primarily engaged in tree care services (many of which belong to the Tree Care Industry Association and were formerly classified in SIC 0783); (2) utilities (electric power and telecommunications) that do their own tree trimming rather than contracting it out to others; and (3) municipalities and other local governments that provide tree care services to their constituents and on local government owned or operated properties such as parks and recreational areas. In addition, tree care operations may also take place in any firm with significant property management responsibilities, such as large property management firms or zoos, museums, and historic sites. OSHA tentatively plans to profile the industry, in large part, by identifying establishments that employ tree trimmers and pruners (Standard Occupational Code 37–013). In 2006, there were 41,000 tree trimmers and pruners. OSHA invites comment on this approach. OSHA also requests information on who currently engages in tree care operations and how and to what extent this standard might affect them.

OSHA also invites comment on regulatory alternatives to reduce injuries and fatalities in tree care operations. In addition, OSHA invites comment on what requirements a standard addressing hazards in tree care operations should include and the potential costs and benefits of such a standard.

A. Tree Care Industry

1. Who performs tree care operation in the US? What industries are they in? How many entities, by industry, perform tree care operations in the United States? Which industries, other than the landscaping services industry, perform tree care operations that may be affected by a tree care operations standard? Are there tree care operations that do not employ employees classified as tree trimmers and pruners?

2. Please describe the job tasks involved in tree care operations and the hazards present in those tasks.

3. What types of tree care operations does your company (or a company representative of your industry) perform? What types of tree care operations comprise the largest part of your company's business? For example, how much of your business involves tree trimming operations and how much involves tree removal operations?

4. How many tree care companies in the United States primarily perform tree trimming and removal operations?

5. How many employees does your company (or a company representative of your industry) employ to perform tree care operations? Of those, how many are permanent employees and how many are temporary employees? What types of tree care operations do those employees perform?

6. To what extent does your company (or a company representative of your industry) rely on or use day laborers in tree trimming and removal operations? What tasks do they typically perform?

B. Accidents, Injuries, and Fatalities

1. How many and what types of accidents, injuries, and fatalities have been reported at your company or in the tree care industry during the past 5 years?

2. In what operations did those accidents, injuries, or fatalities occur,

[3] Source: BLS (*http://stats.bls.gov/iif/oshcfoi1.htm*).

and what operations had the highest number of accidents, injuries, or fatalities?

3. What were the causes (for example, fall, struck by a vehicle or falling tree or limb, cut by chain saw or chipper, and electric shock) of the accidents, injuries, and fatalities? Please explain in detail.

4. What was the average number of days away from work for those injuries?

5. What was the average age and length of employment of the employees injured or killed during tree care operations?

C. Tree Trimming

1. What types of tasks are involved in tree trimming operations and what hazards are present in those tasks?

2. In what setting does your company (or a representative company in your industry) usually perform tree trimming operations (for example, residential property, commercial property, public land, right-of-way, and near telecommunication or electric power lines)?

3. What vehicles, mobile equipment, portable powered hand tools, and other tools and equipment do employees use to perform tree trimming operations?

4. To what extent are tree trimming operations at your company or industry performed from aerial lifts, from ladders, in trees, or on the ground?

5. To what extent do employees at your company or industry get into the tree to perform tree trimming? How do they get into the tree and what equipment do they use to get up there?

6. How do you dispose of the branches and limbs? How are they moved to the street or other disposal area?

7. What controls and work safety practices has your company or industry implemented to protect employees performing or working near tree trimming operations?

8. What fall protection or other personal protective equipment (PPE) does your company provide to protect employees performing or working near tree trimming operations, including performing tree trimming operations from aerial lifts? Which employees receive PPE, what PPE do you pay for, and what does it cost?

9. What provisions and requirements should a standard include to protect employees from hazards in tree trimming operations?

D. Tree Removal

1. What types of tasks are involved in performing tree removal operations and what hazards are present in those tasks?

2. In what setting does your company (or a representative company in your industry) usually perform tree removal operations (for example, residential property, commercial property, public lands, and near telecommunication or electric power lines)? How many trees does your company (or a representative company in your industry) typically remove on a single job or worksite?

3. How does your company or industry remove or cut down trees, particularly where space or clearance is an issue? Please explain in detail.

4. To what extent and in what circumstances does your company or industry remove trees solely using the piece-out method? To what extent and in what circumstances does your company or industry remove trees by cutting them down all at once at the stump?

5. What vehicles, mobile equipment, portable powered hand tools, and other tools and equipment do employees use to perform tree removal operations?

6. To what extent and in what circumstances does your company or industry use cranes to remove trees or tree segments?

7. How does your company dispose of tree trunks and trunk segments? How are they moved to the street or other disposal area?

8. What controls and workplace safety practices has your company or industry implemented to protect employees who perform or work near tree removal operations?

9. What types of fall protection and other PPE does your company provide to protect employees who perform or work near tree removal operations? Which employees receive PPE, what PPE do you pay for, and what does it cost?

10. What requirements should a standard include to protect employees from hazards in tree removal operations?

E. Portable Powered Hand Tools, Ladders, and Other Tools and Equipment

1. What portable powered hand tools (for example, chain saws, and powered pole-mounted tools), ladders, and other tools (for example, cant hooks, chisels, chopping tools, and tongs) and equipment (for example, rope, climbing equipment, and wedges) does your company or industry use to perform tree care operations?

2. What types of chain saws does your company or industry use to cut tree branches and trunks?

3. What controls and safety mechanisms do these tools and equipment have to protect employees from accidents, injuries, and fatalities? What type of kickback protections or other safety mechanisms do the chain saws have to protect employees from being cut or otherwise injured? What do these controls and safety mechanisms cost?

4. What workplace safety practices has your company or industry implemented to protect employees who use or work near portable powered hand tools, chains saws, ladders, and other tools and equipment?

5. What PPE (for example, cut-resistant leg protection, head protection, and eye and face protection) does your company or industry provide to protect employees who use or work near portable powered hand tools, and other tools and equipment? Which employees receive PPE, what PPE do you pay for, and what does it cost?

6. What type of training does your company or industry provide to employees before they are permitted to operate portable powered hand tools, and other tools and equipment? Which employees receive training and how frequently?

7. What provisions and requirements should a standard specific to tree care operations include to protect employees operating portable powered hand tools, and other tools and equipment?

F. Vehicles and Mobile Equipment

1. What types of vehicles and mobile equipment (for example, aerial lifts, sprayers, stump cutters, log loaders, cranes, and winches) does your company or industry use to perform tree care operations?

2. What types of controls and safety mechanisms do vehicles and mobile equipment have to protect employees operating these vehicles or mobile equipment? For example, does your company or industry use vehicles and mobile equipment that are equipped with safety equipment such as seat belts and falling object protective systems (FOPS)? What do these controls and safety mechanisms cost?

3. What workplace safety practices (for example, traffic cones and signs and traffic direction) has your company or industry implemented to protect employees operating or working near vehicles or mobile equipment? What safety work practices and procedures has your company or industry implemented at jobsites to protect employees from on-road vehicular traffic in the area?

4. What PPE (for example, reflective vests) does your company or industry provide to protect employees while operating or working near vehicles or mobile equipment? Which employees receive PPE, what PPE do you pay for, and what does it cost?

5. What training does your company or industry provide for employees who operate vehicles or mobile equipment for tree care operations? Which employees receive training and how frequently?

6. What provisions and requirements should a standard specific to tree care operations include to protect employees operating or working near vehicles and mobile equipment? For example, should a standard require that employers use mobile equipment that is equipped with FOPS and seat belts?

G. Chippers

1. To what extent and in what circumstances does your company or industry perform chipping operations at tree trimming and removal worksites?

2. What types of chippers does your company or industry use?

3. What types of safety mechanisms (for example, safety control bar and hood locks or latches) do chippers have to prevent employees from being pulled into the machine or otherwise injured? What types of safety mechanisms do your chippers have and what do they cost?

4. What types of controls (for example, wooden push sticks) and workplace safety practices has your company or industry implemented to protect employees operating or working near chippers?

5. What types of PPE (for example, safety glasses, head protection, and gloves) does your company or industry provide to employees performing or working near chipper operations? Which employees receive PPE, what PPE do you pay for, and what does it cost?

6. What training does your company or industry provide for employees who perform or work near chipper operations? Which employees receive training and how frequently?

7. What requirements should a standard include to protect employees operating or working near chippers? For example, should a standard require that employers use chippers equipped with safety control bars?

H. General Workplace Safety Practices and Procedures

1. What general workplace safety and health practices or program has your company or industry implemented to protect employees who perform or work near tree care operations? Please describe in detail or submit a copy of the practices or program.

2. To what extent does your company (or a company representative of your industry) conduct hazard assessments before beginning a tree trimming or removal operation? Please describe in detail the hazard assessment process you use.

3. What workplace safety practices and procedures has your company or industry implemented to address environmental conditions (for example, thunderstorms, high winds, snow, and ice) that may pose a risk to employees?

4. What type of accident, near-miss, injury, and fatality records does your company or industry keep and analyze and to what extent does your company use these records to improve workplace safety and health practices or programs?

I. Training

1. What training does your company or industry provide to employees about safe performance of tree care operations? Which employees receive training and how frequently? What does the training cost?

2. What is the content of that training? Please describe in detail and submit a copy of training materials.

3. What training, if any, does your company provide for temporary employees, including day laborers? What is the content of that training and in what language is it provided? Please describe in detail and submit a copy of training materials.

4. To what extent does your company or companies in your industry hold regular safety meetings (for example, toolbox talks)? What do those safety meetings cover and how frequently are they held?

5. What training requirements should a standard include to protect employees performing tree care operations? Should a standard require that employers train all employees, including temporary employees and day laborers, before permitting them to perform tree care operations or related tasks?

J. Medical Services and First Aid

1. What procedures has your company or industry implemented to ensure that injured employees receive timely and effective first aid and cardiopulmonary resuscitation (CPR) if they are injured?

2. What first aid and CPR training does your company or industry provide to employees? Which employees receive training and how frequently? How much does the training cost? If training is not provided, what alternatives are in place to ensure that employees receive timely first aid and CPR?

3. Does your company or industry have first aid kits at the workplace in the event an employee is injured? How many kits do you provide, where are they located, and what types of supplies do they contain? What do the first aid kits and supplies cost?

4. What requirements should a standard contain to address medical services, including first aid and CPR, to help employees who are injured during tree care operations? For example, should a standard include provisions requiring the employees have CPR training or that employers have an automated external defibrillator at the workplace?

K. National Consensus Standards

1. To what extent has your company or industry implemented the provisions and requirements in the ANSI Z133.1 standard and what were the costs? Please explain in detail.

2. What provisions or requirements in ANSI Z133.1 have been most effective in reducing injuries and fatalities at your company or in the industry?

3. What provisions in the ANSI Z133.1 standard, if any, have been difficult to implement at your company or in the industry?

4. What provisions or requirements in ANSI Z133.1 should OSHA include or not include in a standard on tree care operations? Please explain.

5. What provisions or requirements in other national consensus standards should OSHA include in a standard on tree care operations?

L. Economic Impacts

1. What are the potential economic impacts associated with the promulgation of a standard to control hazards and reduce injuries and fatalities in tree care operations? Describe those impacts in terms of benefits from reduction in the number or severity of injuries and from changes in the costs of controls, medical costs, and training; effects on revenue and profit; and any other relevant impact measure. To the extent possible, quantify or provide examples of costs (for example, dollar estimates for controls).

2. What changes, if any, in market conditions would reasonably be expected to result from the promulgation of a standard on tree care operations? Describe any changes in market structure or concentration, and any effects on services that would reasonably be expected.

3. How many and what kinds of small entities perform tree care operations? What percentage of the industry do they comprise?

4. The Regulatory Flexibility Act requires that OSHA assess the impact of proposed and final rules on small entities (5 U.S.C 601 *et seq.*). OSHA requests that members of the small business community and others familiar with small business concerns address

any special circumstances small entities face in controlling hazards and reducing injuries and fatalities in tree care operations. How and to what extent would small entities in your industry be affected by the promulgation of a standard that addresses hazards in tree care operations? Are there special circumstances that make the control of hazards in tree care operations more difficult or more costly in small entities? Describe those circumstances and explain and discuss any alternatives that might serve to minimize these impacts.

5. Are the reasons why the benefits of a standard to control hazards in tree care operations might be different for small entities than for larger establishments? Please explain.

III. Public Participation

You may submit comments in response to this document (1) electronically at *http://www.regulations.gov,* (2) by hard copy, or (3) by facsimile (FAX). All comments, attachments, and other materials must identify the Agency name and the docket number for this document (Docket No. OSHA–2008–0012). You may supplement electronic submissions by uploading document files electronically. If, instead, you wish to mail additional materials in reference to an electronic or FAX submission, you must submit three copies to the OSHA Docket Office (see **ADDRESSES** section). The additional materials must clearly identify your electronic or FAX comments by name, date, and docket number so OSHA can attach them to your comments.

Because of security-related problems there may be a significant delay in the receipt of comments by regular mail. For information about security procedures concerning the delivery of materials by express delivery, hand delivery, and messenger or courier service, please contact the OSHA Docket Office at 202–693–2350 (TTY 877–889–5627).

All comments and submissions in response to this **Federal Register**, including personal information, are placed in the public docket without change. Therefore, OSHA cautions against submitting certain personal information such as social security numbers and birthdates. All comments and submissions are listed in the *http://www.regulations.gov* index; however, some information (for example, copyrighted material) is not publicly available to read or download through the Web site. All comments and submissions are available for inspection and copying at the OSHA Docket Office (see the **ADDRESSES** section of this notice). Information on using *http://www.regulations.gov* to submit comments and access dockets is available at that Web site. Contact the OSHA Docket Office (see **ADDRESSES** section) for information about materials not available through the OSHA Web site and for assistance in using the Web site to locate and download docket submissions.

Electronic copies of this **Federal Register** notice are available at *http://www.regulations.gov.* This document, as well as news releases and other relevant documents, are also available at OSHA's Web site at *http://www.osha.gov.*

IV. Authority and Signature

This document was prepared under the direction of Edwin G. Foulke, Jr., Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor. It is issued pursuant to sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657), 29 CFR part 1911, and Secretary's Order 5–2007 (72 FR 31159).

Signed at Washington, DC, this 15th day of September, 2008.

Edwin G. Foulke, Jr.,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. E8–21851 Filed 9–17–08; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915, 1917, 1918, and 1926

[Docket No. OSHA–2008–0031]

RIN 1218–AC42

Clarification of Remedy for Violation of Requirements To Provide Personal Protective Equipment and Train Employees

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Proposed rule; notice of hearing.

SUMMARY: OSHA is convening an informal public hearing to receive testimony and documentary evidence on the proposed rule for Clarification of Remedy for Violation of Requirements to Provide Personal Protective Equipment and Train Employees.

DATES: *Informal public hearing.* The Agency will hold the informal public hearing in Washington, DC, beginning October 6, 2008. The hearing will commence at 10 a.m. on the first day. If necessary, the hearing will continue on October 7, 2008, beginning at 9 a.m.

Notice of intention to appear to provide testimony at the informal public hearing. Parties must notify OSHA in writing no later than September 26, 2008, of their intention to appear at the hearing to present testimony. OSHA is limiting each party's testimony to 10 minutes. If parties need additional time, they must submit a written request with their notice of intention to appear stating how much time they seek, the topics they will cover during their testimony, and why they cannot cover the topics in the 10 minutes allotted.

ADDRESSES: *Informal Public Hearing.* The informal public hearing will be held in Washington, DC, Conference Room 6, Room C–5320 of the Frances Perkins Building, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC.

Notices of intention to appear at the hearing. Submit notices of intention to appear at the informal public hearing and requests for additional time to testify, identified by the docket number (OSHA–2008–0031) or the regulatory information number (RIN 1218–AC42), using any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting the material.

Facsimile: Send submissions consisting of 10 or fewer pages to the OSHA Docket Office at (202) 693–1648. Hard copies of these documents are not required. Instead of transmitting facsimile copies of attachments that supplement these documents (*e.g.*, studies, journal articles), submit these attachments, in triplicate hard copy, to the OSHA Docket Office, Technical Data Center, Room N–2625, OSHA, U.S. Department of Labor, 200 Constitution Ave., NW., Washington, DC 20210. These attachments must clearly identify the sender's name, date, subject, and docket number (*i.e.*, OSHA–2008–0031) so that the Agency can attach them to the appropriate document.

Regular mail, express delivery, hand delivery, and courier service: Send submissions (single copy only) to the OSHA Docket Office, Docket No. OSHA–2008–0031, Technical Data Center, Room N–2625, OSHA, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693–2350 (OSHA's TTY number is (877) 889–5627). Note that security-related problems may result in significant delays in receiving submissions by regular mail. Please contact the OSHA Docket Office for information about security procedures

concerning delivery of materials by express delivery, hand delivery, or courier service. The OSHA Docket Office and Department of Labor hours of operation are 8:15 a.m. to 4:45 p.m., *e.t.*

Instructions. Each submission must include the Agency name and the OSHA docket number (*i.e.*, OSHA–2008–0031). All submissions, including any personal information, are placed in the public docket without revision, and will be available online at *http://www.regulations.gov*. Therefore, OSHA cautions members of the public against submitting information and statements that should remain private, including comments that contain personal information (either about themselves or others) such as social security numbers, birth dates, and medical data. For additional information on submitting notices of intention to appear, see the Public Participation-Comments and Hearings section in the **SUPPLEMENTARY INFORMATION** section below.

Docket. To read or download comments, notices of intention to appear, and other material in the docket, go to *http://www.regulations.gov* or to the OSHA Docket Office at the address above. All documents in the docket are listed in the *http://www.regulations.gov* index; however, some information (*e.g.*, copyrighted material) is not publicly available to read or download through this Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office.

FOR FURTHER INFORMATION CONTACT: For general information and press inquiries, contact Ms. Jennifer Ashley, Director, Office of Communications, Room N–3647, OSHA, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: (202) 693–1999. For hearing information, contact Ms. Veneta Chatmon, Office of Communications, Room N–3647, OSHA, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: (202) 693–1999. Electronic copies of this **Federal Register** notice, as well as news releases and other relevant documents, are available at OSHA's homepage at *http://www.osha.gov*.

SUPPLEMENTARY INFORMATION: OSHA published the proposed rule for Clarification of Remedy for Violation of Requirements to Provide Personal Protective Equipment and Train Employees on August 19, 2008 (73 FR 48335). The period for submitting written comments expires on September 18, 2008. During this comment period, a number of commentors (see, *e.g.*, Exs. OSHA–2008–0031–006.1, –007.1, –009.1, –0011.1, –0012.1) requested an informal public hearing. With this notice, OSHA is granting these requests.

Public Participation—Comments and Hearings: OSHA encourages members of the public to participate in this rulemaking by providing oral testimony and documentary evidence at the informal public hearing. Accordingly, the Agency invites interested parties having knowledge of, or experience with, the issues raised in the proposal to participate in this process, and welcomes any pertinent data that will provide the Agency with the best available evidence to use in developing the final rule. This section describes the procedures the public must use to schedule an opportunity to deliver oral testimony and to provide documentary evidence at the informal public hearing.

Hearing Arrangements. Pursuant to section 6(b)(3) of the Occupational Safety and Health Act (the Act; 29 U.S.C. 655), members of the public have an opportunity at the informal public hearing to provide oral testimony concerning the issues raised in the proposed rule. An administrative law judge (ALJ) will preside over the hearing, and will resolve any procedural matters related to the hearing on the first day.

Purpose of the Hearing. The legislative history of Section 6 of the Act, as well as the Agency's regulation governing public hearings (29 CFR 1911.15), establish the purpose and procedures of informal public hearings. Although the presiding officer of the hearing is an ALJ, and questions by interested parties are allowed on pertinent issues, the hearing is informal and legislative in purpose. Therefore, the hearing provides interested parties with an opportunity to make effective and expeditious oral presentations in the absence of procedural restraints that could impede or protract the rulemaking process. The hearing is not an adjudicative proceeding subject to the technical rules of evidence. Instead, it is an informal administrative proceeding convened for the purpose of gathering and clarifying information. The regulations that govern the hearing, and the prehearing guidelines issued for the hearing, will ensure that participants are treated fairly and have due process. This approach will facilitate the development of a clear, accurate, and complete record. Accordingly, application of these rules and guidelines will be such that questions of relevance, procedures, and participation will be decided in favor of developing a clear, accurate, and complete record.

Conduct of the Hearing. Conduct of the hearing will conform to the provisions of 29 CFR 1911.5. Although the ALJ presiding over the hearing makes no decision or recommendation on the merits of the proposal or the final rule, the ALJ has the responsibility and authority to ensure that the hearing progresses at a reasonable pace and in an orderly manner. To ensure that interested parties receive a full and fair informal hearing, the ALJ has the authority and power to: regulate the course of the proceedings; dispose of procedural requests, objections, and similar matters; confine the presentations to matters pertinent to the issues raised; use appropriate means to regulate the conduct of the parties who are present at the hearing; question witnesses, and permit others to question witnesses; and limit the time for such questions. As indicated in the proposed rule, OSHA will allow an additional 30-day period for submission of posthearing comments before closing the public comment period (74 FR 48344).

Notice of intention to appear to provide testimony at the informal public hearings. Hearing participants must file a notice of intention to appear that provides the following information: The name, mailing and e-mail addresses, and telephone number of each individual who will provide testimony; the capacity in which the individual will testify (*e.g.*, name of the establishment/organization the individual is representing; the individual's occupational title and position); and whether the individual is appearing as a part of a panel with other individuals. Participants who need projectors and other special equipment for their testimony must contact Ms. Veneta Chatmon at OSHA's Office of Communications, telephone (202) 693–1999.

As noted above, testimony will be limited to 10 minutes. Requests for additional time must be submitted in writing with the notice of intention to appear, and contain a reasoned justification, including identification of the topics to be discussed and an explanation of why these topics cannot be covered in 10 minutes. OSHA will review the request and determine how much, if any, additional time to allot to the individual. Individuals requesting additional time will be notified of OSHA's determination on their request prior to the hearing.

OSHA emphasizes that, while the hearing is open to the public and all interested parties are welcome to attend, only a party who files a proper notice of intention to appear may ask questions and participate fully in the hearing. A party who did not file a notice of

intention to appear may be allowed to testify at the hearing if time permits, but this determination is at the discretion of the presiding ALJ.

Certification of the record and final determination after the informal public hearing. Following the close of the hearing and the posthearing comment period, the ALJ will certify the record to the Assistant Secretary of Labor for Occupational Safety and Health. This record will consist of all of the written comments, oral testimony, documentary evidence, and other material received during the hearing. Following certification of the record, OSHA will review the proposed provisions in light of all the evidence received as part of the record, and then will issue the final determinations based on the entire record.

Authority and Signature

This document was prepared under the authority of Edwin G. Foulke, Jr., Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, pursuant to Sections 6(b) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655), Section 3704 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 3701 *et seq.*), Secretary of Labor's Order 5–2007 (72 FR 31160), and 29 CFR part 1911.

Signed at Washington, DC, this 15th day of September 2008.

Edwin G. Foulke, Jr.,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. E8–21852 Filed 9–17–08; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF AGRICULTURE

Forest Service

36 CFR Part 294

RIN 0596–AC74

Special Areas; Roadless Area Conservation; Applicability to the National Forests in Colorado, Regulatory Risk Assessment

AGENCY: Forest Service, USDA.

ACTION: Proposed rule; risk assessment and request for comments.

SUMMARY: On July 25, 2008, the Forest Service, U.S. Department of Agriculture, proposed to establish a State-specific rule to provide management direction for conserving Colorado roadless areas (73 FR 43544). This proposed rule is estimated to have more than $100,000,000 of economic impact. The proposed rule would satisfy the economic impact and subject matter criteria of 7 U.S.C. 2204e and thus requires a regulatory risk assessment. The Forest Service is seeking comment on the assessment. A copy of the Regulatory Risk Assessment is available at the national roadless Web site *http://www.roadless.fs.fed.us.*

DATES: Comments must be received in writing by October 23, 2008.

ADDRESSES: Comments on the Regulatory Risk Assessment may be incorporated into comments on the proposed rule. Comments may be sent via e-mail to *COcomments@fsroadless.org.* Comments also may be submitted via the internet at *http://www.regulations.gov.* Written comments concerning this notice should be addressed to Roadless Area Conservation—Colorado, P.O. Box 162909, Sacramento, CA 95816–2909, or via facsimile to 916–456–6724. All comments, including names and addresses, when provided, are placed in the record and are available for public inspection and copying.

FOR FURTHER INFORMATION CONTACT: For information on the Regulatory Risk Assessment only, contact Ken Karkula at 202–205–2869. Individuals using telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m. Eastern Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The Forest Service is proposing to establish a State-specific rule to provide management direction for conserving Colorado roadless areas. This rule is estimated to have more than $100,000,000 of economic impact. The rule satisfies the economic impact and subject matter criteria of 7 U.S.C. 2204e and thus requires a regulatory risk assessment.

This risk assessment describes the types of risks to the environment that the proposed rule is designed to reduce, as well as discussing the likelihood that the proposed rule will reduce those risks. Examining risk at the site-specific level is not practical in this assessment therefore this risk assessment will address risks at the broader programmatic level.

The purpose of the proposed rule is to provide lasting protection, within the context of multiple-use management, for roadless areas within the National Forests in Colorado. The regulatory risk assessment assesses the degree to which the rule reduces the risk it was designed to address. In this regulatory risk assessment, the risk that the rule addresses is the risk of not providing lasting protection, within the context of multiple-use management, to the roadless areas within the National Forests in Colorado. The provisions of the proposed rule are intended to provide lasting protection; in the absence of the rule such protection is not guaranteed, as current regulatory direction (2001 Roadless rule) continues to be litigated.

In general, all of the alternatives are expected to reduce the risk of not providing lasting protection to roadless areas in comparison to the condition where no management plans are implemented. Differences between the alternatives are based on the different levels of road construction and reconstruction, tree-cutting, and other activities discussed. Differences in the degree to which the alternatives reduce the risk of not providing lasting protection are small. Due to uncertainty over its legal status, Alternative 1 (2001 Roadless Rule) presents an increased risk of not providing lasting protection over the other two alternatives since it is unclear whether or not the rule will be modified by litigation. Alternative 2 (Proposed Colorado Roadless Rule) reduces the risk of not providing lasting protection over Alternative 3 (Forest Plans) due to the decreased amount of roading, tree-cutting, and mineral development over the amounts estimated if individual forest plans rather than a roadless rule controlled the roadless areas.

Dated: August 28, 2008.

Charles L. Myers,

Associate Deputy Chief for National Forest System.

[FR Doc. E8–21899 Filed 9–17–08; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[FWS-R4-ES-2008-0082; 92210750083-B2]

RIN 1018-AU85

Endangered and Threatened Wildlife and Plants; Proposed Endangered Status for Reticulated Flatwoods Salamander; Proposed Designation of Critical Habitat for Frosted Flatwoods Salamander and Reticulated Flatwoods Salamander

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; supplemental information.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), are providing supplemental information on the proposal to split the listing under the Endangered Species Act of 1973, as amended (Act), of the currently threatened flatwoods salamander (*Ambystoma cingulatum*) into two distinct species: frosted flatwoods salamander (*Ambystoma cingulatum*) and reticulated flatwoods salamander (*Ambystoma bishopi*) due to a change in taxonomy. The frosted flatwoods salamander will maintain the status of threatened, and contained in this document is the threats analysis under section 4(a)(1) of the Act which explains this determination. We are accepting public comments from all interested parties on the proposed rule (73 FR 47258, August 13, 2008), the associated draft economic analysis, the listing status of both species, and the supplemental information we are providing in this document. If you submitted comments previously, then you do not need to resubmit them because we have already incorporated them into the public record and we will fully consider them in preparation of our final determination.

DATES: We will accept comments received on or before October 14, 2008.

ADDRESSES: You may submit comments by one of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- U.S. mail or hand-delivery: Public Comments Processing, Attn: RIN 1018-AU85; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, Suite 222; Arlington, VA 22203.

We will not accept e-mail or faxes. We will post all comments on *http://www.regulations.gov*. This generally means that we will post any personal information you provide us (see the Public Comments section below for more information).

FOR FURTHER INFORMATION CONTACT: Ray Aycock, Field Supervisor, U.S. Fish and Wildlife Service, Mississippi Field Office, 6578 Dogwood View Parkway, Jackson, MS 39213; telephone: 601-321-1122; facsimile: 601-965-4340. If you use a telecommunications device for the deaf (TDD), call the Federal Information Relay Service (FIRS) at 800-877-8339.

SUPPLEMENTARY INFORMATION:

Public Comments

We will accept written comments and information we receive on our before the date listed in the DATES section on our proposed critical habitat designation, proposed endangered status for reticulated flatwoods salamander, the draft economic analysis published in the **Federal Register** on August 13, 2008 (73 FR 47258), and proposed threatened status for frosted flatwoods salamander (as presented in this document). We will consider information and recommendations from all interested parties. Regarding the supplemental information we present in this document, we are particularly interested in comments concerning:

(1) Any available information on known or suspected threats and proposed or ongoing development projects with the potential to threaten either the frosted flatwoods salamander or the reticulated flatwoods salamander or any information on the need to change the status of either species, or

(2) The effects of potential threat factors that are the basis for a listing determination under section 4(a) of the Act, which are:

(a) Present or threatened destruction, modification, or curtailment of the species' habitat or range;

(b) Overutilization for commercial, recreational, scientific, or educational purposes;

(c) Disease or predation;

(d) The inadequacy of existing regulatory mechanisms; or

(e) Other natural or manmade factors affecting its continued existence.

You may submit your comments and materials by one of the methods listed in the **ADDRESSES** section. We will not accept comments you send by e-mail or fax or to an address not listed in the **ADDRESSES** section.

We will post your entire comment—including your personal identifying information—on *http://www.regulations.gov*. If you provide personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so.

Comments and materials we receive, as well as supporting documentation we used in preparing the proposed rule and draft economic analysis, will be available for public inspection on *http://www.regulations.gov*, or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, Mississippi Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Background

It is our intent to discuss only those topics directly relevant to the analysis of the five listing factors affecting the frosted flatwoods salamander. For more information on the flatwoods salamander, refer to the final listing rule published in the **Federal Register** on April 1, 1999 (64 FR 15691) and the proposed designation of critical habitat published in the **Federal Register** on August 13, 2008 (73 FR 47258).

Listing of the Frosted Flatwoods Salamander

History of the Action

The final rule to list the flatwoods salamander (*Ambystoma cingulatum*) as threatened was published on April 1, 1999 (64 FR 15691). On August 13, 2008, we published a proposed rule to split the species into two distinct species: frosted flatwoods salamander (*Ambystoma cingulatum*) and reticulated flatwoods salamander (*Ambystoma bishopi*) due to new taxonomic information (73 FR 47258). In that proposed rule, we provided the analysis of the threats for the reticulated flatwoods salamander and our determination of its endangered status. In this document, we are publishing our analysis and determination to retain threatened status for the frosted flatwoods salamander.

Species Information

Taxonomic revision resulting from research done by Pauly *et al.* (2007, pp. 415-429) split the flatwoods salamander into two species—the frosted flatwoods salamander and the reticulated flatwoods salamander. Based on the best available information, the life-history traits and habitat use of both the frosted flatwoods salamander and the reticulated flatwoods salamander are similar to those previously described for the flatwoods salamander (64 FR 15691, April 1, 1999; 73 FR 47258, August 13, 2008). However, most of our references predate Pauly *et al.* (2007) and, therefore, do not distinguish between the two species.

Both species of flatwoods salamanders are moderately sized salamanders that are generally black to chocolate-black with fine, irregular, light gray lines and specks that form a cross-banded pattern across their backs (back pattern more net-like in the reticulated flatwoods salamander). The frosted flatwoods salamander generally tends to be larger than the reticulated flatwoods salamander. Adults are terrestrial and live underground most of the year. They breed in relatively small, isolated ephemeral ponds where the larvae develop until metamorphosis. Post-metamorphic salamanders migrate out of the ponds and into the uplands where they live until they move back to ponds to breed as adults.

Flatwoods salamanders are endemic to the lower southeastern Coastal Plain and occur in what were historically

longleaf pine-wiregrass flatwoods and savannas. The historical range of what is now considered the frosted flatwoods salamander included parts of the States of Florida, Georgia, and South Carolina. This area encompassed the lower Coastal Plain of the southeastern United States along the Gulf Coast east of the Apalachicola–Flint Rivers, across north Florida, south into north-central Florida, and north along the Atlantic Coast through coastal Georgia and South Carolina.

We have compiled 84 historical (pre-1990) records for the frosted flatwoods salamander. Twenty historical records (with supporting locality information) for the frosted flatwoods salamander are known from eight counties in Florida. Frosted flatwoods salamander breeding has been documented at only four (20 percent) of these sites since 1990. Surveys conducted since 1990 by Federal and State agency personnel, as well as private parties, have resulted in the identification of more than 50 additional frosted flatwoods salamander breeding sites, including two sites in Jefferson County, a county that previously was not known to be occupied by the salamander. Most of these new breeding sites are located on the Apalachicola and Osceola National Forests, and on St. Marks National Wildlife Refuge. Sixteen populations of the frosted flatwoods salamander are known from Baker, Franklin, Jefferson, Liberty, and Wakulla Counties in Florida.

Thirty-four historical records for the frosted flatwoods salamander are known from 20 counties in Georgia. Frosted flatwoods salamanders have not been seen again at any of these sites in recent years; however, surveys conducted since 1990 have resulted in the discovery of 23 new breeding sites. All but one of these new sites are located on the Fort Stewart Military Installation. The one additional pond was discovered on the Townsend Bombing Range. Currently, these breeding sites support six frosted flatwoods salamander populations in Bryan, Evans, Liberty, and McIntosh Counties, Georgia, all on Department of Defense lands. The frosted flatwoods salamander is assumed extirpated from 16 other counties in Georgia where it previously occurred. However, some appropriate habitat still remains on the Okefenokee National Wildlife Refuge and the potential may exist for the species to occur there.

Thirty historical records for the frosted flatwoods salamander are known from five counties in South Carolina. Since 1990, metamorphic frosted flatwoods salamanders have been documented at six (21 percent) of these sites, and one new breeding site has been discovered. Currently, four populations of the frosted flatwoods salamander are known from Berkeley, Charleston, and Jasper Counties in South Carolina. Two populations are on private land in Jasper County: one population occurs on the Francis Marion National Forest in Berkeley County, and one population occurs on the Santee Coastal Preserve (state-owned and -managed) in Charleston County.

The combined data from all survey work completed since 1990 in Florida, Georgia, and South Carolina indicate there are 26 populations of the frosted flatwoods salamander. Some of these populations are inferred from the capture of a single individual. Twenty-three (88 percent) of the known frosted flatwoods salamander populations occur primarily on public land. Sixteen of the populations (62 percent of total populations of the species) on public land represent metapopulations supported by more than one breeding site. A single population occurs on each of the following publicly owned sites: Tate's Hell State Forest and Osceola National Forest in Florida; Townsend Bombing Range in Georgia; and Francis Marion National Forest and Santee Coastal Reserve in South Carolina. In Florida, habitat on Apalachicola National Forest supports 10 populations and on St. Marks National Wildlife Refuge supports 2 populations. In Georgia, five populations occur on Fort Stewart Military Installation. Three (12 percent) frosted flatwoods salamander populations are solely on private land.

Summary of Factors Affecting the Species (Frosted Flatwoods Salamander)

Section 4 of the Act (16 U.S.C. 1531 *et seq.*) and regulations (50 CFR part 424) promulgated to implement the listing provisions of the Act set forth the procedures for adding species to the Federal Lists of Endangered and Threatened Wildlife and Plants. A species may be determined to be endangered or threatened due to one or more of the five factors described in section 4(a)(1) of the Act. The original listing rule for the flatwoods salamander (64 FR 15691; April 1, 1999) contained a discussion of these five factors. Only those factors relevant to the frosted flatwoods salamander (*Ambystoma cingulatum* Cope, 1867) are described below:

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

The major historical threat to the frosted flatwoods salamander was loss of both its longleaf pine–slash pine flatwoods terrestrial habitat and its isolated, seasonally ponded breeding habitat. The combined pine flatwoods (longleaf pine–wiregrass flatwoods and slash pine flatwoods) historical area was approximately 32 million acres (ac) (12.8 million hectares (ha)) (Outcalt 1997, p. 4). This area has been reduced to 5.6 million ac (2.27 million ha) or approximately 18 percent of its original extent (Outcalt 1997, p. 4). These remaining pine flatwoods (non-plantation forests) areas are typically fragmented, degraded, second-growth forests (Outcalt 1997, p. 6). Conversion of pine flatwoods to intensively managed (use of heavy mechanical site preparation, high stocking rates, low fire frequencies) slash or loblolly plantations often resulted in degradation of flatwoods salamander habitat by creating well-shaded, closed-canopied forests with an understory dominated by shrubs or pine needles (Outcalt 1997, pp. 4-6; Palis 1997, pp. 61-63). Disturbance-sensitive groundcover species, such as wiregrass (*Aristida stricta* [= *A. beyrichiana*] Kesler *et al.*2003, p. 9), dropseed (*Sporobolus* spp.), and perennial forbs were either greatly reduced in extent or were replaced by weedy pioneering species (Moore *et al.*1982, p. 216; Outcalt and Lewis 1988, pp. 1-12; Hardin and White 1989, pp. 243-244). Flatwoods salamanders are unlikely to persist in uplands with a disturbed, wiregrass-depauperate groundcover (Palis 1997, p. 63).

Degradation of the remaining frosted flatwoods salamander habitat is a current, ongoing threat. Forest management that includes intensive site preparation may adversely affect flatwoods salamanders directly and indirectly (Means *et al.* 1996, p. 426). Bedding (a technique in which a small ridge of surface soil is elevated as a planting bed) alters the surface soil layers, disrupts the site hydrology, and often eliminates the native herbaceous groundcover. This can have a cascading effect of reducing the invertebrate community that serves as a food source for flatwoods salamander adults. Post-larval and adult flatwoods salamanders occupy upland flatwoods sites where they live underground in crayfish burrows, root channels, or burrows of their own making (Goin 1950, p. 311; Neill 1951, p. 765; Mount 1975, pp. 98-99; Ashton and Ashton 2005, pp. 63, 65,

68-71). The occurrence of these underground habitats is dependent upon protection of the soil structure. Intensive site preparation destroys the subterranean voids and may result in entombing, injuring, or crushing individuals.

Ecologists consider fire suppression the primary reason for the degradation of remaining longleaf pine forest habitat. The disruption of the natural fire cycle has resulted in an increase in slash and loblolly pine on sites formerly dominated by longleaf pine, an increase in hardwood understory, and a decrease in herbaceous ground cover (Wolfe *et al.* 1988, p. 132). Although frosted flatwoods salamanders have been found at sites with predominately loblolly or slash pine, the long-term viability of populations at these sites is unknown. In addition, ponds surrounded by pine plantations and protected from the natural fire regime may become unsuitable as frosted flatwoods salamander breeding sites due to canopy closure and the resultant reduction in emergent herbaceous vegetation needed for egg deposition and larval development sites (Palis 1997, p. 62). Lack of fire may result in the development of a thick shrub zone, making it physically difficult or impossible for adult salamanders to enter the breeding ponds (Ripley and Printiss 2005, pp. 1-2, 11).

Alterations of the longleaf pine ecosystem, as a result of incompatible forest practices, have caused the historic loss of most of the original frosted flatwoods salamander habitat. Although conversion of native pine flatwoods to plantation forests is not considered a significant threat at this time, most of the historic extirpation of frosted flatwoods populations in Florida, Georgia, and South Carolina over the last six decades resulted from habitat degradation on lands managed for timber extraction.

Land use conversions to housing, other development projects, and agriculture eliminated large areas of pine flatwoods in the past (Schultz 1983, pp. 24-47; Stout and Marion 1993, pp. 422-429; Outcalt and Sheffield 1996, pp. 1-5; Outcalt 1997, pp. 1-6). Residential development and conversion to agriculture have resulted in the historical loss of one frosted flatwoods salamander population each from Ben Hill, Berrien, Brooks, Effingham, Emanuel, and Irwin Counties, Georgia (Seyle 1994, pp. 4-5); an additional site has been degraded in Orangeburg County, South Carolina, and is not currently occupied (LaClaire 1995). State forest inventories completed between 1989 and 1995 indicated that flatwoods losses through land use conversion were still occurring (Outcalt 1997, pp. 3-6); however further conversions are likely to impact only the three populations that remain on private lands.

In addition to the loss of upland forested habitat, the number and diversity of small wetlands where frosted flatwoods salamanders breed have been substantially reduced. Threats to breeding sites include alterations in hydrology, agricultural and urban development, road construction, incompatible silvicultural practices, shrub encroachment, dumping in or filling of ponds, conversion of wetlands to fish ponds, domestic animal grazing, soil disturbance, and fire suppression (Vickers *et al.* 1985, pp. 22-26; Palis 1997, p. 58; Ashton and Ashton 2005, p. 72). Hydrological alterations, such as those resulting from ditches created to drain flatwoods sites or fire breaks and plow lines, represent one of the most serious threats to frosted flatwoods salamander breeding sites. Lowered water levels and shortened hydroperiods at these sites may prevent successful flatwoods salamander recruitment because larval salamanders require 11 to 18 weeks to reach metamorphosis and leave the ponds (Palis 1995, p. 352).

U.S. Geological Survey has documented multiple drought periods in the southeastern United States since the 1890s (USGS Open File Report 00-380, p. 1). Among significant periods documented in the last three decades are: 1980-1982, 1984-1988, 1998-2000 (USGS Water Supply Paper 2375), and currently from 2006-2008. Although drought is a naturally occurring condition, it presents additional complications for a species like the frosted flatwoods salamander, which has been extirpated from most of its historic range. Palis *et al.* (2006, (p. 5-6) conducted a study in Florida on a population of the frosted flatwoods salamander during a drought from 1999-2002. This study found 3 consecutive years of reproductive failure and a steadily declining adult immigration to breed at the site as the drought progressed. Taylor *et al.* (2005, p. 792) noted that wide variation in reproductive success is common among pond-breeding amphibians that depend on seasonal filling of these areas, but that adult persistence may buffer against fluctuations in that success, particularly for species that are long-lived.

Although Palis *et al.* (2006) suggested that the flatwoods salamander may only live about 4 years (based on captive animals), we are currently unsure of the exact life span of wild individuals. Because of this, it is difficult to predict how long adults could persist in the landscape without a successful breeding event to replenish the population. However, Taylor *et al.* (2005, pp. 792, 796) constructed a model to look at how many years of reproductive failure would be required to result in local extinction of pond-breeding salamanders (with varying life spans) and found that even without total reproductive failure, populations required moderate to high upland post-metamorphic survival to persist. In the model, catastrophic failure created fluctuations in the population, raised the threshold of survival required to achieve persistence, and imposed the possibility of extinction even under otherwise favorable environmental conditions. Reproductive failure for this species was closely tied to hydrologic conditions; insufficient or short hydroperiod was the primary cause for complete failure. In addition, early filling of the ponds could also facilitate the establishment of invertebrate or vertebrate predators before the salamander eggs hatched (Taylor *et al.*, p. 796). Palis *et al.*. (2006, p. 6-7) discussed the necessity of protecting clusters of flatwoods salamander breeding sites, especially those with different hydrologic regimes, to guard against population declines at any one breeding site resulting from stochastic events, such as droughts (Palis 2006, p. 7). Currently, 16 populations of the frosted flatwoods salamander that occur on public land are supported by multiple breeding sites.

Habitat fragmentation of the longleaf pine ecosystem resulting from habitat conversion is primarily a historical threat to the frosted flatwoods salamander. Large tracts of intact longleaf pine flatwoods habitat are fragmented by pine plantations, roads, and unsuitable habitat. Although the threat of ongoing habitat fragmentation has slowed, the effect of past habitat loss is that many frosted flatwoods salamander populations are widely separated from each other by unsuitable habitat. This has been verified through recent reviews of aerial photography and site visits to localities of historical and current records for the species. Studies have shown that the loss of fragmented populations is common, and recolonization is critical for their regional survival (Fahrig and Merriam 1994, pp. 50-56; Burkey 1995, pp. 527-540). Amphibian populations may be unable to recolonize areas after local extirpations due to their physiological constraints, relatively low mobility, and

site fidelity (Blaustein *et al.* 1994, pp. 60, 67-68). In the case of the frosted flatwoods salamander, 38 percent of populations have only one breeding pond. If the habitat at that site is destroyed, recolonization would be impossible (see further discussion of metapopulation dynamics under Factor E).

Roads have contributed to habitat fragmentation by isolating blocks of remaining contiguous habitat. Roads disrupt migration routes and dispersal of individuals to and from breeding sites. Road construction can result in destruction of breeding ponds, as described above. In addition, vehicles may also cause the death of frosted flatwoods salamanders when they are attempting to cross roads (Means 1996, p. 2). Highway construction and associated development resulted in the destruction of a historic frosted flatwoods salamander breeding pond in Chatham County, Georgia (Seyle 1994, pp. 3-4).

Off-road vehicle (ORV) use within frosted flatwoods salamander breeding ponds and their margins severely degrades the wetland habitat. In the Southeast, ORV use impacts habitat used by frosted flatwoods salamanders, has the potential to cause direct mortality of individual salamanders, and is a threat on both public and private land. On public lands, areas may be designated as off-limits to ORV use (U.S. Forest Service 2007, p. 19), but these restrictions are difficult to enforce. Even a single afternoon of individuals riding their ORVs in a pond can completely destroy the integrity of breeding sites by damaging or killing the herbaceous vegetation and rutting the substrate (Ripley and Printiss 2005, pp. 11-12). There is also the potential for direct injury or mortality of salamanders by ORVs at breeding sites (Ripley and Printiss 2005, p. 12).

In summary, the loss of habitat was a significant historical threat to the frosted flatwoods salamander. This range-wide loss of both upland and wetland habitat occurred primarily due to conversion of flatwoods sites to agriculture, residential development, and intensively managed pine plantations. This historic loss of habitat is presently compounded by current environmental conditions (drought), proposed projects on private land that do not require U.S. Army Corps of Engineers (Corps) Corps permits, under the Clean Water Act (33 U.S.C. 1251 *et seq.*), and the nature of pond-breeding salamanders to undergo periodic reproductive failure. We consider this threat to be primarily a past and future threat of moderate magnitude because most of the remaining occupied habitat of this species occurs on public lands that are managed to support the native longleaf pine ecosystem. However, 12 percent of frosted flatwoods salamander populations are on private land where habitat continues to be degraded by fire suppression and incompatible management. If the remaining frosted flatwoods salamander habitat on public land continues to be protected from fire suppression and other incompatible forest management practices, road construction, and additional habitat fragmentation, the threat of habitat loss is expected to be limited. Localized threats on private lands would include loss or alteration of habitat from agriculture, residential development, road construction, incompatible forest management, ORVs, fire suppression, and ditching or draining wetland breeding sites. As a result, we have determined that the present or threatened destruction, modification, or curtailment of frosted flatwoods salamander habitat and range represents a moderate but significant threat to the species.

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

Overutilization does not appear to be a threat to the frosted flatwoods salamander at this time. There is no evidence of a past or current problem with collection of this species. Consequently, we have determined that overutilization for commercial, recreational, scientific, or educational purposes is not a threat to the frosted flatwoods salamander at this time.

C. Disease or Predation

Although disease has not been specifically documented in the frosted flatwoods salamander thus far, disease outbreaks with mass mortality in other species of salamanders indicate that disease may be a threat for this species as well (Daszak *et al.*1999, p. 736). ''Red-leg'' disease (*Aeromonas hydrophila*), a pathogen bacterium, caused mortality of mole salamanders (*A. talpoideum*) at the breeding pond of the closely related reticulated flatwoods salamander in Miller County, Georgia (Maerz 2006), and reticulated flatwoods salamanders have not been observed at this site since the disease was reported. Whiles *et al.* (2004, p. 211) found a parasitic nematode (*Hedruris siredonis*, family Hedruridae) in larvae of the frosted flatwoods salamander from South Carolina and Florida. This parasite has been found in other ambystomatids and can cause individuals to become undersized and thin, thus reducing their fitness (Whiles *et al.* 2004, p. 212). The infestations were not considered heavy and were probably not having a negative impact on the larvae studied; however, environmental degradation may change the dynamics between salamander populations and normally innocuous parasites (Whiles *et al.* 2004, p. 212). Ranaviruses in the family Iridoviridae and chytrid fungus may be other potential threats, although the susceptibility of the frosted flatwoods salamander to these diseases is unknown. Ranaviruses have been responsible for die-offs of tiger salamanders throughout western North America and spotted salamanders (*A. maculatum*) in Maine (Daszak *et al.* 1999, p. 736). Chytrid fungus has been discovered and associated with mass mortality in tiger salamanders in southern Arizona and California, and the Santa Cruz long-toed salamander (*A. macrodactylum croceum*) (Vredenburg and Summers 2001, p. 151; Davidson *et al.* 2003, p. 601; Padgett-Flohr and Longcore 2005, p. 50). Chytrid has been found at Fort Stewart Military Installation in Georgia, a locality where the frosted flatwoods salamander occurs (Mitchell 2002, p. 191-202). This disease has negatively impacted populations of other ambystomatid salamanders (A. *macrodactylum croceum*) (Vredenburg and Summers 2001; Davidson *et al.* 2003; Padgett-Flohr and Longcore 2005), and it is likely to negatively impact frosted flatwoods salamander populations as well. This discussion of disease in other species of closely related salamanders indicates the potential existence of similar threats to frosted flatwoods salamander populations.

Exposure to increased predation by fish is a threat to the frosted flatwoods salamander when isolated, seasonally ponded wetland breeding sites are changed to or connected to more permanent wetlands inhabited by fish species not typically found in temporary ponds. Studies of other ambystomatid species have demonstrated a decline in larval survival in the presence of predatory fish (Semlitsch 1987, p. 481). Ponds may be modified specifically to serve as fish ponds or sites may be altered because of drainage ditches, firebreaks, or vehicle tracks that can all provide avenues for fish to enter the wetlands.

Red imported fire ants (*Solenopsis invicta*) are potential predators of flatwoods salamanders, especially in disturbed areas. They have been seen in areas disturbed by the installation of drift fences at known frosted flatwoods salamander breeding sites (Palis 2008).

Mortality of amphibians trapped at drift fences has occurred when fire ants were present and traps were not monitored with sufficient frequency (NCASI 2002, p. 6). The severity and magnitude of effects, as well as the long-term effect, of fire ants on frosted flatwoods salamander populations are currently unknown.

In summary, diseases of amphibians in the southeastern United States remain largely unstudied. However, given the incidence of disease in species that could be considered surrogates for the frosted flatwoods salamander, the probability exists for similar infections to occur in frosted flatwoods salamander populations. We consider this to be a potential threat of low magnitude. Predation by fish is a historic threat that continues to be a localized problem when ditches, firebreaks, or vehicle ruts provide connections allowing the movement of fish from permanent water bodies into frosted flatwoods salamander breeding sites. Fire ants also have the potential of being a localized threat, particularly in disturbed areas. We consider these threats to be potential threats of low magnitude because 88 percent of frosted flatwoods salamander populations occur primarily on public lands where they are relatively protected.

D. The Inadequacy of Existing Regulatory Mechanisms

There are no existing regulatory mechanisms for the protection of the upland habitats where frosted flatwoods salamanders spend most of their lives. Section 404 of the Clean Water Act is the primary Federal law that has the potential to provide some protection for the wetland breeding sites of the frosted flatwoods salamander. However, due to recent case law (*Solid Waste Agency of Northern Cook County (SWANCC)* v. *U.S. Army Corps of Engineers* 531 U.S. 159 (2001); *Rapanos* v. *U.S.* 547 U.S. 715 (2006)), isolated wetlands are no longer considered to be under Federal jurisdiction (not regulatory wetlands). Wetlands are only considered to be under the jurisdiction of the Corps if a ''significant nexus'' exists to a navigable waterway or its tributaries. Currently, some Corps Districts do not coordinate with us on flatwoods salamanders and, since isolated wetlands are not considered under their jurisdiction, they are often not included on maps in permit applications (Brooks 2008). However, since most remaining frosted flatwoods salamander populations are on public land, which is unlikely to be developed, we do not consider this to be a significant threat.

Longleaf pine habitat management plans have been written for public lands occupied by the frosted flatwoods salamander. They include management plans for State-owned lands and integrated natural resource management plans (INRMPs) for Department of Defense lands. Most of the plans contain specific goals and objectives regarding habitat management, including prescribed burning, that would benefit frosted flatwoods salamanders. Multiple-use is the guiding principle on most of these public lands, however, and protection of the frosted flatwoods salamander may be just one of many management goals including timber production and military and recreational use.

At the State and local levels, regulatory mechanisms are limited. The flatwoods salamander is listed as a threatened species in the State of Georgia (Jensen 1999, pp. 92-93). This designation protects the species by preventing its sale, purchase, or possession in Georgia and by prohibiting actions that cause direct mortality of the species or the destruction of its habitat on lands owned by the State of Georgia (Ozier 2008). However, there are no known frosted flatwoods salamander populations on lands owned by the State of Georgia. In 2001, the Florida Fish and Wildlife Conservation Commission (FFWCC) listed the flatwoods salamander (which includes the frosted flatwoods salamander) as a species of special concern (FFWCC 2007, p. 2) and prohibited direct take except through permit. As part of the listing process, a Statewide management plan was developed for the salamander in Florida (FFWCC 2001, p. 1-60). This plan sets an ambitious conservation goal of maintaining at least 129 self-sustaining populations of flatwoods salamanders (which includes both frosted and reticulated flatwoods salamander species) in Florida. The plan also outlines a monitoring plan for population status assessment, an implementation strategy for the management of populations, and areas for future research. However, Florida regulations offer no protection against the most significant threat to the frosted flatwoods salamander—loss of habitat.

In summary, although existing regulatory mechanisms provide little direct protection of frosted flatwoods salamanders (beyond the protections afforded by the Act), they do provide a degree of protection for the remaining occupied habitat, primarily on public lands. The record of management on public lands since the original listing of the flatwoods salamander in 1999 indicates that public agencies are actively pursuing longleaf pine ecosystem management programs that benefit the frosted flatwoods salamander. Frosted flatwoods salamander breeding sites on the three private land sites may, in some cases, come under the jurisdiction of the Corps, but most likely they are provided little regulatory protection. We have determined that the threat of inadequate existing regulatory mechanisms is primarily an ongoing threat of moderate magnitude.

E. Other Natural or Manmade Factors Affecting Its Continued Existence

Metapopulations, which are neighboring local populations close enough to one another that dispersing individuals could be exchanged (gene flow) at least once per generation, are important to the long-term survival of temporary pond breeding amphibians. In these species, such as the frosted flatwoods salamander, breeding ponds may differ in the frequency of their ability to support amphibian reproduction. As a result, extirpation and colonization rates can be a function of pond spatial arrangement as well as local habitat quality (Marsh and Trenham 2001, p. 41). Of the 26 known frosted flatwoods salamanders populations, 16 (62 percent) are supported by more than one breeding pond and may be considered metapopulations. However, for 12 percent (3 out of 26) of the known frosted flatwoods salamander populations, any one of the many threats that may render a breeding pond unsuitable could cause the extirpation of the affected population.

Invasive plant species, such as cogongrass (*Imperata cylindrica*), threaten to further degrade existing flatwoods habitat. Cogongrass, a perennial grass native to Southeast Asia, is one of the leading threats to the ecological integrity of native herbaceous flora, including that in the longleaf pine ecosystem (Jose *et al.* 2002, p. 43). Cogongrass can displace most of the existing vegetation except large trees. Especially threatening to the frosted flatwoods salamander is the ability of cogongrass to outcompete wiregrass, a key vegetative component of flatwoods salamander habitat. Changing the species composition in this way can alter the soil chemistry, nutrient cycling, and hydrology of an infested site (Jose *et al.* 2002, p. 43). Frosted flatwoods salamander habitat management plans will need to address threats posed by cogongrass and other invasive plant species and include strategies to control them. An integrated

management approach to controlling cogongrass is outlined in Jose *et al.* (2002, p. 42).

Pesticides (including herbicides) may pose a threat to amphibians, such as the frosted flatwoods salamander, whose permeable eggs and skin readily absorb substances from the surrounding aquatic or terrestrial environment (Duellman and Trueb 1986, pp. 199-200). Negative effects that commonly used pesticides and herbicides may have on amphibians include delayed metamorphosis, paralysis, reduced growth rate, and mortality (Bishop 1992, pp. 67-69). Herbicides used near frosted flatwoods salamander breeding ponds may alter the density and species composition of vegetation surrounding a breeding site and reduce the number of potential sites for egg deposition, larval development, or shelter for migrating salamanders. Aerial spraying of herbicides over outdoor pond mesocosms (semi-field approximations of ponds) has been shown to reduce zooplankton diversity, a food source for larval frosted flatwoods salamanders, and cause very high (68 to 100 percent) mortality in tadpoles and juvenile frogs (Relyea 2005, pp. 618-626). The potential for negative effects from pesticide and herbicide use in areas adjacent to breeding ponds would be reduced by avoiding aerial spraying (Tatum 2004, p. 1047).

Studies of other ambystomatid species have demonstrated a decline in larval survival in the presence of predatory fish, as mentioned above under Factor C. One of the potential reasons for this decline may be the negative effect that these fish have on the invertebrate prey of salamander larvae. The invertebrates found by Whiles *et al.* (2004, p. 212) in a study of larval frosted and reticulated flatwoods salamander gut contents are typical of freshwater habitats in the Southeast that do not contain predatory fish on a regular basis. The presence of predatory fish has a marked effect on invertebrate communities and alters prey availability for larval salamanders with the potential for negative effects on larval fitness and survival (Semlitsch 1987, p. 481). Wherever connections have been created between permanent water and frosted flatwoods salamander ponds, through installation of firebreaks, ditches, and so on, this threat from predatory fish exists.

Studies of frosted flatwoods salamander populations since the original species classification of flatwoods salamander was listed (64 FR 15691; April 1, 1999) have been limited due to drought. Data on the numbers of adults within existing populations does not exist. However, given the low number of individuals encountered even when breeding is verified, populations are likely to be very small at any given breeding site. Small populations are at increased threat of extirpation from natural processes (genetic isolation, inbreeding depression, and drought), as well as the manmade threats described above.

In summary, a variety of natural or manmade factors historically or currently threaten, or have the potential to threaten, the frosted flatwoods salamander. The loss of metapopulation structure in the distribution of frosted flatwoods salamander populations was a range-wide threat that caused historic losses of this species. It continues to be a current threat for 38 percent of the remaining frosted flatwoods salamander populations. Fire suppression and inadequate habitat management continue to cause the degradation of occupied sites, primarily on private land. Invasive plant species probably did not have much of a historic impact on salamander populations, but they are a range-wide potential threat, especially as they become more widespread and difficult to control. Rangewide, low population densities have been a historic threat and continue to be a threat for most frosted flatwoods salamander populations, particularly due to past and current drought conditions, habitat loss, population fragmentation, and periodic reproductive failures that occur naturally in pond-breeding amphibians. The impact that competing predators may have on the salamanders' prey base, and the threat of pesticide and herbicide use, are less clear as historic threats but remain potential localized threats for the species. Therefore, while we have determined that other natural and manmade factors, such as invasive species, pesticides, and competition for the species' prey base, may threaten the frosted flatwoods salamander, the severity and magnitude of these threats are not currently known. Acting in combination with threats listed above under Factors A through D, the threats under Factor E could increase the severity of the other threats.

Determination

We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats to the frosted flatwoods salamander. In summary, the most significant historical threat to the frosted flatwoods salamander, as listed in Factor A (above), is loss of the majority of its habitat. A variety of localized threats (described under Factors A, C, D, and E) have the potential to impact the remaining frosted flatwoods salamander habitat. These include alterations in the hydrology of existing wetland breeding sites, incompatible forest management, ORV use, fire suppression, drought, and disease, but the severity and magnitude of these threats are not currently known. As described in Factor E above, small populations are at increased threat of extirpation from natural processes (genetic isolation, inbreeding depression, and drought), as well as the manmade threats listed above. Finally, there are potential localized threats from fire ants, pesticides, and invasive plants for which the extent of impact is yet undeterminable, but that we believe are legitimate threats due to both their impact on surrogate species and their prevalence in the types of habitats used by this species.

Only 26 frosted flatwoods salamander populations are known. Ten (38 percent) of these populations are supported by only one breeding site. A population with only one breeding site has a tenuous future just given randomly varying environmental factors without considering the additional threats of habitat destruction and degradation that further threaten these populations.

As noted previously, we are currently experiencing drought conditions. Palis *et al.* (2006, pp. 5-6) studied a frosted flatwoods population in Florida during a drought from 1999-2002. This study documented 3 consecutive years of reproductive failure and a steady declining adult immigration to the site for breeding as the drought progressed.

Catastrophic reproductive failure occurs even in healthy populations of pond-breeding amphibians. When it does occur, the modeling efforts of Taylor *et al.* (2005, p. 796) showed that each year of reproductive failure raises the threshold of survival required to achieve persistence and imposes the possibility of extirpation even under otherwise favorable environmental conditions. Taylor *et al.* (2005, p. 799) reminds us that particularly with small populations or low population growth rates (as exists with the frosted flatwoods salamander) effects of reproductive failure are made worse by demographic stochasticity. Even in populations with multiple breeding ponds, amphibian populations may be unable to recolonize areas after local extirpations due to their physiological constraints, relatively low mobility, and site fidelity (Blaustein *et al.* 1994, pp. 60, 67-68).

For frosted flatwoods salamander, 38 percent of populations have only one breeding pond. If the habitat at that site

is destroyed, recolonization would be impossible and the population supported by that breeding pond would be extirpated.

Habitat loss on private lands is an imminent threat that is compounded by a variety of other factors. Fire suppression on private lands occupied by the frosted flatwoods salamander represents one of the biggest threats to the species' habitat and the continued existence of the species on these sites. However, 62 percent of frosted flatwoods salamander populations have an improved chance of surviving demographic and environmental stochasticity given that the distribution of breeding sites occurs within an adult salamander's dispersal distance.

We believe that, when combining the effects of historical, current, and projected habitat loss and degradation, historical and ongoing drought, and the exacerbating effects of disease, predation, small population size, and isolation, the frosted flatwoods salamander continues to be likely to become an endangered species throughout all of its range within the foreseeable future. We believe these threats, particularly the threats to populations resulting from habitat degradation and fragmentation, small population size, and drought, are current and are projected to continue into the future. We have determined that these threats are operating on the species and its habitat with a moderate degree of magnitude throughout most of its range and with a moderate degree of severity, as discussed above.

Based on the best available scientific and commercial information, we have determined that the preferred action is for the frosted flatwoods salamander to retain its status as a threatened species under the Act. Without the protection of the Act, significant management of threats would likely occur on public lands; however, there is still substantial risk of loss of ponds to drought and disease and, on private lands, a variety of potential threats (for example, introduction of fish, predation, pesticides), and development. As discussed previously, declines resulting from drought can occur within only a few years. In the case of the frosted flatwoods salamander, 38 percent of populations have only one breeding pond. If the habitat at that site is destroyed, recolonization would be impossible and the population supported by that breeding pond would be extirpated. This could occur within a few years given recurring drought conditions and existing threats. While not in immediate danger of extinction, the frosted flatwoods salamander is likely to become an endangered species in the foreseeable future throughout all or a significant portion of its range if the present trends that negatively affect the species, and its limited and restricted habitat, continue. Furthermore, because these threats to the species are of comparable magnitude and severity across all of the species' range, we have determined that an analysis of whether a specific portion of the range might require a different listing status is not warranted at this time.

Available Conservation Measures

For additional information on available conservation measures, please refer to the proposed rule published in the **Federal Register** on August 13, 2008 (73 FR 47258).

References Cited

A complete list of all references cited in this document is available upon request from the Field Supervisor Ray Aycock, Mississippi Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Author(s)

The primary authors of this package are the staff of the Mississippi Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Authority

The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: September 5, 2008.

Lyle Laverty,

Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. E8–21878 Filed 9–17–08; 8:45 am]

BILLING CODE 4310-55-S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 600

[Docket No. 0808041047–81182–01]

RIN 0648–AW62

Magnuson-Stevens Act Provisions; Scientific and Statistical Committees; Peer Review; National Standard Guidelines

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 revise National Standard 2 (NS2) guidelines regarding use of best scientific information available, in light of reauthorization of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). NMFS is considering modifying the language describing the content and purpose of the Stock Assessment and Fishery Evaluation (SAFE) Report or related documents, and adding language regarding peer review processes, the role of the scientific and statistical committees (SSCs) of the Regional Fishery Management Councils (Councils), and the relationship between peer reviews and SSCs.

DATES: Written comments must be received on or before 5 p.m., local time, December 17, 2008.

ADDRESSES: You may submit comments, identified by 0648–AW62, 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: William Michaels 301–713–1875.
- Mail: William Michaels, NOAA Fisheries Service, Office of Science and Technology, 1315 East-West Highway, F/ST4, Silver Spring, MD 20910.

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: Bill Michaels, 301–713–2363 x136.

SUPPLEMENTARY INFORMATION: On January 12, 2007, the Magnuson-Stevens Fishery Conservation and Management Reauthorization Act of 2006 (MSRA) was signed into law. The MSRA amendments to the Magnuson-Stevens Act included provisions to improve the use of science in decision-making, provide for a stronger role for Councils' SSCs and enhance peer review processes.

Currently, the NS2 guidelines address the use of best scientific information available to support fishery management actions, prescribe the content and purpose of SAFE reports or similar

documents, and assign responsibility for the preparation and review of SAFE reports to the Secretary of Commerce (Secretary). SAFE reports are intended to provide the Councils with a summary of current scientific information available to make management decisions and are intended to contain information upon which Councils are to base harvest specifications, including annual harvest levels from each stock. At this time, NS2 does not specifically mention that the SAFE should include SSC recommendations for acceptable biological catch from either the SSC or peer review process (established under Section 302(g)(1)(E) of the Magnuson-Stevens Act). SSC recommendations for acceptable biological catch are the basis upon which each Council is to set annual catch limits (ACLs), and ACLs are not to exceed these fishing level recommendations per Section 302(h)(6) of the Magnuson-Stevens Act. NMFS is considering, and is seeking public comment on how to revise the discussion of SAFE reports in the NS2 to include the scientific recommendations that are to be provided by the SSCs under the Magnuson-Stevens Act, as reauthorized.

NMFS is inviting comment on the extent to which the NS2 guidelines should provide guidance as to what constitutes ''best scientific information available.'' In 2004, the National Research Council (NRC) of the National Academies was charged with examining the application of the term ''best scientific information available'' as the basis for fishery conservation and management measures required under NS2 and recommended approaches for a more uniform application of the standard within the context of current and future fisheries management efforts. The NRC recommendations can be found in their publication, ''Improving the Use of the Best Scientific Information Available' Standard in Fisheries Management'' (NRC 2004,*http://books.nap.edu/openbook.php*). Although NMFS has informally adopted many of the NRC recommendations, this advanced notice of proposed rulemaking (ANPR) is an opportunity to solicit and incorporate recommendations into the NS2 guidance.

Section 302(g)(1)(E) of the Magnuson-Stevens Act provides that ''(T)he Secretary and each Council may establish a peer review process for that Council for scientific information used to advise the Council about the conservation and management of the fishery. The review process, which may include existing committees or panels, is deemed to satisfy the requirements of the guidelines issued pursuant to section 515 of the Treasury and General Government Appropriations Act for Fiscal year 2001,'' otherwise known as the Information Quality Act. At present, none of the 10 national standards, or national standard guidelines, directly discuss or provide guidance on peer review processes.

NMFS is considering expanding NS2 to include specific language regarding peer review processes. NS2 appears to be the logical national standard to provide further guidance regarding peer reviews, since a peer review process is one method for ensuring that the best scientific information available is utilized in Council decisions. This language may include minimum criteria for peer review processes, based in part on the public comments received. Furthermore, there may be a need to clarify the relationship between the peer review processes that may be established by the Secretary and each Council and the role of the SSC of that Council vis-á-vis the peer review process.

Finally, NMFS seeks comments from the public on other issues or clarifications to NS2 that the public would like to see addressed in this rulemaking.

Authority: 16 U.S.C. 1851.

Dated: September 15, 2008.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. E8–21837 Filed 9–17–08; 8:45 am]

BILLING CODE 3510–22–S

Notices

Federal Register

Vol. 73, No. 182

Thursday, September 18, 2008

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2008–0099]

Availability of an Environmental Assessment for Field Testing Rabies Vaccine, Live Raccoon Poxvirus Vector

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service has prepared an environmental assessment concerning authorization to ship for the purpose of field testing, and then to field test, an unlicensed Rabies Vaccine, Live Raccoon Poxvirus Vector. The environmental assessment, which is based on a risk analysis prepared to assess the risks associated with the field testing of this vaccine, examines the potential effects that field testing this veterinary vaccine could have on the quality of the human environment. Based on the risk analysis, we have reached a preliminary determination that field testing this veterinary vaccine will not have a significant impact on the quality of the human environment, and that an environmental impact statement need not be prepared. We intend to authorize shipment of this vaccine for field testing following the close of the comment period for this notice unless new substantial issues bearing on the effects of this action are brought to our attention. We also intend to issue a U.S. Veterinary Biological Product license for this vaccine, provided the field test data support the conclusions of the environmental assessment and the issuance of a finding of no significant impact and the product meets all other requirements for licensing.

DATES: We will consider all comments that we receive on or before October 20, 2008.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2008-0099* to submit or view comments and to view supporting and related materials available electronically.
- *Postal Mail/Commercial Delivery:* Please send two copies of your comment to Docket No. APHIS–2008–0099, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. APHIS–2008–0099.

Reading Room: You may read any comments that we receive on the environmental assessment 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.

Other Information: Additional information about APHIS and its programs is available on the Internet at *http://www.aphis.usda.gov*.

FOR FURTHER INFORMATION CONTACT: Dr. Albert P. Morgan, Section Leader, Operational Support Section, Center for Veterinary Biologics, Policy, Evaluation, and Licensing, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737–1231; phone (301) 734–8245, fax (301) 734–4314.

For information regarding the environmental assessment or the risk analysis, or to request a copy of the environmental assessment (as well as the risk analysis with confidential business information removed), contact Dr. Patricia L. Foley, Risk Manager, Center for Veterinary Biologics, Policy, Evaluation, and Licensing VS, APHIS, 510 South 17th Street, Suite 104, Ames, IA 50010; phone (515) 232–5785, fax (515) 232–7120.

SUPPLEMENTARY INFORMATION:

Background

Under the Virus-Serum-Toxin Act (21 U.S.C. 151 *et seq.*), a veterinary biological product must be shown to be pure, safe, potent, and efficacious before a veterinary biological product license may be issued. A field test is generally necessary to satisfy prelicensing requirements for veterinary biological products. Prior to conducting a field test on an unlicensed product, an applicant must obtain approval from the Animal and Plant Health Inspection Service (APHIS), as well as obtain APHIS' authorization to ship the product for field testing.

To determine whether to authorize shipment and grant approval for the field testing of the unlicensed product referenced in this notice, APHIS conducted a risk analysis to assess the potential effects of this product on the safety of animals, public health, and the environment. Based on the risk analysis, APHIS has prepared an environmental assessment (EA) concerning the field testing of the following unlicensed veterinary biological product:

Requester: Fort Dodge Animal Health, Division of Wyeth Corporation.

Product: Rabies Vaccine, Live Raccoon Poxvirus Vector.

Field Test Locations: Iowa, Indiana, Texas, North Carolina, Oklahoma, Wisconsin, New York, Illinois, Minnesota, and Kansas.

The above-mentioned product consists of a live recombinant raccoon poxvirus vector expressing rabies glycoprotein. The vaccine is for use in cats and dogs as an aid in the prevention of rabies virus infection.

The EA has been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Unless substantial issues with adverse environmental impacts are raised in response to this notice, APHIS intends to issue a finding of no significant impact (FONSI) based on the EA and authorize shipment of the above product for the initiation of field tests following

the close of the comment period for this notice.

Because the issues raised by field testing and by issuance of a license are identical, APHIS has concluded that the EA that is generated for field testing would also be applicable to the proposed licensing action. Provided that the field test data support the conclusions of the original EA and the issuance of a FONSI, APHIS does not intend to issue a separate EA and FONSI to support the issuance of the product license, and would determine that an environmental impact statement need not be prepared. APHIS intends to issue a veterinary biological product license for this vaccine following completion of the field test provided no adverse impacts on the human environment are identified and provided the product meets all other requirements for licensing.

Authority: 21 U.S.C. 151–159.

Done in Washington, DC, this 12th day of September 2008.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E8–21820 Filed 9–17–08; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS–2008–0019]

Codex Alimentarius Commission: Meeting of the Codex Committee on Nutrition and Foods for Special Dietary Uses

AGENCY: Office of the Under Secretary for Food Safety, USDA.

ACTION: Notice of public meeting and request for comments.

SUMMARY: The Office of the Under Secretary for Food Safety, U.S. Department of Agriculture (USDA), and the Food and Drug Administration (FDA), U.S. Department of Health and Human Services (HHS), are sponsoring a public meeting on September 24, 2008. The objective of the public meeting is to provide information and receive public comments on agenda items and draft United States positions that will be discussed at the 30th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) of the Codex Alimentarius Commission (Codex), which will be held in Capetown, South Africa, on November 3–November 7, 2008. In addition, a working group will meet on November 1, 2008, to discuss agenda items on the Scientific Basis of Health Claims and Nutrient Reference Values for food labeling purposes, and any other matters related to the World Health Organization's (WHO) Global Strategy on Diet, Physical Activity and Health which are under consideration by the CCNFSDU. The Under Secretary for Food Safety and FDA recognize the importance of providing interested parties the opportunity to obtain background information on the 30th Session of CCNFSDU and to address items on the agenda.

DATES: The public meeting is scheduled for Wednesday, September 24, 2008, from 1 p.m. to 4 p.m.

ADDRESSES: The public meeting will be held in the Auditorium (1A003), Food and Drug Administration, Harvey Wiley Federal Building, 5100 Paint Branch Parkway, College Park, MD 20740. Parking is adjacent to this building and will be available at no charge to individuals who pre-register by the date below (See Pre-Registration). In addition, the College Park metro station is across the street. Codex documents related to the 30th Session of the CCNFSDU will be accessible via the World Wide Web at the following address: *http://www.codexalimentarius.net/current.asp*.

Pre-Registration: To gain admittance to this meeting, individuals must present a photo ID for identification and also *are required to pre-register*. In addition, no cameras or videotaping equipment will be permitted in the meeting room. To pre-register, please send the following information to e-mail address *nancy.crane@fda.hhs.gov* by *September 17, 2008:*

—Your Name
—Organization
—Mailing Address
—Phone number
—E-mail address

FOR FURTHER INFORMATION ABOUT THE 30TH SESSION OF THE CCNFSDU CONTACT: Nancy Crane, Assistant to the U.S. Delegate to the CCNFSDU, Office of Nutrition, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition, FDA, 5100 Paint Branch Parkway (HFS–830), College Park, MD 20740, Phone: (301) 436–1450, Fax: (301) 436–2636, E-mail: *nancy.crane@fda.hhs.gov*.

FOR FURTHER INFORMATION ABOUT THE PUBLIC MEETING CONTACT: Edith Kennard, Staff Officer, U.S. Codex Office, Food Safety and Inspection Service (FSIS), Room 4861, South Building, 1400 Independence Avenue, SW., Washington, DC 20250, Phone: (202) 720–5261, Fax: (202) 720–3157, E-mail: *edith.kennard@fsis.usda.gov*.

SUPPLEMENTARY INFORMATION:

Background

The Codex Alimentarius (Codex) was established in 1963 by two United Nations organizations, the Food and Agriculture Organization and the WHO. Through adoption of food standards, codes of practice, and other guidelines developed by its committees, and by promoting their adoption and implementation by governments, Codex seeks to protect the health of consumers and ensure that fair practices are used in trade.

The CCNFSDU was established to study specific nutritional problems assigned to it by the Commission and advise the Commission on general nutritional issues; to draft general provisions as appropriate concerning the nutritional aspects of all foods; to develop standards, guidelines, or related texts for foods for special dietary uses in cooperation with other committees when necessary; and to consider, amend if necessary, and endorse provisions on nutritional aspects proposed for inclusion in Codex standards, guidelines, and related texts. The Committee is hosted by the Federal Republic of Germany.

Issues To Be Discussed at the Public Meeting

The following items on the agenda for the 30th Session of the CCNFSDU will be discussed during the public meeting:

- Matters Referred to the Committee from Other Codex Bodies (including the Global Strategy on Diet, Physical Activity and Health and Infant Formula Methods of Analysis);
- Guidelines for Use of Nutrition Claims: Draft Table of Conditions for Nutrient Contents: Part B, Containing Provisions on Dietary Fibre
- Draft Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Uses for Infants and Young Children: Part D Advisory List of Food Additives for Special Nutrient Forms: Provisions on Gum Arabic;
- Draft Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses;
- Proposed Draft Recommendations on the Scientific Basis of Health Claims;
- Proposal for New Work to Amend the Codex General Principles for the Addition of Essential Nutrients to Foods;
- Proposal for New Work to Establish a Standard for Processed Cereal-Based

Foods for Underweight Infants and Young Children;

• Additional or Revised Nutrient Reference Values (NRVs).

Each issue listed will be fully described in documents distributed, or to be distributed, by the Secretariat prior to the meeting. Members of the public may access copies of these documents at *http://www.codexalimentarius.net/current.asp.*

Public Meeting

At the September 24, 2008, public meeting, draft U.S. positions on these agenda items will be described and discussed, and attendees will have the opportunity to pose questions and offer comments. Written comments may be offered at the meeting or sent to the U.S. Delegate for the 30th Session of CCNFSDU, Dr. Barbara Schneeman, at *CCNFSDU@fda.hhs.gov.* Written comments should state that they relate to activities of the 30th Session of the CCNFSDU.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that minorities, women, and persons with disabilities are aware of this notice, FSIS will announce it online through the FSIS Web page located at *http://www.fsis.usda.gov/regulations/2008_Notices_Index/.* FSIS will also make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. Through the Listserv and Web page, FSIS is able to provide information to a much broader and more diverse audience. In addition, FSIS offers an e-mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at *http://www.fsis.usda.gov/news_and_events/email_subscription/.* Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves, and they have the option to password protect their accounts.

Done at Washington, DC, on September 15, 2008.

Karen L. Hulebak,

Acting U.S. Manager for Codex Alimentarius.

[FR Doc. E8–21829 Filed 9–17–08; 8:45 am]

BILLING CODE 3410–DM–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) invites comments on the following information collections for which RUS intends to request approval from the Office of Management and Budget (OMB).

DATES: Comments on this notice must be received by November 17, 2008.

FOR FURTHER INFORMATION CONTACT: Michele Brooks, Director, Program Development and Regulatory Analysis, USDA Rural Development, 1400 Independence Ave., SW., STOP 1522, Room 5818, South Building, Washington, DC 20250–1522. *Telephone:* (202) 690–1078. *Fax:* (202) 720-8435.

SUPPLEMENTARY INFORMATION: The Office of Management and Budget's (OMB) regulation (5 CFR 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 information collections that RUS is submitting to OMB for extension.

Comments are invited on: (a) Whether this 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 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 respondents, 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 Brooks, Director, Program Development and Regulatory Analysis, USDA Rural Development, STOP 1522, 1400 Independence Ave., SW., Washington, DC 20250–1522. Fax: (202) 720–8435.

Title: Review Rating Summary, RUS Form 300, 7 CFR Part 1730.

OMB Control Number: 0572–0025.

Type of Request: Extension of a currently approved collection.

Abstract: The RUS manages loan programs in accordance with the RE Act of 1936, as amended (7 U.S.C. 901 *et seq.*). An important part of safeguarding loan security is to see that RUS financed facilities are being responsibly used, adequately operated, and adequately maintained. Future needs have to be anticipated to ensure that facilities will continue to produce revenue and that loans will be repaid as required by the RUS mortgage. A periodic operations and maintenance (O&M) review, using the RUS Form 300, in accordance with 7 CFR Part 1730, is an effective means for RUS to determine whether the borrowers systems are being properly operated and maintained, thereby protecting the loan collateral. An O&M review is also used to rate facilities and can be used for appraisals of collateral as prescribed by OMB Circular A–129, Policies for Federal Credit Programs and Non-Tax Receivables.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 4 hours per response.

Respondents: Not-for-profit institutions.

Estimated Number of Respondents: 229.

Estimated Number of Responses per Respondent: 10.

Estimated Total Annual Burden on Respondents: 916 hours.

Title: Use of Consultants Funded by Borrowers, 7 CFR Part 1789.

OMB Control Number: 0572–0115.

Type of Request: Extension of a currently approved collection.

Abstract: Section 18(c) of the Rural Electrification Act of 1936 (RE Act), as amended (7 U.S.C. 901 *et seq.*) authorizes RUS to use consultants voluntarily funded by borrowers for financial, legal, engineering and other technical services. Consultants may be used to facilitate timely action on loan applications by borrowers for financial assistance and for approvals required by RUS, pursuant to the terms of outstanding loans, or otherwise. RUS may not require borrowers to fund consultants. The provision of section 18(c) may be utilized only at the borrower's request. This collection of

information implements RUS policies and procedures for use of consultants funded by RUS borrowers to facilitate timely action on a borrower's loan application for financial assistance and for RUS approvals.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 2 hours per response.

Respondents: Not-for-profit institutions; business or other for-profit entities.

Estimated Number of Respondents: 6.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 12 hours.

Copies of this information 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: September 11, 2008.

James M. Andrew,

Administrator, Rural Utilities Service.

[FR Doc. E8–21797 Filed 9–17–08; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF COMMERCE

Foreign–Trade Zones Board

[Docket 24–2008]

Foreign–Trade Zone 161 - Sedgwick County, Kansas

Amendment to Application for Subzone Status

Hawker Beechcraft Corporation

(Aircraft Manufacturing)

Wichita and Salina, Kansas

A request has been submitted to the Foreign–Trade Zones Board (the Board) by Hawker Beechcraft Corporation (HBC) to amend the company's application requesting special–purpose subzone status for the company's aircraft manufacturing facilities located in Wichita and Salina, Kansas.

HBC is now requesting to include additional finished products in the company's requested scope of authority. The additional finished products will be manufactured using the same imported parts and components (duty–free to 15 percent) as described in the original **Federal Register** notice (73 FR 21903–21904, 4/23/08). The additional finished products (duty–free) are as follows: propellers, rotors and parts thereof (8803.10); undercarriages and parts thereof (8803.20); and, other parts of airplanes (8803.30).

Public comment is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at the address listed below. The closing period for their receipt is October 20, 2008. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15–day period (to November 3, 2008).

A copy of the application amendment and accompanying exhibits will be available at each of the following addresses: U. S. Department of Commerce Export Assistance Center, 150 North Main Street, Suite 200, Wichita, Kansas; and, Office of the Executive Secretary, Foreign–Trade Zones Board, Room 2111, U.S. Department of Commerce, 1401 Constitution Avenue, NW, Washington, D.C., 20230. For further information contact Christopher Kemp at christopher__kemp@ita.doc.gov or (202) 482–0862.

Dated: September 4, 2008.

Andrew McGilvray,

Executive Secretary.

[FR Doc. E8–21850 Filed 9–17–08; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

Foreign–Trade Zones Board

[Order No. 1571]

Application for Subzone Status Not Approved

Johnson Controls Battery Group, Inc.

Yuma, Arizona

Pursuant to its authority under the Foreign–Trade Zones Act, of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign–Trade Zones Board (the Board) adopts the following Order:

Whereas, the Foreign–Trade Zones Act provides for ''. . . the establishment . . . of foreign–trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes,'' and authorizes the Foreign–Trade Zones Board to grant to qualified corporations the privilege of establishing foreign–trade zones in or adjacent to U.S. Customs and Border Protection ports of entry;

Whereas, the Board's regulations (15 CFR Part 400) provide for the establishment of special–purpose subzones when existing zone facilities cannot serve the specific use involved, and when the activity results in a significant public benefit and is in the public interest;

Whereas, the Yuma County Airport Authority, grantee of FTZ 219, has made application to the Board for authority to establish special–purpose subzone status at the lead–acid battery manufacturing facility of Johnson Controls Battery Group, Inc., located in Yuma, Arizona (FTZ Docket 48–2007, filed 09–28–07);

Whereas, notice inviting public comment has been given in the **Federal Register** (72 FR 57287–57288, 10/09/2007); and,

Whereas, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and the Board's regulations have not been satisfied and that approval of the application would not be in the public interest;

Now, therefore, the Board hereby does not approve the application for subzone status at the lead–acid battery manufacturing facility of Johnson Controls Battery Group, Inc., located in Yuma, Arizona.

Signed at Washington, DC, this 2 nd day of September 2008.

David M. Spooner,

Assistant Secretary of Commerce for Import Administration.

Alternate Chairman Foreign–Trade Zones Board.

ATTEST:

Andrew McGilvray,

Executive Secretary.

[FR Doc. E8–21848 Filed 9–17–08; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

Foreign–Trade Zones Board

[Order No. 1573]

Approval for Manufacturing Authority

Fuji Vegetable Oil, Inc.

(Vegetable Oil Products)

Savannah, Georgia

Pursuant to its authority under the Foreign–Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign–Trade Zones Board (the Board) adopts the following Order:

WHEREAS, the Savannah Airport Commission, grantee of FTZ 104, has requested manufacturing authority within FTZ 104 -- Site 2, in Savannah, Georgia (FTZ Docket 51–2007, filed 12/14/07);

WHEREAS, notice inviting public comment has been given in the **Federal Register** (72 FR 73314, 12/27/07); and,

WHEREAS, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and the Board's regulations are satisfied, and that approval of the application is in the public interest;

NOW, THEREFORE, the Board hereby grants authority for the manufacture of vegetable oil products within FTZ 104 on behalf of Fuji Vegetable Oil, Inc., as described in the application and **Federal Register** notice, subject to the FTZ Act and the Board's regulations, including Section 400.28.

Signed at Washington, DC, this 2nd day of September 2008.

David M. Spooner,

Assistant Secretary of Commerce for Import Administration.

Alternate Chairman Foreign–Trade Zones Board.

ATTEST:

Andrew McGilvray,

Executive Secretary.

[FR Doc. E8–21849 Filed 9–17–08; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

Foreign–Trade Zones Board

[Order No. 1574]

Grant of Authority For Subzone Status

Banner Pharmacaps, Inc.

(Prescription Pharmaceuticals and Soft Gelatin Capsules)

High Point, North Carolina

Pursuant to its authority under the Foreign–Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign–Trade Zones Board (the Board) adopts the following Order:

WHEREAS, the Foreign–Trade Zones Act provides for " . . . the establishment . . . of foreign–trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes," and authorizes the Foreign–Trade Zones Board to grant to qualified corporations the privilege of establishing foreign–trade zones in or adjacent to U.S. Customs and Border Protection ports of entry;

WHEREAS, the Board's regulations (15 CFR Part 400) provide for the establishment of special–purpose subzones when existing zone facilities cannot serve the specific use involved, and when the activity results in a significant public benefit and is in the public interest;

WHEREAS, the Piedmont Triad Partnership, grantee of FTZ 230, has made application to the Board for authority to establish special–purpose subzone status at the pharmaceutical manufacturing plant of Banner Pharmacaps, Inc., located in High Point, North Carolina (FTZ Docket 8–2008, filed 2/12/08);

WHEREAS, notice inviting public comment has been given in the **Federal Register** (73 FR 10421, 2/27/08); and,

WHEREAS, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and the Board's regulations are satisfied, and that approval of the application is in the public interest;

NOW, THEREFORE, the Board hereby grants authority for subzone status for activity related to certain prescription pharmaceutical product and soft gelatin capsule manufacturing at the Banner Pharmacaps, Inc., facility located in High Point, North Carolina (Subzone 230C), as described in the application and **Federal Register** notice, and subject to the FTZ Act and the Board's regulations, including Section 400.28.

Signed at Washington, DC, this 2nd day of September 2008.

David M. Spooner,

Assistant Secretary of Commerce for Import Administration.

Alternate Chairman Foreign–Trade Zones Board.

ATTEST:

Andrew McGilvray,

Executive Secretary.

[FR Doc. E8–21847 Filed 9–17–08; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 1572]

Grant of Authority for Subzone Status; Kravet, Inc.

(Textile Distribution and Sampling) Anderson, SC

Pursuant to its authority under the Foreign-Trade Zones Act, of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Foreign-Trade Zones Act provides for "* * *the establishment* * * of foreign-trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes," and authorizes the Foreign-Trade Zones Board to grant to qualified corporations the privilege of establishing foreign-trade zones in or adjacent to U.S. Customs and Border Protection ports of entry;

Whereas, the Board's regulations (15 CFR Part 400) provide for the establishment of special-purpose subzones when existing zone facilities cannot serve the specific use involved, and when the activity results in a significant public benefit and is in the public interest;

Whereas, the South Carolina State Ports Authority, grantee of Foreign-Trade Zone 38, has made application to the Board for authority to establish a special-purpose subzone at the textile distribution and sampling facility of Kravet, Inc., located in Anderson, South Carolina (FTZ Docket 10–2007, filed 3–6–07);

Whereas, notice inviting public comment was given in the **Federal Register** (72 FR 13081, 3/20/2007); and,

Whereas, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and the Board's regulations would be satisfied, and that approval of the application would be in the public interest if subject to the restrictions and limitations listed below;

Now, therefore, the Board hereby grants authority for subzone status for activity related to the distribution and sampling of textiles at the facility of Kravet, Inc., located in Anderson, South Carolina (Subzone 38G), as described in the application and **Federal Register** notice, subject to the FTZ Act and the Board's regulations, including section 400.28, and further subject to the following restrictions and limitations:

1. Privileged foreign status (19 CFR 146.41) shall be elected on all foreign status merchandise;

2. No activity under FTZ procedures shall be permitted that would result in a shift in HTSUS classification.

Signed at Washington, DC, this 10th day of September 2008.

David M. Spooner,

Assistant Secretary of Commerce for Import Administration, Alternate Chairman, Foreign-Trade Zones Board.

ATTEST:

Andrew McGilvray,
Executive Secretary.

[FR Doc. E8–21882 Filed 9–17–08; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–552–802]

Third Antidumping Duty Administrative Review of Certain Frozen Warmwater Shrimp from the Socialist Republic of Vietnam: Extension of Time Limit for the Preliminary Results

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: September 18, 2008.

FOR FURTHER INFORMATION CONTACT: Paul Walker, AD/CVD Operations, Office 9, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington DC 20230; telephone: (202) 482–0413.

Background

On April 7, 2008, the Department of Commerce (''Department'') published a notice of initiation of an administrative review of certain frozen warmwater shrimp from the Socialist Republic of Vietnam (''Vietnam''), covering the period February 1, 2007 – January 31, 2008. *See Notice of Initiation of Administrative Reviews of the Antidumping Duty Orders on Frozen Warmwater Shrimp from the Socialist Republic of Vietnam and the People's Republic of China*, 73 FR 18739 (Aprl 7, 2008) (''Initiation''). On June 9, 2008, after receiving comments on U.S. Customs and Border Protection data, the Department selected the mandatory respondents for this review. From July 1, 2008 to August 13, 2008, the mandatory respondents responded to the Department's antidumping duty questionnaire. The preliminary results of this administrative review are currently due on October 31, 2008.

Extension of Time Limit for the Preliminary Results

Section 751(a)(3)(A) of the Tariff Act of 1930, as amended (''the Act''), requires the Department to issue the preliminary results of an administrative review within 245 days after the last day of the anniversary month of an order for which a review is requested. If it is not practicable to complete the review within the time period, section 751(a)(3)(A) of the Act allows the Department to extend this deadline to a maximum of 365 days.

The Department determines that completion of the preliminary results of this review within the statutory time period is not practicable, given the extraordinarily complicated nature of the proceeding. The Department requires more time to gather and analyze a significant amount of information pertaining to each of the mandatory respondents' corporate structure and ownership, sales practices, and manufacturing methods. The Department also requires additional time to analyze the questionnaire responses and to issue supplemental questionnaires. Therefore, given the number and complexity of issues in this case, and in accordance with section 751(a)(3)(A) of the Act, we are extending the time period for issuing the preliminary results of review by 120 days until March 2, 2009. The final results continue to be due 120 days after the publication of the preliminary results.

This notice is published pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(2).

Dated: September 11, 2008.

Stephen J. Claeys,

Deputy Assistant Secretary for Import Administration.

[FR Doc. E8–21883 Filed 9–17–08; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

Notice: Request for Applications, Commerce Spectrum Management Advisory Committee; Correction

AGENCY: National Telecommunications and Information Administration, U.S. Department of Commerce.

ACTION: Reopening of Application Period; Date Correction

SUMMARY: On September 10, 2008, the National Telecommunications and Information Administration (NTIA) published a notice in the **Federal Register**, 73 Fed. Reg. 52646, reopening the deadline for applications from persons interested in serving on the Commerce Spectrum Management Advisory Committee (CSMAC) for new two year terms to commence in December 2008. Due to an administrative error, the application due date published in that notice was incorrect. This notice corrects that error.

DATES: Applications must be postmarked or electronically transmitted on or before September 26, 2008.

ADDRESSES: Persons wishing to submit applications should send their resume or curriculum vita and a statement summarizing the qualifications of the nominee and identifying any particular expertise or area of interest relevant to the CSMAC's work to the attention of Eric Stark, Designated Federal Officer, by mail to Office of Policy Analysis and Development, National Telecommunications and Information Administration, 1401 Constitution Avenue N.W., Room 4725, Washington, DC 20230; by facsimile transmission to (202) 482–6173; or by electronic mail to *spectrumadvisory@ntia.doc.gov.*

FOR FURTHER INFORMATION CONTACT: Eric Stark at (202) 482–1880 or *estark@ntia.doc.gov*; or Joe Gattuso at (202) 482–0977 or *jgattuso@ntia.doc.gov*.

SUPPLEMENTARY INFORMATION: For more information regarding the Commerce Spectrum Management Advisory Committee, please refer to NTIA's website at *http://www.ntia.doc.gov/advisory/spectrum/.*

Dated: September 15, 2008.

Kathy D. Smith,

Chief Counsel, National Telecommunications and Information Administration.

[FR Doc. E8–21893 Filed 9–17–08; 8:45 am]

BILLING CODE 3510–60–S

DEPARTMENT OF DEFENSE

Department of the Air Force

Notice of Intent

AGENCY: United States Air Force, Air Mobility Command, Federal Aviation Administration.

ACTION: Notice of intent.

Authority: 42 U.S.C. 4321—4347; 40 CFR Parts 1500–1508; and 32 CFR part 989.

SUMMARY: The Air Force issues this notice to advise the public of its intent to prepare an Environmental Impact Statement (EIS) for the Beddown and Flight Operations of Unmanned Aerial Systems (UAS) at Grand Forks Air Force Base, North Dakota. The EIS will assess the potential environmental impacts associated with the proposed beddown and flight operations of unmanned aerial systems (UASs) at Grand Forks Air Force Base (GFAFB). The proposal responds to the 2005 Base Realignment and Closure (BRAC) decision to beddown the emerging UAS mission at GFAFB and entails restructuring airspace in the vicinity of GFAFB to allow for the safe training and operations of UASs. Additional information is available at the project Web site listed below.

DATES: Four scoping meetings will be held as follows:

1. October 6, 2008; 4 p.m., Grand Forks, ND.

2. October 7, 2008; 4 p.m., Devils Lake, ND.

3. October 8, 2008; 4 p.m., Langdon, ND.

4. October 9, 2008, 4 p.m., Carrington, ND.

ADDRESSES: 1. Grand Forks—Red River High School, 2211 17th Avenue.

2. Devils Lake—Lake Region State College, Dining Room, 1801 College Drive.

3. Langdon—North Dakota State University, Langdon Research Extension Center, 9280 107th Ave NE.

4. Carrington—Carrington High School Common Area, 100 3rd Ave S.

FOR FURTHER INFORMATION CONTACT: Mr. Doug Allbright, 618–229–0846.

SUPPLEMENTARY INFORMATION: Headquarters Air Mobility Command (HQ AMC), the Air National Guard (ANG), the Air Combat Command (ACC) and the 319th Airlift Refueling Wing (319 ARW) would provide the required equipment, facilities, necessary infrastructure, staffing and airspace to support the 2005 Base Realignment and Closure (BRAC) decision to beddown the emerging UAS mission at GFAFB. The Federal Aviation Administration is participating in this process as a Cooperating Agency.

The proposed action, Alternative A, would restructure airspace in the vicinity of GFAFB to allow for the safe training and operations of UASs. These modifications would include establishing a restricted area above GFAFB, converting a portion of the existing Tiger and Devils Lake Military Operations Areas (MOAs) to restricted airspace, expanding the Camp Grafton restricted area (R–5401) for the use of non-eye safe lasers, and creating restricted corridors to link the training areas with GFAFB. Use of non-eye safe lasers at Camp Grafton would be contained within the existing land boundaries of Camp Grafton. These airspace changes would allow UAS pilots to receive the training necessary to remain proficient in operating these aircraft.

Alternatives: Three action alternatives and a no-action alternative have initially been identified for analysis, they include:

Alternative A: This alternative consists converting a portion of the Tiger and Devils Lake MOAs to restricted airspace, creating four new restricted airspace areas and expanding airspace at Camp Grafton. The new areas consist of a UAS arrival and departure airspace area, two Predator transit corridors, and a north-south Predator access corridor. Existing restricted airspace above Camp Grafton would be expanded for use of the non-eye safe Predator laser. Minor building renovations and the installation of two aviation fuel tanks at GFAFB would also be required.

Alternative B: This alternative consists of converting the entire Tiger and Devils Lake MOAs to restricted airspace, establishing three new restricted areas and expanding airspace at Camp Grafton for use of the non-eye safe Predator laser. The new airspace would consist of a UAS arrival and departure airspace area and two Predator transit corridors. The minor renovation and tank installation would also occur under this alternative.

Alternative C: This alternative consists of the actions proposed in Alternative A along with the construction of a new UAS hangar at GFAFB.

No Action: This alternative consists of no changes to the existing airspace structure around GFAFB and no renovation or construction would occur at GFAFB to accommodate the 2005 BRAC recommendations.

Direct written comments to: HQ AMC/A7PI, 507 Symington Drive; Scott Air Force Base, Illinois 62225 or via the project Web site at: *http://www.grandforksuaseis.com*. All are encouraged to provide comments on the proposed action either at the scoping meetings or by mail, postmarked no later than 30 October 2008 to ensure proper consideration in the environmental impact analyses.

Bao-Anh Trinh,

Air Force Federal Register Liaison Officer.

[FR Doc. E8–21880 Filed 9–17–08; 8:45 am]

BILLING CODE 5001–05–P

DEPARTMENT OF DEFENSE

Air Force Department

Exchange of Air Force Real Property for Military Construction

ACTION: Notice.

Authority: Title 10, United States Code, Section 2869(d)(1).

SUMMARY: This Notice identifies excess Federal property under the administrative jurisdiction of the United States Air Force that the Air Force intends to exchange for military construction beneficial to the Air Force.

FOR FURTHER INFORMATION CONTACT: Mr. Sam Rupe, Office of the Air Force General Counsel (SAF/GCN–RPO), 143 Billy Mitchell Blvd., Suite 1, San Antonio, TX 78226–1816; telephone (210) 925–0227, (this telephone number is not toll-free).

SUPPLEMENTARY INFORMATION: In accordance with 10 U.S.C. 2869(d)(1), the Air Force is publishing this Notice to identify Federal real property that the Air Force intends to dispose of in exchange for military construction beneficial to the Air Force.

Description of the Air Force property:

Former Lynn Haven Defense Fuel Depot, Lynn Haven, FL.

Property Number:

Status: Excess.

Comments: Fuel operations at the Fuel Depot ceased in 1992, and the property has undergone considerable environmental remediation. The property proposed for exchange is approximately 144 acres of real property located off West 10th Street, Lynn Haven, FL 32444. About 50 acres is a railway right-of-way extending about 3.7 miles that intersects several major arterial roads.

Military construction sought:

After completion of a competitive bid process, the Air Force will enter into an agreement with the selected offeror/property recipient to construct military construction projects at Tyndall Air Force Base, FL. The specific projects that will be constructed will depend on the amount of construction value offered by the prospective property recipient.

Bao-Anh Trinh,

Air Force Federal Register Liaison Officer.

[FR Doc. E8–21833 Filed 9–17–08; 8:45 am]

BILLING CODE 5001–05–P

DEPARTMENT OF EDUCATION

Submission for OMB Review; Comment Request

AGENCY: Department of Education.

ACTION: Correction notice.

SUMMARY: On September 11, 2008, a 30-day notice published a comment period notice in the **Federal Register**, (Page 52848, Column 3) for the information collection, ''Leveraging Educational Technology to Keep America Competitive: National Teacher Technology Study.'' In that notice 2,300 responses and 750 burden hours were provided. This correction notice provides the correct number of responses as 3,285 and 882 burden hours. The IC Clearance Official Regulatory Management Services, Office of Management, hereby issues a correction notice as required by the Paperwork Reduction Act of 1995.

Dated: September 11, 2008.

Angela C. Arrington,

IC Clearance Official, Regulatory Information Management Services, Office of Management.

[FR Doc. E8–21609 Filed 9–17–08; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Submission for OMB Review; Comment Request

AGENCY: Department of Education.

SUMMARY: The IC Clearance Official, Regulatory Information Management Services, Office of Management invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before October 20, 2008.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Education Desk Officer, Office of Management and Budget, 725 17th Street, NW., Room 10222, Washington, DC 20503. Commenters are encouraged to submit responses electronically by e-mail to *oira_submission@omb.eop.gov* or via fax to (202) 395–6974. Commenters should include the following subject line in their response ''Comment: [insert OMB number], [insert abbreviated collection name, e.g., ''Upward Bound Evaluation'']. Persons submitting comments electronically should not submit paper copies.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The IC Clearance Official, Regulatory Information Management Services, Office of Management, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g. new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.

Dated: September 10, 2008.

Angela C. Arrington,

IC Clearance Official, Regulatory Information Management Services, Office of Management.

Office of Special Education and Rehabilitative Services

Type of Review: New.

Title: Annual Progress Report for the Access to Telework Program under the Rehabilitation Act of 1973, as Amended.

Frequency: Annually.

Affected Public: Individuals or household; Not-for-profit institutions; Federal Government; State, Local, or Tribal Gov't, SEAs or LEAs.

Reporting and Recordkeeping Hour Burden:

Responses: 19.

Burden Hours: 238.

Abstract: Nineteen states currently have Access to Telework programs that provide financial loans to individuals with disabilities for the purchase of computers and other equipment that support teleworking for an employer or self-employment on a full or part-time basis. These grantees are required to report annual data on their programs to the Rehabilitation Services Administration. This information collection provides a standard format for the submission of those annual performance reports and a follow-up survey to be administered to individuals who receive loans.

Requests for copies of the information collection submission for OMB review may be accessed from *http://edicsweb.ed.gov,* by selecting the ''Browse Pending Collections'' link and by clicking on link number 3757. 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., LBJ, Washington, DC 20202–4537. Requests may also be electronically mailed to *ICDocketMgr@ed.gov* or faxed to 202–401–0920. 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* 202–260–9404. 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. E8–21610 Filed 9–17–08; 8:45 am]

BILLING CODE 4000–01–P

ELECTION ASSISTANCE COMMISSION

Publication of State Plan Pursuant to the Help America Vote Act

AGENCY: U.S. Election Assistance Commission (EAC).

ACTION: Notice.

SUMMARY: Pursuant to sections 254(a)(11)(A) and 255(b) of the Help America Vote Act (HAVA), Public Law 107–252, the U.S. Election Assistance Commission (EAC) hereby causes to be published in the **Federal Register** changes to the HAVA State plan previously submitted by Georgia.

DATES: This notice is effective upon publication in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Bryan Whitener, Telephone 202–566–3100 or 1–866–747–1471 (toll-free).

Submit Comments: Any comments regarding the plans published herewith should be made in writing to the chief election official of the individual State at the address listed below.

SUPPLEMENTARY INFORMATION: On March 24, 2004, the U.S. Election Assistance Commission published in the **Federal Register** the original HAVA State plans filed by the fifty States, the District of Columbia and the Territories of American Samoa, Guam, Puerto Rico, and the U.S. Virgin Islands. 69 FR 14002. HAVA anticipated that States, Territories and the District of Columbia would change or update their plans from time to time pursuant to HAVA section 254(a)(11) through (13). HAVA sections 254(a)(11)(A) and 255 require EAC to publish such updates. This is Georgia's first revision to its State plan.

The revised State plan from Georgia addresses changes in the budget of the previously submitted State plan and accounts for the use of Fiscal Year 2008 requirements payments. The State has changed the focus of its plan from the initial deployment of voting system components and the related education of the public and local election officials to the continued maintenance of Georgia's voting system and the replacement of the State's voter registration database. In accordance with HAVA section 254(a)(12), the State plan submitted for publication provides information on how the State succeeded in carrying out its previous State plan. The State confirms that these changes to its State plan were developed and

submitted for public comment in accordance with HAVA sections 254(a)(11), 255, and 256.

Upon the expiration of thirty days from September 18, 2008, the State is eligible to implement the changes addressed in the plan that is published herein, in accordance with HAVA section 254(a)(11)(C).

EAC wishes to acknowledge the effort that went into revising this State plan and encourages further public comment, in writing, to the State election official listed below.

Chief State Election Official

The Honorable Karen C. Handel, Secretary of State, 2 Martin Luther King Jr. Drive SE., Suite 1104 West Tower, Atlanta, Georgia 30334, Phone: (404) 657–5380, Fax: (404) 657–5371. Thank you for your interest in improving the voting process in America.

Dated: September 12, 2008.

Thomas R. Wilkey,

Executive Director, U.S. Election Assistance Commission.

2008 STATE PLAN, AMENDED

Help America Vote Act of 2002

State of Georgia

Plan amended and submitted by Karen Handel, Secretary of State, August 6, 2008.

As required by Public Law 107–252, Help America Vote Act 2002, Section 253(b).

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Appendix 1—2003 Status & Implementation

Preamble

This document is Georgia's current plan for continuing implementation of the Help America Vote Act (HAVA). The 2008 HAVA State Plan, Amended presents Georgia's historic election reform process that supported the creation of the 2003 HAVA State Plan, a summary of how the 2003 plan was implemented, and plans for upcoming years.

Part One of this plan memorializes important historical context preceding the 2003 Georgia State Plan. Georgia is justifiably proud of having initiated important election reforms in anticipation of HAVA. Many of HAVA's requirements had already been implemented in Georgia by the November 2002 general election. Hence, Georgia's 2003 HAVA State Plan reflected a starting place that was significantly further ahead of most other states at that time.

Part Two of the 2008 HAVA State Plan, Amended describes how Georgia has implemented its previous state plan (Chapter 4) and presents its plans for upcoming years (Chapter 5). While fully compliant with HAVA, Georgia is committed to on-going improvements. In that spirit, the 2008 HAVA State Plan, Amended focuses on: (1) Replacing Georgia's 1993 computer system supporting voter registration and elections management; (2) replacing components to preserve the reliable, accurate performance of Georgia's statewide uniform electronic voting system; and (3) continuing other successful initiatives that have proven valuable during the past 7 years.

Activity under the 2003 State Plan had $77,304,946 in Federal funds available, plus State funds in excess of the required 5 percent match. Funds available for activity in the 2008 State Plan, Amended total $4,971,521 as shown in Table 1.

TABLE 1—AVAILABLE FUNDING FOR 2008 HAVA STATE PLAN, AMENDED

	Federal funds	State match	Total
Remaining Title I Funds	$1,137,260	(already spent)	$1,137,260
Remaining Title II Funds	497,587	(already spent)	497,587
2008 Funds Title II	3,169,840	$166,834	3,336,674
Total Funds Available			4,971,521

Part One

Chapter 1—Historical Election Challenges

America's elections were primarily conducted by county and municipal governments through the year 2000. In Georgia, each county was responsible for the selection and purchase of the county voting system. The local election superintendent was responsible for the maintenance and testing of the voting systems as well as for the layout and printing of election ballots pursuant to state law.

In the November 2000 General Election, 93,991 ballots in the State of Georgia did not register a vote in the Presidential race, because: (1) The voter accidentally marked more than one vote for the office; (2) the voter attempted to make a choice, but did not mark the ballot correctly; (3) the voting device failed to count the vote cast; or (4) the voter chose not to vote for the President.

To evaluate the conduct of elections in Georgia during the weeks following the November 2000 General Election, the Secretary of State compiled and analyzed information from citizen complaints, minutes of public hearings conducted by the NAACP, concerns submitted by the League of Women Voters, and dozens of interviews of local election superintendents, voter registrars, and political party leaders. As a result of this analysis, the following issues were identified as affecting Georgia's elections:

1. Outdated voting equipment;
2. Ballot problems;
3. Lines too long & other polling place deficiencies;
4. Shortage of trained poll workers;

5. Election law violations;

6. Slow processing of Absentee Ballots;

7. Growth of ''language minorities'';

8. State mainframe computer system unreliable;

9. Counties slow to report election results; and

10. Voter registration process costly and slow.

The Secretary of State also noted that the state was using four different types of voting systems, that no uniformity existed among the counties for counting votes, and that each system experienced a significant amount of under-votes. An analysis was then conducted of the under-votes that occurred on each type of voting system on a county-by county basis. In the 2000 General Election, the average percentage of under-votes for each system used in the State for all counties was 3.6%.

A summary of results is shown in Table 2 below.

TABLE 2—VOTING EQUIPMENT PERFORMANCE

[2000 general election]

Voting system	Year invented	Introduced in Georgia	Counties using system	Under vote percentage	Votes not counted
Paper ballot	1889	1900	2	3.3	113
Punch card	1890	1964	17	4.6	38,065
Lever machine	1892	1950	73	4.2	16,926
Optical-scan	1980	1986	67		
—Central count				4.2	21,999
—Precinct count				4.7	16,196

A report compiling the results of the study was prepared and presented to the Governor and the Members of the General Assembly with the following recommendations:

1. *Adopt a Statewide Uniform Electronic Voting Initiative*—Authorize, fund, and deploy a Statewide Uniform Electronic Voting Initiative (SUEVI) to create a single uniform method of voting consistent in every county in the state;

2. *Implement Early Voting*—Enhance polling place convenience and reduce Election Day waiting;

3. *Overhaul the Voter Registration System*—Upgrade the state's voter registration database from the slow, unreliable, inflexible, and expensive mainframe system to a flexible state-of-the-art server-based system;

4. *Pursue Poll Worker & Poll Location Alternatives*—Seek new alternatives to assist counties in securing new poll locations and recruiting and training poll workers, both of which are in short supply;

5. *Streamline Polling Place Procedures*—Reduce or eliminate burdensome paperwork and procedures at the polls and move voters more quickly through the voting process;

6. *Consolidate Authority to Remove Deceased Voters from Voter List*—Authorize the Secretary of State to remove deceased voters from the voter rolls to assure a more accurate voter list, (responsibility that previously rested solely with the counties); and

7. *Modernize Voter Information Resources*—Use new centralized technology solutions to offer citizens quicker, easier means to locate their precinct and verify their voter registration.

The Secretary's report to the Governor and the Members of the General Assembly recommended that the State adopt a single uniform voting platform. Importantly, it also initiated a shift in policy—transferring a portion of election responsibilities from the counties and election superintendents to the State for funding and deployment of a new statewide election system.

Chapter 2—Election Reform (2001–2002)

2.1 Direction in Code and Rule

Recognizing the need to address concerns with the elections process, the General Assembly enacted bipartisan legislation, Senate Bill 213, (hereinafter ''SB 213'') which the Governor signed into law on April 18, 2001. *Official Code of Georgia Code Annotated § 21–2–300* (hereinafter O.C.G.A. § 21–2–300). This legislation established the policy and the statutory framework for Georgia to begin identifying and deploying essential changes to its election system.

Chief among the changes to the election system was the policy directive that the Secretary of State would purchase and deploy a uniform voting system for casting and counting votes in all county, state and federal elections by the July 2004 General Primary. The Secretary of State was authorized to deploy to the counties a voting system that met requirements established by the Secretary of State. *O.C.G.A. § 21–2–300 (a).* On August 30, 2002, the State Election Board advanced the implementation date to the November 2002 General Election with Rule 183–1–12–.01. With adoption of this directive, Georgia became the first state in the nation to set a deadline for the implementation of a modern uniform statewide voting system.

O.C.G.A. § 21–2–300 also authorized the Secretary of State to conduct a pilot project to test and evaluate the use of electronic voting systems during the 2001 municipal elections. It created the 21st Century Voting Commission (hereinafter ''Voting Commission'') to oversee the pilot project. The statute further authorized the Voting Commission to make recommendations to the General Assembly and the Secretary of State.

2.2 The 21st Century Voting Commission

The purpose of the Voting Commission was to:

1. Oversee the electronic voting pilot project,

2. Test direct recording electronic (DRE) voting equipment,

3. Advise the Secretary of State on the choice of voting equipment to be used statewide in all counties pursuant to O.C.G.A. § 21–2–300, and

4. Report findings to the Governor and the General Assembly by December 31, 2001.

The Voting Commission included four Democrats, four Republicans, eight Non-Partisan members, one Independent, and one member of the Libertarian Party of Georgia, six local county election officials, the Director of the State Elections Division, as well as five members of the Georgia General Assembly (three from the House and two from the Senate). The Voting Commission also accepted input from various public interest groups representing minorities, disabled voters and multi-lingual groups.

As its first priority, the Voting Commission investigated voting systems and established standards that a voting system would have to meet in order to

be considered for the pilot project and use in the State of Georgia. The standards included:

1. A convenient and intuitive voter interface;
2. Features that prohibit duplicate, or over-votes;
3. Opportunity to correct under-vote or over-votes on ballot;
4. Strong security components to assure that votes cannot be lost or cast without authorization;
5. The capability to print, if required, a written record of each ballot cast;
6. The flexibility to store and present thousands of different ballot variations or ''styles'';
7. The capability to be fully accessible to blind voters and those with other disabilities and allow disabled voters to cast their ballot independently and without assistance;
8. The ability to compute final results and generate a variety of election reports very quickly; and
9. A turnkey system that would allow each county to conduct any election from start to finish without any assistance from the Vendor.

2.3 Pilot Project

Upon establishing the system standards of the voting platform, the Voting Commission prepared for the November 2001 Pilot Project. In response to a request-for-proposals (RFP) commissioned by the Voting Commission, seven DRE system vendors petitioned to participate in the November 2001 Pilot Project. At a June meeting of the Voting Commission in Atlanta, all seven vendors demonstrated their systems and presented their experience and track record in the industry. The Voting Commission recommended that all seven vendors be allowed to participate in the project, provided that each vendor obtained the necessary national and state certifications in time to adequately prepare for the November 2001 Election.

The Secretary of State entered into contracts with six certified vendors to conduct the Pilot Project. Using a lease agreement, the vendors agreed to provide voting systems for the Pilot Project at a special rate of $600 per voting unit. The contracts required that vendors transport the units to and from the cities, provide training for both election superintendents and poll workers, assist with voter education efforts via public demonstrations, and have staff present in precincts to provide Election Day support.

The Voting Commission held five public hearings and additional sub-committee work sessions across the State of Georgia. In these hearings, the Voting Commission reviewed data on voting error rates, heard presentations from manufacturers of electronic voting equipment and testimony from election officials from Georgia and other states, considered comments from interest groups, stakeholders, and the general public on voting issues, and reviewed the election results from the Pilot Project. Several Voting Commission delegations also traveled to other states to personally observe elections in which DRE voting equipment was used.

Based on information obtained from the extensive analysis and review of data, public testimony, and observations obtained from the Pilot Project, the Voting Commission made the following system recommendations to the Governor and members of the General Assembly:

1. Georgia's uniform election platform should be a DRE voting system used for Election Day in-precinct voting, for in-person absentee voting, and, if authorized by new legislation, for in-person ''advance'' or ''early'' voting. The DRE system selected should have the capability to prevent duplicate, or over-votes, provide voters with a ''summary screen'' to warn voters of potential under-votes or selection errors, and include a process for voters to correct errors or omissions before a final vote is cast. The system should include on-board battery back-up in case of power failure, have the capability to produce an independent and paper audit trail of every ballot cast and should permit a visually impaired voter, and others with disabilities, to cast a ballot independently and without assistance.
2. For absentee voting by mail, the uniform system should include an optical scan component. The optical scan component should integrate seamlessly with the DRE components of the system for ballot preparation and tabulation.
3. The uniform election system should be controlled by an Election Management System or software program that will allow election officials to easily design both DRE and optical scan ballot formats simultaneously, that will integrate all results into a single vote tallying report and that will easily interface with existing and future voter registration systems.
4. The state should seek to maximize the benefits of statewide negotiating and purchasing capacity by securing a statewide software license, as well as favorable pricing for technical support, maintenance and additional or replacement equipment that is made available for the benefit of local governments.

The Voting Commission unanimously adopted these recommendations and submitted them to the Governor and members of the General Assembly in December 2001.

2.4 System Selection

Based upon the success of the Pilot Project and the recommendation from the Voting Commission, the Governor authorized and the General Assembly approved a Statewide Uniform Electronic Voting Initiative Fund (SUEVI) and authorized $54 million in bond funds for the purchase of a statewide uniform electronic voting system. An additional $3.8 million was authorized to establish the voter education fund and $500,000 for the creation of an Election Center for election official training and support at the Kennesaw State University Center for Election Systems (hereinafter ''KSU Center for Election Systems'').

Upon establishment of the election fund, the Secretary of State and the Georgia Technology Authority (hereinafter ''GTA'') initiated an RFP process in January 2002 and began evaluating proposals from vendors capable of supplying a Direct Recording Electronic Voting System on a statewide basis for 2,926 precincts in 159 counties. The RFP required each vendor to submit a proposal that included: Voting system specifications, pricing plans, deployment plan and schedule, training plan and schedule for hardware and software training, short term and long term service plans, and a proposal for voter education efforts.

In response to the RFP, nine vendors submitted bids for the deployment of a statewide voting system. An intensive proposal and demonstration process then began with the assistance of the Georgia Technology Authority. Through an extensive evaluation process conducted by GTA and the evaluation committee, Diebold Election Systems, Inc. (hereinafter ''Diebold'') was selected as the state's vendor for election equipment.

The State of Georgia entered into a contract with Diebold on May 3, 2002, wherein the State of Georgia and Diebold agreed to deploy a uniform voting system in every county within a 6-month implementation period (186 days prior to the November 5, 2002 election).

2.5 System Deployment

The deployment plan Diebold provided in response to the State's RFP included the following phases: System testing, system development, system training and voter education.

2.5.1 System Testing

System testing involved 19,015 DRE voting stations, 400 absentee ballot systems and 161 voting system servers to be tested a minimum of 4 times including at the:

1. Manufacturer's warehouse;
2. Central processing warehouse;
3. County acceptance testing location by KSU; and
4. Logic and Accuracy testing conducted by Diebold and County election staff days before the November election.

2.5.2 System Deployment

Secretary of State created a formula based on one DRE unit per 200 active registered voters in each county to determine the number of DRE units each county would receive. Before delivery, intergovernmental agreements were created between the State and each county which included terms for the storage, protection and use of the voting system. To facilitate deliveries and support, counties were grouped into 12 delivery regions. Dates were then established for delivery of components of the voting system to the Counties. Site surveys were conducted of polling places for assurances of adequate electrical supply, structural support of the building and security of the building for protection of the voting system.

2.5.3 System Training

Extensive training and support of local election officials was an important factor in the successful initial deployment of equipment, as well as of its subsequent use. Election official training on the operation of the voting system officials was provided by Diebold. On-site county training at the request of the county was provided on behalf of the Secretary of State's office by the KSU Center for Election Systems. Additional regional ''refresher'' sessions were conducted by the Secretary of State's State Elections Division. Preparations included poll worker training (at least 2 trained per precinct for all 2,926 precincts) provided at each county by Diebold. Further training was conducted by KSU Center for Election Systems and Diebold upon the request of individual county election officials.

2.5.4 Voter Education

The Secretary of State's Office conducted direct voter education and supported outreach conducted by county election officials. A poll worker training video was created and used statewide to ensure uniform use of the equipment in polls on Election Day. A voter education video and a 30-second public service announcement entitled ''Touch the Future'' was developed and distributed for use statewide. State, regional and county level ''Voter Education Coordinators'' were deployed by the Secretary of State's Office to conduct hands-on DRE demonstrations in every county. Printed materials were distributed through U.S. mail and selected community groups. Comprehensive voter education Web site with interactive equipment demonstration was established and DRE unit demonstrations were conducted in a variety of settings including public meetings, school assemblies, and community festivals.

2.5.5 Deployment Outcome

There were significant improvements in the conduct of the November 2002 General Election in Georgia. The under-vote rate for the 2002 U.S. Senate Election was a historically low 0.86% (a dramatic reduction, compared to the 2000 Presidential Election under-vote rate of 3.5% and the 1998 U.S. Senate Election under-vote rate of 4.8%). Emphasis on election official training, voter education coordination at the regional and local level, and enthusiastic participation by state and county election officials, poll workers, and voters contributed to this success.

Chapter 3—2003 HAVA Status and Steps for Completing Compliance

3.1 2003 HAVA Status

Georgia's successful use of its uniform statewide electronic voting system in the November 2002 General Election put it substantially in compliance with Help America Vote Act requirements. Steps already taken in anticipation of HAVA legislation are shown in Appendix 1—2003 Compliance Status. Remaining steps which were still pending completion in December, 2003 are also identified in Appendix 1.

3.2 2003 Legislative Steps for Completing Compliance

To complete compliance with HAVA requirements the Georgia General Assembly provided certain authorizations which could be included in the HAVA 2003 State Plan. This was accomplished with passage of Senate Bill 258 (hereinafter ''SB 258''), which was signed by the Governor on June 2, 2003. Upon approval of SB 258 by the United States Department of Justice, the State of Georgia had the statutory framework in place to implement all necessary procedures to bring Georgia into full compliance with the Help America Vote Act.

SB 258 revised the following six areas of the Election Code:

1. Definition of a vote—The Election Code previously provided the definition of a vote for each election system used in the State of Georgia for federal, state and local elections. SB 258 authorized the State Election Board (SEB) to promulgate rules (*SEB Rule 183–1–15–.02*) to consolidate and define a vote as required by HAVA and the establishment of a Vote Review Panel to review ballots rejected by optical scan tabulators (see *O.C.G.A. § 21–2–483(g)(2)(B)).*

2. Military and Overseas Ballots—SB 258 amended the Election Code to give responsibility for military and overseas civilian absentee voting procedures to the Secretary of State's Office. SB 258 also provided that applications for absentee ballots for military and overseas voters shall be valid for two election cycles as required for those voting under the Uniformed and Overseas Civilians Absentee Voting Act (UOCAVA). It also authorized the Secretary of State to adopt a new ballot oath created by the Federal Voting Assistance Program (FVAP).

3. Registration of first-time voters by mail—SB 258 amended the Election Code to provide that citizens who register for the first time by U.S. Mail are required to include with that registration application one of the forms of identification specified in HAVA. Those who register by mail and do not include such documentation will be required to present identification at the polling place. Persons who are entitled to vote other than in person under federal law, including UOCAVA, are exempt from this provision. *(HAVA Section 303(b)(3) and O.C.G.A. § 21–2–220(c)(2)).*

4. Provisional Ballots—SB 258 amended the Election Code to provide that ballots cast during an election with federal candidates on the ballot at a polling place during court-ordered extended polling hours shall be treated as provisional ballots. It also required county election officials to provide notification to the voter regarding how to obtain information on whether the provisional ballot was counted and also requires county registrars to create a free access system that allows the voter to determine whether the provisional ballot was counted or not.

5. ''Overvote'' Instructions—Georgia's DRE voting system precludes a voter from casting too many votes for an office (an ''overvote'') at the polling place. SB 258 amended the Election Code to provide that the absentee ballot instructions for optical scan mail in ballots include information about overvotes and explain how to avoid them. SB 258 also required that optical

scan tabulators be programmed to return (reject) ballots containing overvotes or improper marks.

6. State Administrative Complaint Procedures—SB 258 amended the Election Code to authorize the Secretary of State (as the designated Chief Election Official) to establish and administer an administrative complaint procedure for processing complaints related to HAVA Title III. (see Secretary of State Rule 590–8–1–.01)

3.3 2003 Administrative Actions and Certifications

Georgia's 2003 HAVA State Plan provided in Chapter IV reflects that Georgia had taken steps to meet and implement the following:

1. *Early Money Out Certification*, HAVA Section 101(a): The 2003 State Plan indicated that Georgia had certified and indicated participation for receipt of Title I payments through the GSA Web site. Funds were subsequently received.

2. *Accessibility of polling places for disabled voters*, HAVA Section 101(b)(1)(G): The 2003 State Plan indicated Georgia's intent to survey and supervise the improvement of accessibility and quality of polling places providing physical access for individuals with disabilities. A statewide survey was subsequently made and used as the basis to implement a state-administered grant program for polling place accessibility improvements.

3. *Toll-free Access System*, HAVA Section 101(b)(1)(H): The 2003 State Plan indicated Georgia's intent to study and evaluate a toll-free hotline that voters may use to:

a. Report possible voting fraud and voting rights violations,

b. Obtain general election information, and

c. Access detailed automated information on their voter registration status, specific polling place locations, and other relevant information.

Georgia subsequently implemented a toll-free hot line.

4. *Certify Replacement of Punch Card or Lever Voting Machines*, HAVA Section 102: The 2003 State Plan indicted that Georgia had certified that it had replaced punch card and lever voting systems and intended to use Section 102 funding to reimburse the State treasury as HAVA allowed. Reimbursements were subsequently made.

5. *Membership of Standards Board*, HAVA Section 213: Two representatives to the Standard's Board were appointed as required. New appointments have been made as necessary.

6. *Certification of Use of Title II Requirements Payments*, HAVA Section 253: The 2003 State Plan indicated Georgia's intent to certify that it would use Requirements payments in the manner required. Certification was provided and funds were subsequently received.

7. *Administrative Complaint Procedure*, HAVA Section 402: The 2003 State Plan indicated Georgia's intent to implement rules to administer the Administrative Complaint Procedure pursuant to authority granted in SB 258 to the Secretary of State. Rule 590–8–1–.1 ''Administrative Complaint Procedure for Violations of Title III of the Help America Vote Act of 2002'' was adopted on May 11, 2004 and published by the EAC in the **Federal Register**, Vol. 70, No.169, Thursday, September 1, 2005 on page 52183.

8. *Military and Overseas Voting Information Office*, HAVA Sections 702 and 703: The Secretary of State pursuant to SB 258 became the Designated Military and Overseas Voting Information Office and assumed related responsibilities for reporting to the Election Assistance Commission.

9. *State Plan Submitted*, HAVA Section 254: The 2003 State Plan indicated that it was meeting the requirements of HAVA Section 254. The 2003 State Plan was submitted on December 10, 2003. It was published by the EAC in the **Federal Register**, Vol. 69, No. 57, Wednesday, March 24, 2004 on pages 14247 to 14263.

Part Two

Chapter 4—Change and Implementation Summary

This chapter describes how the 2008 amendments change Georgia's HAVA State Plan and report on how Georgia succeeded in carrying out the previous state plan (in fulfillment of the Help America vote Act of 2002, Section 254(a)(12)). The 2008 amendments to the State Plan were developed in accordance with HAVA Section 255 and the requirements for public notice and comment prescribed in Section 256 of HAVA.

4.1 Overview of Changes to the 2003 State Plan

Part One of Georgia's 2008 HAVA State Plan, Amended presents the historic election reform process that preceded and supported the creation of the 2003 HAVA State Plan. Part One is comprised of: Chapter 1, Historical Election Challenges; Chapter 2, Election Reform (2001 and 2002); and Chapter 3, 2003 HAVA Status and Steps for Completing Compliance. These three chapters contain the background information previously contained in Chapters I through IV of the 2003 HAVA State Plan.

Part Two of Georgia's 2008 HAVA State Plan, Amended, is comprised of Chapters 4 and 5 which update the previous plan from 2003. Chapter 4 presents the required summary of changes and reports on how the 2003 plan was carried out. This chapter is completely new material because there have been no amendments to the Georgia HAVA State Plan prior to 2008.

Chapter 5, Implementation of the 2008 HAVA State Plan, Amended presents plans for future activity. It has 13 sections, one for each part of HAVA, Section 254(a) which specifies required parts of the HAVA State Plan. This chapter replaces the implementation Chapter V from 2003 HAVA State Plan. While the 2003 plan focused heavily on the initial deployment of voting system components and the related education of the public and local election officials, emphasis in the 2008 plan is on continuing the integrity Georgia's voting system (including component replacements) and on replacing the 1993 computer system supporting statewide voter registration and state elections administration.

4.2 Successful Implementation of the 2003 State Plan

After enactment of Georgia's Senate Bill 258 on June of 2003, the Georgia HAVA State Plan was adopted on December 10, 2003 and published by the U.S. EAC in the **Federal Register** on March 24, 2004. Implementation followed immediately in 2004.

Implementation of Georgia's 2003 HAVA State Plan has been a success. Financial reporting on annual expenditures, use of the State's five percent funding match, and of Georgia's on-going maintenance of effort at or above the State Fiscal Year 2000 amount have been reported separately in Georgia's annual Financial Status Report and accompanying narrative. Only the replacement of the computer system supporting statewide voter registration and election administration was deferred from the previous plan for action in the current plan. A summary of accomplishments and activity is presented in the following sections.

4.2.1 2004 Implementation of the 2003 State Plan

1. In 2002 Georgia replaced all punch card and lever voting machines through State purchase and deployment of 19,015 DRE voting units (approximately one for every 200 active voters) to establish a statewide uniform, accessible

voting system. During 2004 the state was reimbursed under HAVA provisions for voting system replacement.

2. To improve voting machine availability and to support in-person absentee voting, an additional 955 DRE voting units were purchased and distributed to counties prior to the November 2004 General Election.

3. The State purchased 24,250 additional flash memory cards for the DRE voting units to provide greater efficiency in preparing for federal, state, and local runoffs resulting from elections held during the 2004 General Election Cycle.

4. The State acquired state-specific voter access cards and supervisor cards for use with DRE voting units purchased in compliance with Title II and the voting system standards of Title III Section 201. These state-specific cards enabled the State of Georgia to provide increased security for the state's uniform voting system.

5. The State provided election officials in all counties with three days of technical support for DRE voting units and GEMS servers technology for each of the following elections held in 2004: Presidential Preference Primary, Primary Election, Primary Runoff, General Election and General Election Runoff.

6. The Department of State Audits completed an audit of the State HAVA Fund.

7. Ballot building became a cooperative program between the Secretary of State's Office and the Kennesaw State University Center for Election Systems to support statewide ballot quality and timeliness. Related instructional materials were provided on voting system components and voting system supplies to all 159 counties for use during 2004 federal and state election cycle.

8. Acceptance testing for all voting equipment and the responsibilities for related equipment evaluation, local election official training and support, and overall voting system security were added to duties that Kennesaw State University Center for Election Systems conducts for the Secretary of State.

9. The State developed and distributed statewide HAVA compliant polling place posters, voter registration materials and other forms for elections administration.

10. The State presented training to support implementation to local election officials through: The Georgia Election Official Certification program; conferences of statewide election official associations (Georgia Election Officials Association, Voter Registrars Association of Georgia, and Georgia Municipal Association); classes at Kennesaw State University Center for Elections; and through regional and county level sessions.

11. The State provided voting system demonstrations and education to voters and assisted county officials in doing so as well.

12. The statewide voter registration system was enhanced with system upgrades, and counties were supported with related instruction, helpdesk support and connectivity support.

13. Compliant provisional voting procedures were implemented using newly created materials.

14. Accessibility for voters with disabilities was assessed for each polling place by surveying each county. Results were used by the Secretary of State to help define training needs, create a training video and brochure, and to guide grant participation in the program administered by the U.S. Department of Health and Human Services for polling place accessibility improvements.

15. The required administrative complaint process was put in place through rule-making and implementation by the Secretary of State. Information relating to the Administrative Complaint Process can also be found on the Secretary of State's Web site at *http://www.sos.state.ga.us.*

4.2.2 2005 Implementation of the 2003 State Plan

1. An optical scan ballot tabulator was purchased and deployed to every county to improve the processing of mailed absentee ballots.

2. Electronic poll books (ExpressPolls) were purchased for each polling place to streamline the voting process and further enhance the voting system and the preparation of registered voter lists. ExpressPolls also replaced the encoder component necessary for accessing election ballots on the DRE voting units.

3. The Secretary of State conducted regional training for the 159 county election superintendents and their staff on the use of DRE voting systems, related HAVA requirements and additional federal laws for improved elections administration.

4. Proper management of the State HAVA Fund was assured through an audit by the Department of State Audits.

5. The State acquired three backup computer servers, memory card duplication equipment for ExpressPolls and extended warranty on the DRE voting units to ensure proper maintenance in preparation for the 2006 General Election.

6. The Secretary of State made initial assessments of the availability of vendors who might provide a new voter registration system and of the higher level requirements of such a system.

7. The Secretary of State continued programs for voter education and outreach programs; local election official training, voting system procedures and security enhancements, ballot building, polling place accessibility, and for the voter registration system's security monitoring, maintenance, and system upgrades.

4.2.3 2006 Implementation of the 2003 State Plan

1. Equipment to duplicate flash cards for use in ExpressPolls was purchased to improve processing for each election.

2. The security of the statewide voter registration system was improved with the addition of a dynamic security password for database access.

3. The Secretary of State provided local election officials in every county with three days of technical support for DRE voting units, GEMS servers technology, and electronic poll books (ExpressPolls) in each of the following elections: Primary Election, Primary Runoff, General Election and General Election Runoff.

4. Programs continued for voter education and outreach programs; local election official training, voting system procedures and security enhancements, ballot building, polling place accessibility, and for the voter registration system's security monitoring, maintenance, and system upgrades.

4.2.4 2007 Implementation of the 2003 State Plan

1. Electronic poll book (ExpressPolls) were upgraded to facilitate uploading to the statewide voter registration system the voters' record of having participated in the election and other enhancements recommended by local election officials.

2. The Secretary of State contracted for regional quick response teams to be available for technical support to county election officials for electronic poll books, voting units and GEMS servers technology for the February 2008 Presidential Preference Primary.

3. Prepared to contract a 2008 statewide program for maintenance and limited replacement of GEMS servers used in each county.

4. Polling place accessibility was again surveyed, program materials updated, additional grant funds received, and reimbursements were made for approved remedial improvements completed by counties.

5. Programs continued for voter education and outreach programs; local election official training, voting system procedures and security enhancements, ballot building, and for the voter registration system's security monitoring, maintenance, and system upgrades.

4.2.5 2008 Implementation of the 2003 State Plan

1. The Secretary of State contracted for regional quick response teams to be available for technical support to county election officials for electronic poll books, voting units and GEMS servers technology for the following elections held in 2008: Presidential Preference Primary, Primary Election, Primary Runoff, General Election and General Election Runoff.

2. A statewide program for maintenance and limited replacement of GEMS servers used in each county was carried out.

3. Programs continued for voter education and outreach programs; local election official training, voting system procedures and security enhancements, polling place accessibility, ballot building, and for the voter registration system's security monitoring, maintenance, and system upgrades.

Chapter 5—Implementation of the 2008 HAVA State Plan, Amended

Chapter 5 presents Georgia's plans for 2008 and following years. It consists of 13 parts, one for each section of HAVA 254(a), which sets forth the required content of the state plan. Parts 5.1 through 5.13 each begin with the statutory requirement of that part of the plan and the following portion provides Georgia's fulfillment of that requirement.

5.1 Use of Requirements Payments

Part 5.1 of Georgia's State Plan implementation describes ''*how the State will use the requirements payments to meet the requirements of Title III, and if applicable under Section 251(a)(2), to carry out other activities to improve administration of elections*'' as required by Public Law 107–252, Help America Vote Act of 2002, Section 254(a)(1).

To continue meeting the requirements of Title III in 2008 and following years, Georgia will expend funds for the following purposes:

1. A portion of the Requirements Payments will be used to conduct maintenance on servers used as part of the statewide uniform electronic voting system, and to replace aging servers and other voting system components.

2. A portion of the Requirements Payments will be used to replace the fifteen-year-old (1993) centralized voter registration system currently being used by the State. The new system will allow an easier interface and more efficient system functions (e.g., electronic sharing and comparison of data among units of government to confirm voter eligibility).

3. Additional expenditures may be made in the following areas:

- Voter education activities;
- Election official training activities;
- Development of Statewide Uniform Poll Worker Training Curriculum and Handbook;
- Any other activities allowed under HAVA.

5.2 Distribution and Monitoring

Part 5.2 of Georgia's State Plan implementation describes ''*how the State will distribute and monitor the distribution of the requirements payment to units of local government or other entities in the State for carrying out the activities described in paragraph (1), including a description of—(A) the criteria to be used to determine the eligibility of such units or entities for receiving the payment; and (B) the methods to be used by the State to monitor the performance of the units or entities to whom the payment is distributed, consistent with the performance goals and measures adopted under paragraph 8*'' as required by Public Law 107–252, Help America Vote Act of 2002, Section 254(a)(2).

5.2.1 Distribution of Requirements Payments—Section 254(a)(2)(A)

As the State's chief election official, the Secretary of State is authorized by O.C.G.A. § 21–2–300 to implement and deploy a statewide uniform voting system for use by local election officials in county, state, and federal elections.

The Secretary of State will centrally administer expenditures to maintain the reliability of the statewide uniform voting system so there will be no related fund distributions among counties. In 2008, emphasis will be on conducting server maintenance and assessing the need to replace individual servers. Servicing, replacement of components, and replacement of servers will be as deemed prudent by the Secretary of State. The HAVA State Plan, Amended anticipates replacing up to all 170 servers used to tabulate votes in each of Georgia's 159 counties during 2008 and following years, including a small inventory for emergency replacement and dedicated training units.

An individual county will be deemed eligible to receive a replacement server when, in the judgment of the Secretary of State, replacement of the existing unit is warranted based on considerations including, but not limited to, the age of the unit, the service history of the unit, the nature of pending repairs, and the continuing availability of parts.

Intergovernmental Agreements for use of voting equipment remain in place as do past practices of maintaining inventory listings and access logs.

The Secretary of State will centrally administer expenditures supporting the replacement of the 1993 statewide voter registration system with a modern system so there will be no related fund distributions among counties. Counties will all receive training and helpdesk support in the use of the new system.

5.2.2 Monitoring of Requirements Payments—Section 254(a)(2)(B)

The Secretary of State is responsible for disbursing and tracking Title I and Title II funds for the projects to enhance election administration.

If local units of government (or other entities) receive payments, the Secretary of State will monitor the performance of those parties consistent with performance goals and measures adopted under Section 8 of this chapter. Allocation request forms and expense codes created to implement the 2003 HAVA State Plan would continue to be used, or modified, as appropriate to monitor and track HAVA spending. Agreements specifying the use of the funds would be entered into prior to disbursements being made. Recipients may be required to submit written reports to the Secretary of State indicating the status and level of success of any project or activity receiving funding through the Secretary of State.

Audits conducted by the State of Georgia Department of Audits and Accounts will be used to monitor HAVA expenditures.

5.3 Voter Education and Training

Part 5.3 of Georgia's State Plan implementation describes ''*how the State will provide for programs for voter education, election official education and training, and poll worker training which will assist the State in meeting the requirements of Title III*'' as required by Public Law 107–252, Help America Vote Act of 2002, Section 254(a)(3).

5.3.1 Voter Education

Since the 2002 general election, introduction of Georgia's uniform statewide voting system, voters have become very familiar with their voting equipment through educational

programs and its use in 3 statewide election cycles.

Continuing voter education focuses on reaching voters who are new to Georgia's voting process. This includes youth who are about to reach voting age, as well as newly registered adults. The Secretary of State's Web site posts information showing current voting equipment and how it is used, to which all voters may refer. In addition, county election officials publically display demonstration voting units before elections. The Secretary of State will continue to explore voter education outreach in cooperation with local election officials and non-governmental organizations.

5.3.2 Election Official Training

The Secretary of State's Office continues to train local election officials on the use of Georgia's voting system to properly conduct elections. The Secretary of State's Office maintains an election lab for voting equipment training and offers local election officials regularly scheduled classes on the use of the statewide uniform voting system components for specific elections tasks.

Georgia's election law requires local election officials to become certified by completing up to 64 hours of courses approved by the Secretary of State. O.C.G.A. 21–2–101. Georgia's certification program for local election officials continues to be updated based on lessons learned from previous elections. It is anticipated that this program will be further expanded and customized for county election superintendents and registrars, as well as for municipal election officials.

Georgia election law also requires local election officials to obtain on-going training. O.C.G.A. 21–2–100(a). Annual training conferences have been, and continue to be, conducted in collaboration with statewide election official associations.

Certification and on-going training programs include the electronic voting system; polling place procedures and poll worker training; local, state, and federal election laws governing administrative duties; disability access initiatives; voter registration and education initiatives; new legislation that affects local, state, and federal election laws; and any other topics that may enhance the administration of elections.

5.4 Voting System Standards

Part 5.4 of Georgia's State Plan implementation describes ''*how the State will adopt voting system guidelines and processes, which are consistent with the requirements of Section 301*'' as required by Public Law 107–252, Help America Vote Act of 2002, Section 254(a)(4).

Voting System Guidelines adopted by the 21st Century Voting Commission and used to select the statewide uniform electronic voting system used in the 2002 General Election were established in 2001 and passed into law by the Georgia General Assembly in 2001 through Senate Bill 213. O.C.G.A. 21–2–300.

5.5 Election Fund Established

Part 5.5 of Georgia's State Plan implementation describes ''*how the State will establish a Fund described in subsection (b) for purposes of administering the State's activities under this part, including information on fund management*'' as required by Public Law 107–252, Help America Vote Act of 2002, Section 254(a)(5).

With the approval from the State of Georgia Department of Audits, the Office of Secretary of State established a separate bank account for the Election Fund and has assigned an internal identification code for tracking the expenditures. The Election Fund has been designated as a federal election fund account that shall only be used for the enhancement and continuation of election administration. The Fund also contains individual expenditure codes for tracking Section 101, Section 102, Title II, and matching fund expenditures.

5.6 Proposed Budget

Part 5.6 of Georgia's State Plan implementation describes ''*how the State's proposed budget for activities under this part, based on the State's best estimates of the costs of such activities and the amount of funds to be made available, including specific information on:*

(A) The costs of the activities required to be carried out to meet the requirements of Title III;

(B) The portion of the requirements payment which will be used to carry out activities to meet such requirements; and

(C) The portion of the requirements payment which will be used to carry out other activities'' as required by Public Law 107–252, Help America Vote Act of 2002, Section 254(a)(6).

5.6.1 Available Funds

The U.S. Omnibus Appropriations Act for Fiscal Year 2008 (Pub. L. 110–161) includes $115 million in ''Requirements Payments'' to help states improve the administration of Federal elections under HAVA, Title II, Subtitle D, Part 1. Georgia is eligible for $3,169,840 of these funds. To receive its allocated portion, Georgia will certify its eligibility as prescribed in HAVA Section 253. As part of this certification, Georgia will affirm the state's appropriation of the required match of at least 5 percent ($166,834).

As of July 2008 the State of Georgia had approximately $1,137,260 remaining from earlier HAVA disbursements under Title I and $497,587 remaining from disbursements under Title II.

Activities are planned anticipating the full availability of new funds appropriated in 2008 and of funds retained from appropriations in earlier years.

TABLE 3—AVAILABLE HAVA FUNDS

	Federal funds	State match	Total
Remaining Title I Funds	$1,137,260	(already spent)	$1,137,260
Remaining Title II Funds	$497,587	(already spent)	$497,587
2008 Funds Title II	$3,169,840	$166,834	$3,336,674
Total Funds Available			$4,971,521

5.6.2 Planned Activities

To address requirements of Title III in 2008 and following years, Georgia will expend funds for the following purposes contingent upon priorities discussed below as well as the availability of funds:

TABLE 4—PLANNED ACTIVITY AND COSTS

Activity	Estimated costs
1. Voting System Maintenance and Component Replacement	$100,000 to $450,000.
2. Centralized Voter Registration System	$8 million to $15 million.
3. Training, Outreach, and Other Activities	$50,000 to $500,000.

1. Voting System Maintenance and Component Replacement: A portion of the available funds will be used to conduct maintenance of voting systems and to repair or replace components as needed. Many components of Georgia's statewide electronic voting system were put in place in 2002. To ensure the on-going integrity of Georgia's voting system, a preventive maintenance program will extend the operational life of servers, improve security, and identify any current or potential component replacement needs.

The replacement of aging servers at each county will be a high priority. Actions necessary to support county voting system servers in an approaching election will have first priority. It is anticipated that 168 servers will be replaced during 2008 and the following years at a cost of approximately $400,000. This will accommodate one server per county, as well as a small State inventory for emergency replacement and dedicated training units.

2. Centralized Voter Registration System: A portion of the available funds will be used to replace the fifteen-year old (1993) statewide voter registration database currently being used by the State. The 1993 system is antiquated and requires extensive maintenance. Very high operating costs (by the keystroke) and high maintenance costs of this system are an on-going burden. Replacing the system will: allow for more effective use of elections funds; help ensure the quality and reliability of voter registration data management; give every county a more reliable and efficient interface with the centralized voter registration system; and allow improved integration with related election administration and reporting functions.

Under the 2003 HAVA State Plan, the Secretary of State conducted a preliminary assessment of available vendors that were capable of replacing the current system with a state-of-the-art system. The Secretary of State also compiled a high level requirements analysis for the successor system. The next steps of this process are to prepare detailed performance specifications, including a functional requirements analysis of the new system, and then to proceed with building, testing, and deployment.

The estimated cost of the new system is $8 to $15 million. The use of HAVA funds from both Title I and Title II is anticipated.

3. Training, Outreach, and Other Activities: As described in Section 5.3, the State of Georgia will continue to conduct outreach to voters who need to be introduced to the voting system used throughout the state. In addition, training will continue to be provided to local election officials on the use of Georgia's voting system and voter registration system to properly conduct elections. Enhancing voters' access to processes related to poll location, registration status confirmation, complaints, and status of absentee and provisional balloting may also be addressed. In the future, consideration may also be given to evaluating replacement of Georgia's present electronic voting equipment as it begins to age. Use of HAVA funds for these activities is contingent upon the availability of funds.

5.7 Maintenance of Effort

Part 5.7 of Georgia's State Plan implementation describes ''*how the State, in using the requirements payment, will maintain the expenditures of the State for activities funded by the payment at a level that is not less than the level of such expenditures maintained by the State for the fiscal year prior to November 2000*'' as required by Public Law 107–252, Help America Vote Act of 2002, Section 254(a)(7).

The State of Georgia will continue to maintain or exceed that level of election administration expenditures incurred during the State Fiscal Year 2000 ($4,598,813) while conducting activities that fall under the Title III requirements of the Help America Vote Act.

5.8 Performance Goals and Measures

Part 5.8 of Georgia's State Plan implementation describes ''*how the State will adopt performance goals and measures that will be used by the State to determine its success and the success of units of local government in the State in carrying out the plan, including timetables for meeting each of the elements of the Plan, descriptions of the criteria the State will use to measure performance and the process used to develop such criteria, and a description of which official is to be held responsible for ensuring that each performance goal is met*'' as required by Public Law 107–252, Help America Vote Act of 2002, Section 254(a)(8).

In collaboration with local election officials, the Secretary of State establishes goals and performance measures to ensure compliance with HAVA requirements. Regular reviews of Georgia's election laws, policies, and procedures help ensure that election administration and voter registration processes are impartial and efficient and subject to on-going improvements.

5.8.1 Performance Goals

For the initial implementation and deployment of the statewide uniform electronic voting system Georgia developed milestones and goals through the 21st Century Voting Commission as described earlier in detail. Milestones remain for having system components in place and tested before each election, local election officials trained in a timely manner, and for Election Day performance reporting. Scheduling for individual milestones is periodically reviewed and subject to change by the Secretary of State in consultation with local election officials and other parties knowledgable in the matters under consideration.

In 2008, and the years following, maintenance and replacement of GEMS servers in each county will be done in a manner to continue past performance of the statewide uniform electronic voting system. Any additional goals and measures will be addressed by the Secretary of State in the particular contract's statement of work under which the task is carried out.

5.8.2 Performance Measures

As preparations begin to develop Georgia's new voter registration system, the Secretary of State will develop a project team to develop project goals and measures to be incorporated in related RFPs and contract statement-of-work clauses. It is anticipated that input will be solicited from local election officials as well as from other Georgia State Agencies who will interact with the Secretary of State in replacing the

existing system, and in using the new system.

Additionally, the Secretary of State periodically convenes an Elections Advisory Committee of local officials which provides input on enhancing election administration within the State. Through this process additional goals and measures may also be developed to further other objectives of HAVA.

5.9 Administrative Complaint Procedures

Part 5.9 of Georgia's State Plan implementation provides *''a description of the uniform, nondiscriminatory state-based administrative complaint procedures in effect under section 402''* as required by Public Law 107–252, Help America Vote Act of 2002, Section 254(a)(9).

5.9.1 Georgia Rulemaking and Certification

Georgia's administrative complaint process is provided in Georgia Rule 590–8–1–.01 ''Administrative Complaint Procedure for Violations of Title III of the Help America Vote Act of 2002'' adopted May 11, 2004 under authority provided in O.C.G.A. Secs. 21–2–1 and 21–2–50.2. Text of Georgia Rule 590–8–2–.01 was certified to the EAC which published it in the **Federal Register**, Vol. 70, No. 169, Thursday, September 1, 2005 at page 52160. These procedures, described below, provide a uniform manner in which to receive and resolve any complaints alleging a violation of HAVA.

5.9.2 Administrative Complaint Process

Georgia Rule 590–8–1–.01 ''Administrative Complaint Procedure for Violations of Title III of the Help America Vote Act of 2002'' provides as follows:

(1) Any person who believes that a violation of any provision of Title III of the Help America Vote Act of 2002 (Public Law 107–252; 42 U.S.C. 15301, et seq.) has occurred, is occurring, or is about to occur may file a complaint with the Secretary of State. Such complaint shall be open to inspection by the public during business hours upon reasonable notice.

(2) Such complaint shall be in writing and shall be signed and sworn to by the person making the complaint and shall be properly notarized in accordance with state law. The complaint shall be delivered to and served upon the Secretary of State as the chief state election official in person, by U.S. Mail, or by guaranteed overnight delivery.

(3) The Secretary of State shall investigate the allegations of such complaint. If more than one complaint is filed concerning the same alleged violation, the Secretary of State may consolidate such complaints for investigation.

(4) If the complainant requests, the Secretary of State or a designee thereof shall conduct a hearing on the allegations of the complaint. Such hearing may be by telephone, conference call, or in person and shall be recorded.

(5) If the Secretary of State or a designee thereof determines that such complaint is unfounded, the Secretary of State may dismiss the complaint and notify the complainant of her decision. The Secretary of State shall make the results of her investigation into the complaint available for public inspection during normal business hours upon reasonable notice after the matter has been resolved

(6) The Secretary of State or designee thereof shall make a determination of the validity of the complaint within 90 days following the date on which the complaint is received by and filed with the Secretary of State unless the complainant agrees to an extension of such time period.

(7) If the Secretary of State or designee thereof determines that such complaint is valid, the Secretary of State shall take all necessary and appropriate actions within her authority to address the violation; and

(8) If the Secretary of State or designee thereof does not render a final determination on a complaint filed pursuant to this rule within 90 days after the complaint is filed, or within any extension period to which the complainant has agreed, the Secretary of State or designee thereof will, on or before the third business day after the final determination was due to be issued, initiate proceedings for alternative dispute resolution;

(a) To facilitate alternative dispute resolution, the Secretary of State shall maintain a list of qualified independent professionals who are capable of acting as a mediator, from which the Secretary of State or designee thereof and the complainant shall each choose one mediator to review the case.

(b) The Secretary of State or designee thereof shall designate in writing to the complainant the name of a mediator from the list referenced in section (a) to serve on an alternative dispute resolution panel (resolution panel) to review the complaint.

1. If proceedings for alternative dispute resolution are initiated pursuant to this paragraph, not later than 3 business days after the complainant receives such a designation from the Secretary of State or designee thereof, the complainant shall designate in writing to the Secretary of State or designee thereof the name of a second mediator. If the complainant fails to designate a mediator within the time allowed above, the sole mediator shall review the record from the hearing and make a final recommendation based on the submitted record. Not later than 3 business days after such a designation by the complainant, the two mediators so designated shall select a third mediator to complete the resolution panel. If the complainant fails to designate a mediator within the time allowed above, the sole mediator shall review and dispose of the matter without selecting a second or third mediator.

2. The mediator or resolution panel may review the record compiled in connection with the complaint, including, without limitation, the investigative file on the matter, the audio recording of the hearing, any transcript of the hearing and any briefs or memoranda submitted by the parties but shall not receive any additional testimony or evidence to resolve the matter.

3. The mediator or resolution panel by a majority vote, shall after reviewing the record referenced above, provide a recommendation to the Secretary of State not later than 50 days after the final determination of the Secretary of State was due. This period for issuing a written recommendation will not be extended.

4. Upon receipt of the recommendation from the mediator or resolution panel, the Secretary of State or designee thereof shall issue a final order pursuant to the authority granted under O.C.G.A. 21–2–50.2(c), but such remedy shall not exceed the remedies available under Title III of the Help America Vote Act of 2002.

5. The final order of the Secretary of State or designee thereof will be:

(i) Mailed to the complainant, each respondent and any other person who requested in writing to be advised of the final resolution;

(ii) Posted on the website of the Secretary of State; and

(iii) Made available by the Secretary of State, upon request by any interested person.

6. A final determination by the Secretary of State or designee thereof is not subject to appeal in any state or federal court.

5.10 Effect of Title I Payments

Part 5.10 of Georgia's State Plan implementation provides *''if the State received any payment under Title I, a*

description of how such payment will affect the activities proposed to be carried out under the plan, including the amount of funds available for such activities'' as required by Public Law 107–252, Help America Vote Act of 2002, Section 254(a)(10).

As set forth in the 2003 HAVA State Plan, Title I, Section 102 funds were used to service bond indebtedness generated by the purchase of a statewide electronic voting system to replace all punch card and lever voting systems in Georgia. This program was timely concluded.

Title I, Section 101 funds will allow the State to begin the process of acquiring a new voter registration system to replace the 1993 system currently in use. This activity is described in Section 5.6. This project was anticipated in the 2003 HAVA State Plan. While preliminary assessments were started, detailed requirements analysis, acquisition, testing and deployment remain. Title I, Section 101 funds available for this activity are estimated as being $1,137,260.

5.11 Management of the Plan

Part 5.11 of Georgia's State Plan implementation describes *''how the state will conduct ongoing management of the Plan''* as required by Public Law 107–252, Help America Vote Act of 2002, Section 254(a)(11).

The Elections Division of the Secretary of State will manage the Plan. The Election Division will continue to oversee continuation of existing projects as well as newly created election projects.

''Material Changes'' to the Plan may be developed on a periodic basis as necessary to reflect new milestones and performance measures used to gauge the effectiveness of the Plan and to accommodate emerging needs in the future.

5.12 Previous State Plan Implementation and Changes

Part 5.12 of Georgia's State Plan implementation describes how *''the case of a State with a State Plan in effect * * * during the previous fiscal year, * * * how the Plan reflects changes from the State Plan for the previous fiscal year and of how the State succeeded in carrying out the State Plan for such previous fiscal year''* as required by Public Law 107–252, Help America Vote Act of 2002, Section 254(a)(12).

The summary of the changes that the 2008 HAVA State Plan, Amended makes to the 2003 plan, and of how the State succeeded in carrying out the 2003 HAVA State Plan previously in effect is provided in detail in the preceding chapter.

5.13 State Plan Committee

Part 5.13 of Georgia's State Plan implementation provides *''a description of the committee, which participated in the development of the State Plan in accordance with section 255 and the procedures followed by the committee under such section and section 256''* as required by Public Law 107–252, Help America Vote Act of 2002, Section 254(a)(13).

The ''2008 HAVA State Plan Committee'' is comprised of the following appointees:

1. Secretary of State's Office, Wesley Tailor, Elections Division Director;
2. Fulton County: April Pye, Interim Election Supervisor;
3. DeKalb County: Linda Latimore, Election Supervisor;
4. Clarke County: Gail Schrader, Supervisor of Elections and Registration;
5. Rockdale County: Cynthia Welch, Election Supervisor;
6. Muscogee County: Nancy Boren, Elections and Voter Registration Director;
7. Richmond County: Lynn Bailey, Election Supervisor;
8. Georgia State ADA Office, Mike Galifianakis, Coordinator.

The 2008 HAVA State Plan Committee continues the work of groups described in Part One of this report. The success of earlier, larger initiatives and the much smaller scope of the 2008 amendments allowed the process in 2008 to be more streamlined than in 2003.

Initial review drafts of the 2008 HAVA State Plan, Amended were prepared by the Secretary of State's Office and distributed to members of the State Plan Committee. After reviewing the initial working draft, the Committee discussed the draft and proposed edits. After incorporating input, the Preliminary 2008 State Plan, Amended was posted for public comment. Comments were compiled by the Secretary of State's Office, shared with the Committee, and addressed as appropriate in the Final 2008 HAVA State Plan, Amended before being submitted to the Election Assistance Commission for publishing in the **Federal Register**.

Appendix 1—2003 Status & Implementation

12/10/03 Status	Provision mandated by HAVA	Implemented
	Voting System Standards	
v	Permit voter to verify votes selected before casting ballot	2002.
v	Provide voter opportunity to change/correct ballot before casting ballot	2002.
v	Offer notice if voter selects votes for more than 1 candidate for a single office	2002.
v	Voting system shall ensure that any notification required preserves voter privacy	2002.
v	System must produce a record with an audit capacity (satisfied by audit capacity redundant electronic storage).	2002.
	Accessibility for Individuals With Disabilities	
v	Voting system must be accessible for individuals with disabilities, including visual impairment and must preserve voter privacy and must offer independence in voting.	2002.
v	At least 1 DRE with accessibility for disabled individuals at each place	2002.
	Error Rates of System	
v	Error rates of system shall comply with error rate standards of FEC	2002.

12/10/03 Status	Provision mandated by HAVA	Implemented
	Uniform Definition of What Constitutes a Vote	
~	State must adopt uniform and nondiscriminatory standards that define what constitutes a vote and what will be counted as vote for each voting system used in state.	State Election Board Rule 183–1–15–.02, May, 2004.
	Provisional Voting	
v	Must have provisional vote option	2002.
v	To cast provisional ballot, voter must (1) affirm in writing that the person is a registered voter in the jurisdiction; (2) is eligible to vote in that election.	2002.
~	Provisional voter must be given information as to how to determine if vote was counted, and if not, the reason vote was not counted.	Authorized by SB 258 and Implemented 2004.
~	Provisional voter must be given access to a toll-free number or Web site that may be used to determine whether vote was counted or not; access may be provided at county level.	Authorized by SB 258 and Implemented 2004.
	Voting Information Requirements	
~	Voting information (sample ballot, date/hours of election, instructions on casting a ballot/provisional ballot, instructions for mail-in registrants who are first time voters, information on federal and state election laws) must be publicly posted at each polling place on each election for federal office.	Implemented 2004.
~	Voters casting ballots after normal hours (i.e., court ordered extension) must vote a provisional ballot kept separate from other provisional ballots.	Authorized by SB 258 and Implemented 2004.
	Computerized Statewide Voter Registration List Requirement	
v	Implement a single, uniform, centralized, interactive, computerized statewide voter registration list defined and administered at state level.	Implemented before 2002.
v	Computerized list shall serve as the single system for storing and managing official list of registered voters (first time voters must be identified on list).	Authorized by SB 258 and Implemented 2004.
v	List shall have unique identifier for each registered voter of state	Implemented before 2002.
v	List shall be coordinated with other state agency databases (in conjunction with on-going system upgrade).	Implemented before 2002.
v	Registration information must be promptly entered into database upon receipt of local election officials.	Implemented before 2002.
v	Electronic list shall serve as official list for federal elections	Implemented before 2002.
v	Names to be removed from list must follow procedures outlined in NVRA	Implemented before 2002.
v	List is to be maintained to remove ineligible voters, including: • Convicted felons • Death • Duplicate Names	Implemented before 2002.
v	Appropriate technological security measures shall be provided to protect list	Implemented before 2002.
v	The election system must be set up for minimum maintenance standards consistent with NVRA.	Implemented before 2002.
v	Upon application for voter registration, applicant must provide a unique identifying number as prescribed by HAVA [Note: States using a SSN are grandfathered into this provision as unique identifier requirement is met].	Implemented before 2002, modified 2004.
v	The chief election official and the state motor vehicle authority shall enter into an agreement to match data to the extent required to verify the accuracy of data provided for voter registration.	Implemented before 2002 (with on-going enhancements).
	Requirements for First Time Voters Who Register by Mail	
v	For individuals that register by mail and have not previously voted within the state • IF VOTING IN PERSON: (1) Presents current and valid photo ID; or (2) presents a copy of a current utility bill, bank statement, government check, paycheck or other government document showing name and address of voter • IF PERSON VOTES BY MAIL: Absentee ballot must contain (1) Copy of current and valid photo ID; or (2) a copy of a current utility bill, bank statement, government check, paycheck or other government document that shows name and address of voter	Authorized by SB 258 and Implemented 2004.
v	FAIL SAFE VOTING: For first-time voters registering by mail that do not provide required identification may be allowed to cast a provisional ballot.	Authorized by SB 258 and Implemented 2004.
v	Registration forms must conform to NVRA and HAVA (including first time voter information.	Modified 2004 Forms.

v = Mandate met.
~ = Minor administrative adjustment required.

[FR Doc. E8–21800 Filed 9–17–08; 8:45 am]

BILLING CODE 6820–KF–P

DEPARTMENT OF ENERGY

Agency Information Collection Extension

AGENCY: Department of Energy.

ACTION: Submission for Office of Management and Budget (OMB) review; comment request.

SUMMARY: The Department of Energy (DOE) has submitted an information collection request to the OMB for extension under the provisions of the Paperwork Reduction Act of 1995. The information collection requests a three-year extension of its ''Technology Partnerships Ombudsmen Reporting Requirements'', OMB Control Number 1910–5188. This information collection request covers information necessary to implement a statutory requirement that the Technology Transfer Ombudsmen report quarterly on complaints they receive.

DATES: Comments regarding this collection must be received on or before October 20, 2008. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, please advise the OMB Desk Officer of your intention to make a submission as soon as possible. The Desk Officer may be telephoned at 202–395–4650.

ADDRESSES: Written comments should be sent to the: DOE Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10102, 735 17th Street, NW., Washington, DC 20503; and to Kathleen M. Binder, GC–12, Director, Office of Conflict Prevention and Resolution, U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT: Kathleen M. Binder at the address listed in **ADDRESSES** .

SUPPLEMENTARY INFORMATION: This information collection request contains: (1) OMB No. 1910–5188; (2) Information Collection Request Title: Technology Partnerships Ombudsmen Reporting Requirements (3) Purpose: The information collected will be used to determine whether the Technology Partnerships Ombudsmen are properly helping to resolve complaints from outside organizations regarding laboratory policies and actions with respect to technology partnerships. (4) Estimated Number of Respondents: 22 (5) Estimated Total Burden Hours: 50 (6) Number of Collections: The information collection request contains 6 information and/or recordkeeping requirements.

Statutory Authority: Public Law 106–404, Technology Transfer Commercialization Act of 2000.

Issued in Washington, DC, on September 12, 2008.

Kathleen M. Binder,

Director, Office of Conflict Prevention and Resolution, Office of General Counsel.

[FR Doc. E8–21823 Filed 9–17–08; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Agency Information Collection Extension

AGENCY: U.S. Department of Energy.

ACTION: Notice and request for comments.

SUMMARY: The Department of Energy (DOE), pursuant to the Paperwork Reduction Act of 1995, intends to extend for three years, an information collection request with the Office of Management and Budget (OMB) where Foreign Travel Management System (FTMS) has been identified as a DOE system that is part of OMB's eGov initiative. Comments are invited on: (a) Whether the extended collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; and (c) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Comments regarding this proposed information collection must be received on or before 60 days after date of publication in the **Federal Register**. If you anticipate difficulty in submitting comments within that period, contact the person listed below as soon as possible.

ADDRESSES: Written comments may be sent to Julie Squires by fax at (202) 586–0406 or by e-mail at *julie.squires@hq.doe.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Julie Squires at *julie.squires@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: This information collection request contains: (1) OMB No. 1910–1800; (2) Information Collection Request Title: Foreign Travel Management System (FTMS); (3) Type of Review: Renewal; (4) Purpose: FTMS is the Department of Energy's (DOE) centralized web-based system which tracks, records, and secures approval of all travel conducted by DOE federal employees and contractors. The system allows DOE to have full accountability of all travel and in cases of emergency; the Department is able to quickly retrieve information as to who is traveling, where the individual is traveling, and the dates of travel. (5) Respondents: 2,465; (6) Estimated Number of Burden Hours: 5,000.

Statutory Authority: DOE O 551.1C, ''Official Foreign Travel''.

Issued in Washington, DC, on June 24, 2008.

Julie Squires,

Acting Director, Office of International Travel and Exchange Visitor Programs.

[FR Doc. E8–21825 Filed 9–17–08; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2008–0259; FRL–8717–2]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; Application for Registration of Pesticide-Producing and Device-Producing Establishments (EPA Form 3540–8) and Pesticide Report for Pesticide-Producing and Device-Producing Establishments (EPA Form 3540–16); EPA ICR No. 0160.09, OMB Control No. 2070–0078

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. The ICR, which is abstracted below, describes the nature of the information collection and its estimated burden and cost.

DATES: Additional comments may be submitted on or before October 20, 2008.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–

OECA–2008–0259 by one of the following methods:

(1) *www.regulations.gov* (follow the on-line instructions for submitting comments);

(2) By e-mail to *docket.oeca@epa.gov;*

(3) *Fax:* (202) 566–1511;

(4) *Mail:* EPA Docket Center, Environmental Protection Agency, Enforcement and Compliance Docket and Information Center (ECDIC), Mail code: 2201T, 1200 Pennsylvania Ave., NW., Washington, DC 20460;

(5) *Hand Delivery:* EPA Docket Center, Environmental Protection Agency, Enforcement and Compliance Docket and Information Center (ECDIC), EPA West, Room 3334, 1301 Constitution Avenue, NW., Washington, DC. The EPA Docket Center is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. Such deliveries are only accepted during the Docket Center's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

FOR FURTHER INFORMATION CONTACT: Robin Nogle, Office of Compliance, Agriculture Division (2225A), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 564–4154; fax number: (202) 564–0085; e-mail address: *nogle.robin@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On April 14, 2008 (73 FR 20042), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments during the comment period. Any additional comments on this ICR should be submitted to EPA and OMB within 30 days of this notice.

EPA has established a public docket for this ICR under Docket ID No. EPA–HQ–OECA–2008–0259, which is available for online viewing at *www.regulations.gov*, or in person viewing at the Enforcement and Compliance Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room is open from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is 202–566–1744, and the telephone number for the Enforcement and Compliance Docket is 202–566–1752.

Use EPA's electronic docket and comment system at *www.regulations.gov*, to submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the docket that are available electronically. Once in the system, select ''docket search,'' then key in the docket ID number identified above. Please note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing at *www.regulations.gov* as EPA receives them and without change, unless the comment contains copyrighted material, confidential business information (CBI), or other information whose public disclosure is restricted by statute. For further information about the electronic docket, go to *www.regulations.gov.*

Title: Application for Registration of Pesticide-Producing and Device-Producing Establishments (EPA Form 3540–8) and Pesticide Report for Pesticide-Producing and Device-Producing Establishments (EPA Form 3540–16).

ICR numbers: EPA ICR No. 0160.09, OMB Control No. 2070–0078.

ICR Status: This ICR is scheduled to expire on September 30, 2008. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9 and are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 7(a) requires that any person who produces pesticides or pesticide devices subject to the Act must register with the Administrator of EPA the establishment in which the pesticide or the device is produced. This section further requires that application for registration of any establishment shall include the name and address of the establishment and of the producer who operates such an establishment. EPA Form 3540–8, Application for Registration of Pesticide-Producing and Device-Producing Establishments, is used to collect the establishment registration information required by this section.

FIFRA section 7(c) requires that any producer operating an establishment registered under section 7 report to the Administrator within 30 days after it is registered, and annually thereafter by March 1st for certain pesticide/device production and sales/distribution information. The producers must report which types and amounts of pesticides, active ingredients, or devices are currently being produced, were produced during the past year, and sold or distributed in the past year. The supporting regulations at 40 CFR part 167 provide the requirements and time schedules for submitting production information. EPA Form 3540–16, Pesticide Report for Pesticide-Producing and Device-Producing Establishments, is used to collect the pesticide production information required by section 7(c) of FIFRA.

Establishment registration information, collected on EPA Form 3540–8, is a one-time requirement for all pesticide-producing and device-producing establishments. Pesticide and device production information, reported on EPA Form 3540–16, is required to be submitted within 30 days after the company is notified of their pesticide-producing or device-producing establishment number, and annually thereafter on or before March 1st.

Burden Statement

The annual public reporting and recordkeeping burden for this collection of information is estimated to average about 1.5 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements which have subsequently changed; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: 13,250.

Estimated Number of Respondents: 13,250.

Frequency of Response: Annually.

Estimated Total Annual Hour Burden: 19,158.

Estimated Total Annual Cost: $1,415,159. There are no annualized capital or O&M costs associated with

this ICR since all equipment associated with this ICR is present as part of ordinary business practices.

Changes in the Estimates: There is an increase of 358 hours in the total estimated burden currently identified in the OMB Inventory of Approved ICR Burdens. This increase is due to an adjustment in the estimates of the number of respondents.

Dated: September 12, 2008.

Sara Hisel-McCoy,

Director, Collection Strategies Division.

[FR Doc. E8–21828 Filed 9–17–08; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2003–0085; FRL–8717–3]

Agency Information Collection Activities; Proposed Collection; Comment Request; NESHAP for Radionuclides (Renewal); EPA ICR No. 1100.13, OMB Control No. 2060–0191

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), this document announces that EPA is planning to submit a request to renew an existing approved Information Collection Request (ICR) to the Office of Management and Budget (OMB). This ICR is scheduled to expire on January 31, 2009. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection as described below.

DATES: Comments must be submitted on or November 17, 2008.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2003–0085, by one of the following methods:

- *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *E-mail: littleton.brian@epa.gov.*
- *Fax:* (202) 343–2304.
- *Mail:* EPA Docket Center (EPA/DC), Air and Radiation Docket, Mail Code 2822T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460.
- *Hand delivery:* EPA Docket Center, EPA West (Room 3334), 1301 Constitution Avenue, NW., Washington, DC. Such deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m.–4:30 p.m.), and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OAR–2003–0085. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through www.regulations.gov or e-mail. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm*.

FOR FURTHER INFORMATION CONTACT: Brian Littleton, Radiation Protection Division, Office of Radiation and Indoor Air, (Mailcode 6608J), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 343–9216; fax number: (202) 343–2304; e-mail address: *littleton.brian@epa.gov*.

SUPPLEMENTARY INFORMATION:

How Can I Access the Docket and/or Submit Comments?

EPA has established a public docket for this ICR under Docket ID No. EPA–HQ–OAR–2003–0085, which is available for online viewing at *http://www.regulations.gov*, or in person viewing at the Air and Radiation Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is 202–566–1744, and the telephone number for the Air and Radiation Docket is 202–566–1742.

Use *http://www.regulations.gov* to obtain a copy of the draft collection of information, submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the docket ID number identified in this document.

What Information Is EPA Particularly Interested In?

Pursuant to section 3506(c)(2)(A) of the PRA, EPA specifically solicits comments and information to enable it to:

(i) 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;

(ii) 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;

(iii) enhance the quality, utility, and clarity of the information to be collected; and

(iv) 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. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

What Should I Consider When I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible and provide specific examples.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Offer alternative ways to improve the collection activity.

6. Make sure to submit your comments by the deadline identified under **DATES**.

7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

What Information Collection Activity or ICR Does This Apply to?

Docket ID No. EPA–HQ–OAR–2003–0085

Affected entities: Entities potentially affected by this action are the following industries and associated NAICS Codes: Elemental Phosphorous—325188; Phosphogypsum Stacks—212392; Underground Uranium Mines—212291; and Uranium Mills—212291.

Title: NESHAP for Radionuclides (40 CFR part 61, subparts B, K, R and W) (Renewal).

ICR numbers: EPA ICR No. 1100.13, OMB Control No. 2060–0191.

ICR status: This ICR is currently scheduled to expire on January 31, 2009. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9, are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: In the context of the Clean Air Act (42 U.S.C. 1857), Section 114 authorizes the Administrator of EPA to require any person who owns or operates any emission source or who is subject to any requirements of the Act to: (1) Establish and maintain records, (2) Make reports, install, use, and maintain monitoring equipment or method, (3) Sample emissions in accordance with EPA-prescribed locations, intervals and methods, and (4) Provide information as may be requested. EPA's regional offices use the information collected to ensure that public health continues to be protected from the hazards of radionuclides by compliance with health based standards. This information is required for those facilities meeting the definition of each Subpart. EPA's compliance monitoring activities vary widely. EPA could issue a letter requesting information about compliance or could conduct a full scale investigation, including on-site inspections.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 148 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements which have subsequently changed; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

The ICR provides a detailed explanation of the Agency's estimate, which is only briefly summarized here:

Estimated total number of potential respondents: 62.

Frequency of response: Annual.

Estimated total average number of responses for each respondent: 1.

Estimated total annual burden hours: 148 hours.

Estimated total annual costs: $1,270,000. This includes an estimated burden cost of $460,000 and an estimated cost of $810,000 for capital investment or maintenance and operational costs.

Are There Changes in the Estimates From the Last Approval?

There is an increase of 4,984 hours in the total estimated respondent burden compared with that identified in the ICR currently approved by OMB. This increase reflects an increase in the number of facilities affected due to both renewed interest in uranium mining and phosphgypsum usage.

What Is the Next Step in the Process for This ICR?

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. At that time, EPA will issue another **Federal Register** notice pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

Dated: September 5, 2008.

Jonathan Edwards,

Acting Director, Radiation Protection Division.

[FR Doc. E8–21856 Filed 9–17–08; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection Requirement Submitted to OMB for Review and Approval, Comments Requested

September 15, 2008.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden, invites the general public and other Federal agencies to take this opportunity to comment on the following information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before October 20, 2008. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, Office of Management and Budget, via Internet at *Nicholas_A._Fraser@omb.eop.gov* or via fax at (202) 395–5167 and to Cathy Williams, Federal Communications Commission, Room 1–C823, 445 12th

Street, SW., Washington, DC or via Internet at *Cathy.Williams@fcc.gov* or *PRA@fcc.gov*.

To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the Web page *http://www.reginfo.gov/public/do/PRAMain*, (2) look for the section of the Web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the title of this ICR (or its OMB control number, if there is one) and then click on the ICR Reference Number to view detailed information about this ICR.''

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection(s), contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0906.

Title: Annual DTV Report, FCC Form 317; 47 CFR 73.624(g).

Form Number: FCC Form 317.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities; Not-for-profit institutions.

Number of Respondents and responses: 1,815 respondents, 3,630 responses.

Frequency of Response: Recordkeeping requirement; Annual reporting requirement.

Obligation to Respond: Required to obtain benefits—Statutory authority for this collection of information is contained in Sections 154(i), 303, 336 and 403 of the Communications Act of 1934, as amended.

Estimated Time per Response: 2–4 hours.

Total Annual Burden: 10,890 hours.

Total Annual Costs: $181,500.

Confidentiality: No need for confidentiality required.

Privacy Impact Assessment: No impact(s).

Needs and Uses: Congress has mandated that after February 17, 2009, full-power television broadcast stations must transmit only in digital signals, and may no longer transmit analog signals. On December 22, 2007, the Commission adopted a Report and Order in the matter of the Third Periodic Review of the Commission's Rules and Policies Affecting the Conversion to Digital Television, MB Docket No. 07–91, FCC 07–228 (''Third DTV Periodic Report and Order'') to establish the rules, policies and procedures necessary to complete the nation's transition to DTV. As a result of the Third DTV Periodic Report and Order, DTV stations that are permittees must now comply with the requirements for feeable ancillary or supplementary services in Section 73.624(g) (using FCC Form 317). This new requirement in 47 CFR § 73.624(g) adds a new group of respondents to this collection (namely, ''DTV permittees''). The Commission has also revised FCC Form 317 and its instructions to indicate that DTV permittees are required to file the form and report their ancillary and supplementary services.

Each commercial and noncommercial educational (NCE) digital television (DTV) broadcast station licensee and permittee is required to file FCC Form 317 annually. The licensees/permittees report whether they provided ancillary or supplementary services at any time during the reporting cycle. The report indicates which services were provided, fee related services, gross revenues received from all feeable ancillary and supplementary services, and the amount of bitstream used to provide ancillary or supplementary service.

Concurrent with the submission of FCC Form 317, each commercial and noncommercial educational DTV licensee and permittee is required to remit to the Commission a payment, FCC Form 159 (3060–0589), in the amount of 5% of the gross revenues derived from the provision of its ancillary or supplementary services.

Each licensee and permittee is required to retain the records supporting the calculation of the fees due for three years from the date of remittance of fees. Noncommercial DTV licensees/permittees must also retain for eight years documentation sufficient to show that their entire bitstream was used ''primarily'' for noncommercial education broadcast services on a weekly basis.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. E8–21862 Filed 9–17–08; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission for Extension Under Delegated Authority, Comments Requested

September 12, 2008.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3520. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Persons wishing to comment on this information collection should submit comments November 17, 2008. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, Office of Management and Budget (OMB), 202–395–5887, or via fax at 202–395–5167, or via the Internet at *Nicholas_A._Fraser@omb.eop.gov* and to *Judith-B.Herman@fcc.gov*, Federal Communications Commission (FCC). To submit your comments by e-mail send them to: *PRA@fcc.gov.*

To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the Web page *http://www.reginfo.gov/public/do/PRAMain*, (2) look for the section of the Web page called ''Currently Under Review'', (3) click the downward-pointing arrow in the ''Select Agency'' box below the

''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box and (6) when the list of FCC ICRs currently under review appears, look for the title of this ICR (or its OMB Control Number, if there is one) and then click on the ICR Reference Number to view detailed information about this ICR.

FOR FURTHER INFORMATION CONTACT: For additional information, send an e-mail to Judith B. Herman at 202–418–0214.

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060–0147.

Title: Section 64.804, Extension of Unsecured Credit for Interstate and Foreign Communication Services to Candidates for Federal Office.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit.

Number of Respondents: 13 respondents; 13 responses.

Estimated Time per Response: 8 hours.

Frequency of Response: Annual reporting requirement and recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection (IC) is contained in section 401 of the Federal Election Campaign Act of 1971, Public Law 92–225 together with the 1971 Revenue Act, Public Law 92–178.

Total Annual Burden: 104 hours.

Annual Cost Burden: N/A.

Privacy Act Impact Assessment: N/A.

Nature and Extent of Confidentiality: Ordinarily questions of a sensitive nature are not involved in the filed data. The Commission contends that areas in which information is required are fully subject to regulation and the issue of data being regarded as sensitive will arise on special circumstances only. In such circumstances, the respondent is instructed on the appropriate procedures to follow to safeguard data. If respondents wish to request confidential treatment of their documents, they may do so under 47 CFR 0.459 of the Commission's rules.

Needs and Uses: This collection will be submitted as an extension (no change in the reporting requirement and/or recordkeeping requirement) after this 60 day comment period to Office of Management and Budget (OMB) in order to obtain the full three year clearance. There is no change in the number of respondents/responses and estimated burden hours. Collection of this information is required by statute—section 401 of the Federal Election Campaign Act of 1971, Public Law 92–225, together with the 1971 Revenue Act, Public Law 92–178.

Pursuant to Section 64.804(c), a carrier must obtain a signed, written application for service which shall identify the applicant and the candidate and state whether or not the candidate assumes responsibility for charges, and which shall state that the applicant or applicants are liable for payment and that the applicant understands that service will be discontinued if payment is not rendered. Section 64.804(f) also requires that the records of each account, involving the extension by a carrier of unsecured credit to a candidate or person on behalf of such candidate for common carrier communications services shall be maintained by the carrier as to show separately, for interstate and foreign communications services all charges, credits, adjustments, and security, if any, and balance receivable. Section 64.804(g) requires communications common carriers with operating revenues exceeding $1 million who extend unsecured credit to a political candidate or person on behalf of such candidate for Federal office to report annually, data including due and outstanding balances.

The information is used by the Commission to monitor the extent of credit extended to candidates for Federal office.

OMB Control No.: 3060–0704.

Title: Sections 42.10, 42.11, 64.1900 and Section 254(g): Policies and Rules Concerning the Interstate, Interexchange Marketplace.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit.

Number of Respondents: 700 respondents; 700 responses.

Estimated Time per Response: .50–2 hours.

Frequency of Response: Annual reporting requirements, third party disclosure requirements and recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in section 254(g) of the Communications Act of 1934, as amended.

Total Annual Burden: 2,450 hours.

Annual Cost Burden: N/A.

Privacy Act Impact Assessment: N/A.

Nature and Extent of Confidentiality: The Commission is not requesting that the respondents submit confidential information to the Commission. If the Commission requests respondents to submit information which respondents believe is confidential, respondents may request confidential treatment of such information under 47 CFR section 0.459 of the Commission's rules.

Needs and Uses: The Commission will submit this information collection as an extension (no change in reporting, third party disclosure requirements, and/or recordkeeping requirements) after this 60 day comment period in order to obtain the full three year clearance from the OMB. The estimated number of respondents/responses has increased due to an increase in alternate providers (*i.e.*, VoIP providers) and prepaid calling card providers. The estimated burden hours has been adjusted due to −81,887 hours due to a recalculation of each requirement. Finally, the total annual burden hours have significantly decreased because the Commission assumes that respondents have adapted to the requirements and therefore require less time to comply with the posting, disclosure, and certification requirements. Therefore, the Commission has decreased the estimated time per response for each of the requirements in this information collection. The four information collection requirements under this OMB Control Number are information disclosure requirements, internet posting requirements, recordkeeping requirements, and annual certification requirements. These requirements are necessary to provide consumers ready access to information concerning the rates, terms, and conditions governing the provision of interstate, domestic, Interexchange services offered by nondominant Interexchange carriers (IXCs) in a detariffed and increasingly competitive environment. These information collections are consistent with OMB's ''strong recommendation'' earlier in this proceeding that the Commission consider mechanisms to make pricing information available to consumers, State regulators, and other interested parties.

The information collected under the information disclosure requirement and the Internet posting requirement must be disclosed to the public to ensure that consumers have access to the information they need to select a telecommunications carrier and to bring to the Commission's attention possible violations of the Communications Act without a specific public disclosure requirement. The information collected under the recordkeeping and certification requirements will be used by the Commission to ensure that affected Interexchange carriers fulfill

their obligations under the Communications Act, as amended.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. E8–21864 Filed 9–17–08; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS–10137 and CMS–10237 and 10214]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Center for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR part 1320(a)(2)(iii). This is necessary to ensure compliance with an initiative of the Administration. We cannot reasonably comply with the normal clearance procedures because the use of normal clearance procedures is reasonably likely to cause a statutory deadline to be missed.

The Balanced Budget Act of 1997, established a new ''Part C'' in the Medicare statute, sections 1851 through 1859 of the Social Security Act, which provided for a Medicare+Choice (M+C) program. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) was enacted on December 8, 2003. The MMA established the Medicare Prescription Drug Benefit Program under section 101 of the MMA and is codified in section 1860D of the Social Security Act which establishes the voluntary Prescription Drug Benefit Program (''Part D''), and made revisions to the provisions of Medicare Part C, governing what is now called the Medicare Advantage (MA) program (formerly Medicare+Choice). The MMA was amended on July 15, 2008 by the enactment of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA).

CMS is in the process of publishing regulations that are intended to be released as an interim final rule with comment. Many of the provisions included in MIPPA that impact the Part C and Part D programs are self-implementing, meaning these provisions will go into effect without any further regulatory clarification or changes to the Part C and Part D solicitations. As part of the revised information collection request, CMS will implement into the Part C solicitations, sections 163, 164, and 165 of MIPPA, and implement into the Part D solicitations, sections 171, 172 and 173 of MIPPA. These sections amend the contractual requirements that Part C and Part D sponsors (applicants) must have with CMS and with any downstream or related entities performing Part C and Part D functions on the sponsor's behalf. Currently CMS provides templates that contain the required language for the contracts based on the statute and regulations. While applicants do not have to use the exact CMS contract templates, they will be responsible for including the required language in the contracts when they submit materials to CMS for the 2010 contract year.

The solicitations do not represent new policy, but rather implement the provisions that will exist in the forthcoming regulations, and include clarifying edits and updates as well. Therefore, CMS is seeking an emergency PRA clearance to amend the Part C and Part D solicitations to reflect the new MIPPA requirements.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Application for Prescription Drug Plans (PDP); Application for Medicare Advantage Prescription Drug (MA–PD); Application for Cost Plans to Offer Qualified Prescription Drug Coverage; Application for Employer Group Waiver Plans to Offer Prescription Drug Coverage; Service Area Expansion Application for Prescription Drug Coverage; *Use:* Collection of this information is mandated in Part D of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and under supporting regulations Subpart K of 42 CFR 423 entitled ''Application Procedures and Contracts with PDP Sponsors.''

Coverage for the prescription drug benefit is provided through contracted prescription drug plans (PDPs) or through Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage (MA–PD plans). Cost Plans that are regulated under Section 1876 of the Social Security Act, and Employer Group Waiver Plans (EGWP) may also provide a Part D benefit. Organizations wishing to provide services under the Prescription Drug Benefit Program must complete an application, negotiate rates and receive final approval from CMS. Existing Part D Sponsors may also expand their contracted service area by completing the Service Area Expansion (SAE) application. The information will be collected under the solicitation of proposals from PDP, MA–PD, Cost Plan, PACE, and EGWP Plan applicants. The collected information will be used by CMS to: (1) Ensure that applicants meet CMS requirements, (2) support the determination of contract awards. *Form Number:* CMS–10137 (OMB#: 0938–0936); *Frequency:* Reporting—Once; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 455 *Total Annual Responses:* 455; *Total Annual Hours:* 11,890.

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Advantage Applications—Part C; *Use:* Collection of this information is mandated in Part C of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) in Subpart K of 42 CRF 422 entitled ''Contracts with Medicare Advantage Organizations.'' Under section 1851(a)(1) of the Act, every individual entitled to Medicare Part A and enrolled under Part B, except for most individuals with end-stage renal disease, could elect to receive benefits either through the Original Medicare

Program or an M+C plan, if one was offered where he or she lived.

Coverage for the prescription drug benefit is provided through contracted prescription drug plans or through Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage (MA–PD plans). Cost plans that are required under section 1876 of the Social Security Act, and Employer Group Waiver Plans (EGWP) may also provide a Part D benefit. Organizations wishing to provide services under the MA and MA–PD plans must complete an application, negotiate rates and receive final approval from CMS. Certain existing MA plans may also expand their contracted area by completing the Service Area Expansion (SAE) application. The information will be collected under the solicitation of proposals from MA–PD, Cost Plan, EGWP Plan applicants. The collection information will be used by CMS to: (1) ensure that applicants meet CMS requirements, (2) support the determination of contract awards. *Form Number:* CMS–10237 and 10214 (OMB#: 0938–0935); *Frequency:* Reporting—Yearly; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 267; *Total Annual Responses:* 267; *Total Annual Hours:* 6,709.

CMS is requesting OMB review and approval of this collection by *December 12, 2008*, with a 180-day approval period. Written comments and recommendation will be considered from the public if received by the individuals designated below by the noted deadline below.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *October 20, 2008*:

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov*. Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850; and, OMB Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number: (202) 395–6974.

Dated: September 8, 2008.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E8–21669 Filed 9–15–08; 9:00 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects:

Title: Interstate Referral Guide (IRG).

OMB No.: 0970–0209.

Description: The purpose of the Intergovernmental Referral Guide (IRG) project is to provide States, Foreign Nations and Tribes with an effective and efficient way of viewing and updating their profiles with child support enforcement policies and procedures, and their address and location code information by consolidating data available through numerous discrete sources into a centralized, automated repository.

Respondents: State IV–D Child Support Programs, Foreign Nation Child Support Programs and Tribes.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
IRG State User Guide (States and Territories)	54	18	0.30	291.60
IRG State User Guide (Foreign Nations	23	2	0.10	4.60
IRG Tribal User Guide	44	18	0.30	237.60
Estimated Total Annual Burden Hours				533.80

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: August 19, 2008.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E8–21853 Filed 9–17–08; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & 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 Initial Review Group, Developmental Biology Subcommittee.

Date: October 13–14, 2008.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Crowne Plaza Washington National Airport, 1489 Jefferson Davis Hwy, Arlington, VA 22202.

Contact Person: Norman Chang, PhD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892, (301) 496–1485, *changn@mail.nih.gov.*

(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: September 10, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–21788 Filed 9–17–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & 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 Initial Review Group Reproduction, Andrology, and Gynecology Subcommittee.

Date: October 15, 2008.

Time: 8 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: The Legacy Hotel, 1775 Rockville Pike, Rockville, MD 20852.

Contact Person: Dennis Leszczynski, PhD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, NIH, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892, (301) 435–2717, *leszczyd@mail.nih.gov.*

(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: September 10, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–21789 Filed 9–17–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & 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 Initial Review Group, Obstetrics and Maternal-Fetal Biology Subcommittee.

Date: October 20–21, 2008.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Gaithersburg Hilton, 620 Perry Parkway, Gaithersburg, MD 20877.

Contact Person: Gopal M. Bhatnagar, PhD, Scientific Review Administrator, National Institute of Child Health and Human Development, National Institutes of Health, 6100 Executive Boulevard, Rm 5B01, Rockville, MD 20852, (301) 435–6889, *bhatnagg@mail.nih.gov.*

(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: September 10, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–21790 Filed 9–17–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & 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) and552b(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 Initial Review Group Pediatrics Subcommittee.

Date: October 20–21, 2008.

Time: 8:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Rita Anand, PhD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892, (301) 496–1487, *anandr@mail.nih.gov.*

(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: September 10, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–21791 Filed 9–17–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Sporting Conservation Council

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of meeting.

SUMMARY: We announce a meeting of the Sporting Conservation Council (Council). The meeting agenda includes outcomes of the October 1–3, 2008, White House Conference on North American Wildlife Policy, at which the culmination of the 10-year Conservation Plan agenda Executive Order (E.O.) 13443 calls for, along with other E.O. issues, will have been covered. This Council meeting is open to the public, and will include a session for the public to comment.

DATES: We will hold the meeting on October 3, 2008, from 1:30 p.m. to 4 p.m.; the public comment session will be from 2 to 2:30 p.m.

ADDRESSES: The meeting will be held in Ballroom 5 at the Reno Ballroom at 401 North Center Street, Reno, NV 89501.

FOR FURTHER INFORMATION CONTACT: Phyllis T. Seitts, 9828 North 31st Avenue, Phoenix, AZ 85051–2517; 602–906–5603 (phone); or *Twinkle_Thompson-Seitts@blm.gov* (e-mail).

SUPPLEMENTARY INFORMATION: The Secretary of the Interior established the Council in February 2006 (71 FR 11220, March 6, 2006). The Council's mission is to provide advice and guidance to the Federal Government through the Department of the Interior on how to increase public awareness of: (1) The importance of wildlife resources, (2) the social and economic benefits of recreational hunting, and (3) wildlife conservation efforts that benefit recreational hunting and wildlife resources.

The Secretary of the Interior and the Secretary of Agriculture signed an amended charter for the Council in June 2006 and July 2006, respectively. The revised charter states that the Council will provide advice and guidance to the Federal Government through the Department of the Interior and the Department of Agriculture.

The Council will hold a meeting on the date shown in the **DATES** section at the address shown in the **ADDRESSES** section. The meeting will include a session for the public to comment. Previous Council meetings this year occurred on April 8 in Denver, CO (73 FR 14997, March 20, 2008), on June 17 in Washington, DC (73 FR 31501, June 2, 2008) and on September 17 in Washington, DC (73 FR 51645, September 4, 2008).

Dated: September 12, 2008.

Phyllis T. Seitts,

Designated Federal Officer, Sporting Conservation Council.

[FR Doc. E8–21793 Filed 9–17–08; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[ES–956–1910–07–5MMS; ES–055517 Group No. 180 Wisconsin]

Eastern States: Filing of Plat of Survey

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Filing of Plat of Survey; Wisconsin.

SUMMARY: The Bureau of Land Management (BLM) will file the plat of survey of the lands described below in the BLM-Eastern States, Springfield, Virginia, 30 calendar days from the date of publication in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Bureau of Land Management, 7450 Boston Boulevard, Springfield, Virginia 22153, Attn: Cadastral Survey.

SUPPLEMENTARY INFORMATION: This survey was requested by the Bureau of Indian Affairs.

The lands we surveyed are:

Fourth Principal Meridian, Wisconsin

T. 35 N., R. 12 E.

The plat of survey represents the dependent resurvey of a portion of the west boundary, and a portion of the subdivisional lines; a corrective dependent resurvey of a portion of the west boundary, and a portion of the subdivisional lines; a corrective resurvey of the subdivision of section 20; and the survey of the subdivision of sections 15, 16, 17, 21, and 22, Township 35 North, Range 12 East, Fourth Principal Meridian, Wisconsin, and was accepted September 5, 2008.

We will place a copy of the plat we described in the open files. It will be available to the public as a matter of information. If BLM receives a protest against this survey, as shown on the plat, prior to the date of the official filing, we will stay the filing pending our consideration of the protest.

We will not officially file the plat until the day after we have accepted or dismissed all protests and they have become final, including decisions on appeals.

Dated: September 10, 2008.

Ronald J. Eberle,

Acting Chief Cadastral Surveyor.

[FR Doc. E8–21826 Filed 9–17–08; 8:45 am]

BILLING CODE 4310–GJ–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[ES–956–1910–BK–5YMG; ES–055518 Group No. 181, Wisconsin]

Eastern States: Filing of Plat of Survey

AGENCY: Bureau of Land Management, Interior

ACTION: Notice of Filing of Plat of Survey; Wisconsin.

SUMMARY: The Bureau of Land Management (BLM) will file the plat of survey of the lands described below in the BLM-Eastern States, Springfield, Virginia, 30 calendar days from the date of publication in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Bureau of Land Management, 7450 Boston Boulevard, Springfield, Virginia 22153, Attn: Cadastral Survey.

SUPPLEMENTARY INFORMATION: This survey was requested by the Bureau of Indian Affairs.

The lands we surveyed are:

Fourth Principal Meridian, Wisconsin

T. 22 N., R. 3 W.

The plat of survey represents the dependent resurvey of a portion of the subdivisional lines; and the survey of the subdivision of section 33, Township 22 North, Range 3 West, Fourth Principal Meridian, Wisconsin and was accepted September 5, 2008.

We will place a copy of the plat we described in the open files. It will be available to the public as a matter of information. If BLM receives a protest against this survey, as shown on the plat, prior to the date of the official filing, we will stay the filing pending our consideration of the protest.

We will not officially file the plat until the day after we have accepted or dismissed all protests and they have become final, including decisions on appeals.

Dated: *September 11, 2008.*

Ronald J. Eberle,

Acting Chief Cadastral Surveyor.

[FR Doc. E8–21827 Filed 9–17–08; 8:45 am]

BILLING CODE 4310–GJ–P

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337–TA–656]

In the Matter of: Certain Integrated Circuits and Products Containing Same; Notice of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Institution of investigation pursuant to 19 U.S.C. 1337.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on August 15, 2008, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of Freescale Semiconductor, Inc. of Austin, Texas. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain integrated circuits and products containing same that infringe certain claims of U.S. Patent Nos. 5,467,455, 5,776,798, and 6,473,349. The complaint further alleges that an industry in the United States exists as required by subsection (a)(2) of section 337.

The complainant requests that the Commission institute an investigation and, after the investigation, issue an exclusion order and cease and desist order.

ADDRESSES: The complaint, except for any confidential information contained therein, is available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E. Street, SW., Room 112, Washington, DC 20436, telephone 202–205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810. 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. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*.

FOR FURTHER INFORMATION CONTACT: Mareesa A. Frederick, Esq., Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2055.

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2008).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on September 11, 2008, ordered that—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain integrated circuits or products containing the same that infringe one or more of claims 22, 24 and 26 of U.S. Patent No. 5,467,455; claims 1, 2, and 12 of U.S. Patent No. 5,776,798; and claims 1, 4, and 7 of U.S. Patent No. 6,473,349, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is—

Freescale Semiconductor, Inc., 6501 William Cannon Drive West, Austin, Texas 78735.

(b) The respondent is the following entity alleged to be in violation of section 337, and is the party upon which the complaint is to be served: LSI Corporation, 1621 Barber Lane, Milpitas, California 95035.

(c) The Commission investigative attorney, party to this investigation, is Mareesa A. Frederick, Esq., Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E. Street, SW., Suite 401, Washington, DC 20436; and

(3) For the investigation so instituted, Paul J. Luckern, Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(d) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of the respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: September 12, 2008.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. E8–21721 Filed 9–17–08; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

[OMB Number 1122–0008]

Office on Violence Against Women; Agency Information Collection Activities: Revision of a Currently Approved Collection; Comments Requested

ACTION: 30-Day Notice of Information Collection Under Review: Semi-Annual Progress Report for the Enhanced

Training and Services to End Violence Against and Abuse of Women Later in Life Program.

The Department of Justice, Office on Violence Against Women (OVW), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** Number 73, page 40375 on July 14, 2008, allowing for a 60-day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until October 20, 2008. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503. Additionally, comments may be submitted to OMB via facsimile to (202) 395–5806.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Revision of a currently approved collection.

(2) *Title of the Form/Collection:* Semi-Annual Progress Report for Grantees from the Enhanced Training and Services to End Violence Against and Abuse of Women Later in Life Program (Training Program).

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: 1122–0008. U.S. Department of Justice, Office on Violence Against Women.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* The affected public includes the approximately 18 grantees of the Training Program. Training Program grants may be used for training programs to assist law enforcement officers, prosecutors, and relevant officers of Federal, State, tribal, and local courts in recognizing, addressing, investigating, and prosecuting instances of elder abuse, neglect, and exploitation and violence against individuals with disabilities, including domestic violence and sexual assault, against older or disabled individuals. Grantees fund projects that focus on providing training for criminal justice professionals to enhance their ability to address elder abuse, neglect and exploitation in their communities and enhanced services to address these crimes.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that it will take the approximately 18 respondents (Training Program grantees) approximately one hour to complete a semi-annual progress report. The semi-annual progress report is divided into sections that pertain to the different types of activities in which grantees may engage. A Training Program grantee will only be required to complete the sections of the form that pertain to its own specific activities.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total annual hour burden to complete the data collection forms is 36 hours, that is 18 grantees completing a form twice a year with an estimated completion time for the form being one hour.

If additional information is required contact: Lynn Bryant, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Suite 1600, Patrick Henry Building, 601 D Street NW., Washington, DC 20530.

Dated: September 12, 2008.

Lynn Bryant,

Department Clearance Officer, PRA, United States Department of Justice.

[FR Doc. E8–21868 Filed 9–17–08; 8:45 am]

BILLING CODE 4410–FX–P

DEPARTMENT OF JUSTICE

[OMB Number 1122–0012]

Office on Violence Against Women; Agency Information Collection Activities: Revision of a Currently Approved Collection; Comments Requested

ACTION: 30-Day Notice of Information Collection Under Review: Semi-Annual Progress Report for Education, Training and Enhanced Services to End Violence Against and Abuse of Women With Disabilities Grant Program.

The Department of Justice, Office on Violence Against Women (OVW), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** Volume 73, Number 135, page 40375, on July 14, 2008, allowing for a 60-day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until October 20, 2008. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503. Additionally, comments may be submitted to OMB via facsimile to (202) 395–5806.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including

whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Revision of a currently approved collection.

(2) *Title of the Form/Collection:* Semi-Annual Progress Report for Education, Training and Enhanced Services to End Violence Against and Abuse of Women With Disabilities Grant Program (Disability Grant Program).

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: 1122–0012. U.S. Department of Justice, Office on Violence Against Women.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* The affected public includes the approximately 18 grantees of the Disability Grant Program. Grantees include states, units of local government, Indian tribal governments or tribal organizations and non-governmental private organizations. The goal of this program is to build the capacity of such jurisdictions to address such violence against individuals with disabilities through the creation of multi-disciplinary teams. Disability Grant Program recipients will provide training, consultation, and information on domestic violence, dating violence, stalking, and sexual assault against individuals with disabilities and enhance direct services to such individuals.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that it will take the approximately 18 respondents (Disability Program grantees) approximately one hour to complete a semi-annual progress report. The semi-annual progress report is divided into sections that pertain to the different types of activities in which grantees may engage. A Disability Program grantee will only be required to complete the sections of the form that pertain to its own specific activities.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total annual hour burden to complete the data collection forms is 36 hours, that is 18 grantees completing a form twice a year with an estimated completion time for the form being one hour.

If additional information is required contact: Lynn Bryant, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Suite 1600, Patrick Henry Building, 601 D Street, NW., Washington, DC 20530.

Dated: September 12, 2008.

Lynn Bryant,

Department Clearance Officer, PRA, United States Department of Justice.

[FR Doc. E8–21870 Filed 9–17–08; 8:45 am]

BILLING CODE 4410–FX–P

DEPARTMENT OF JUSTICE

[OMB Number 1122–NEW]

Office on Violence Against Women; Agency Information Collection Activities: New Collection

ACTION: 30-Day Notice of Information Collection Under Review: Quarterly Conference Planning and Reporting Data Collection Form.

The Department of Justice, Office on Violence Against Women (OVW) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** Volume 73, Number 135, page 40374 on July 14, 2008, allowing for a 60-day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until October 20, 2008. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to The Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503. Additionally, comments may be submitted to OMB via facsimile to (202) 395–5806.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* New collection.

(2) *Title of the Form/Collection:* Quarterly Conference Planning and Reporting Data Collection Form.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: None yet. U.S. Department of Justice, Office on Violence Against Women.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* The affected public includes the approximately 100 entities providing technical assistance as recipients under the OVW Technical Assistance Program (TA Program). OVW's TA Program provides grantees from the different OVW grant programs with training, expertise, and problem-solving strategies to enhance their efforts to meet the challenges of addressing domestic violence, sexual assault, dating violence, and stalking. OVW's Technical Assistance providers offer educational opportunities, conferences, peer-to-peer consultations, site visits, and tailored assistance that allows OVW grantees and others to learn from experts and one another about how to effectively respond to crimes of violence against women.

Technical Assistance providers routinely hold meetings, conferences and trainings for OVW grantees to enhance the success of local projects they are implementing with VAWA grant funds. Section 218 of the Department of Justice Appropriations Act, 2008 (Title II, Division B, Pub. L. 110–161) requires the Attorney General to submit quarterly reports to the Inspector General regarding the costs and contracting procedures for certain conferences. In addition, section 1173 of Public Law 109–162, the Violence Against Women and Department of Justice Reauthorization Act of 2005 requires the Attorney General to prepare an annual report to the Chairman and ranking minority members of the Committees on the Judiciary of the Senate and of the House of Representatives that provides specified details about trainings and conferences. This new data collection form will enable OVW to collect information in order to respond to these reporting requirements in a timely manner.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that it will take the 100 respondents (Technical Assistance providers) approximately 15 minutes to complete the data collection form four times a year. The form collects basic information about conferences, meetings and trainings including location, purpose, costs, and number of attendees. This is information that is routinely collected by Technical Assistance providers in the ordinary course of business.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total annual hour burden to complete the data collection form is 100 hours. It will take approximately 15 minutes for the Technical Assistance providers to complete the form four times a year.

If additional information is required contact: Lynn Bryant, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Suite 1600, Patrick Henry Building, 601 D Street, NW., Washington, DC 20530.

Dated: September 12, 2008.

Lynn Bryant,

Department Clearance Officer, PRA, United States Department of Justice.

[FR Doc. E8–21871 Filed 9–17–08; 8:45 am]

BILLING CODE 4410–FX–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms, and Explosives

[OMB Number 1140–0003]

Agency Information Collection Activities: Proposed Collection; Comments Requested

ACTION: 30-Day Notice of Information Collection Under Review: Report of Multiple Sale or Other Disposition of Pistols and Revolvers.

The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** Volume 73, Number 135, page 40376 on July 14, 2008, allowing for a 60 day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until October 20, 2008. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to The Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503. Additionally, comments may be submitted to OMB via facsimile to (202) 395–5806.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—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 agencies 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.

Overview of This Information Collection

(1) *Type of Information Collection: Revision.*

(2) *Title of the Form/Collection:* Report of Multiple Sale or Other Disposition of Pistols and Revolvers.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: ATF F 3310.4. Bureau of Alcohol, Tobacco, Firearms and Explosives.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Business or other for-profit. *Other:* Federal Government, State, Local, or Tribal Government. *Abstract:* The form has been changed to allow for multiple disposition dates. Also, input fields have changed to more accurately reflect the information that is required.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* There will be an estimated 61,000 respondents, who will complete the form within approximately 15 minutes.

(6) *An estimate of the total burden (in hours) associated with the collection:* There are an estimated 61,000 total burden hours associated with this collection.

If additional information is required contact: Lynn Bryant, Department Clearance Officer, United States Department of Justice, Policy and Planning Staff, Justice Management Division, Suite 1600, Patrick Henry Building, 601 D Street, NW., Washington, DC 20530.

Dated: September 12, 2008.

Lynn Bryant,

Department Clearance Officer, PRA, United States Department of Justice.

[FR Doc. E8–21875 Filed 9–17–08; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms, and Explosives

[OMB Number 1140–0046]

Agency Information Collection Activities: Proposed Collection; Comments Requested

ACTION: 30-Day Notice of Information Collection Under Review: Certification on Agency Letterhead Authorizing Purchase of Firearm for Official Duties of Law Enforcement Officer.

The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** Volume 73, Number 135, page 40377 on July 14, 2008, allowing for a 60 day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until October 20, 2008. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to The Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503. Additionally, comments may be submitted to OMB via facsimile to (202) 395–5806.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—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 agencies 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.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Certification on Agency Letterhead Authorizing Purchase of Firearm for Official Duties of Law Enforcement Officer.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: None. Bureau of Alcohol, Tobacco, Firearms and Explosives.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* State, Local or Tribal Government. *Other:* none. *Abstract:* The letter is used by a law enforcement officer to purchase handguns to be used in his/her official duties from a licensed firearm dealer anywhere in the country. The letter shall state that the officer will use the firearm in official duties and that a records check reveals that the purchasing officer has no convictions for misdemeanor crimes of domestic violence.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* There will be an estimated 50,000 respondents, who will file the letter within approximately 5 seconds.

(6) *An estimate of the total burden (in hours) associated with the collection:* There are an estimated 69 total burden hours associated with this collection.

If additional information is required contact: Lynn Bryant, Department Clearance Officer, United States Department of Justice, Policy and Planning Staff, Justice Management Division, Suite 1600, Patrick Henry Building, 601 D Street, NW., Washington, DC 20530.

Dated: September 12, 2008.

Lynn Bryant,

Department Clearance Officer, PRA, United States Department of Justice.

[FR Doc. E8–21876 Filed 9–17–08; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms, and Explosives

[OMB Number 1140–0005]

Agency Information Collection Activities: Proposed Collection; Comments Requested

ACTION: 30-Day Notice of Information Collection Under Review: Application and Permit for Importation of Firearms and Ammunition and Implements of War.

The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** Volume 73, Number 135 page 40377 on July 14, 2008, allowing for a 60 day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until October 20, 2008. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to The Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503. Additionally, comments may be submitted to OMB via facsimile to 202–395–5806.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—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 agencies 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.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Application and Permit for Importation of Firearms and Ammunition and Implements of War.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: ATF F 6, Part 1 (5330.3A). Bureau of Alcohol, Tobacco, Firearms and Explosives.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. *Other:* Business or other for-profit, Federal Government, State, Local or Tribal Government. Abstract: The form is used to determine whether firearms, ammunition and implements of war are eligible for importation into the United States. It is also used to secure authorization to import such articles and serves as authorization to the U.S. Customs Service to allow these articles entry into the United States.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* There will be an estimated 11,000 respondents, who will complete the form within approximately 30 minutes.

(6) *An estimate of the total burden (in hours) associated with the collection:* There are an estimated 5,500 total burden hours associated with this collection.

If additional information is required contact: Lynn Bryant, Department Clearance Officer, United States Department of Justice, Policy and Planning Staff, Justice Management Division, Suite 1600, Patrick Henry Building, 601 D Street, NW., Washington, DC 20530.

Dated: September 12, 2008.

Lynn Bryant,

Department Clearance Officer, PRA, United States Department of Justice.

[FR Doc. E8–21877 Filed 9–17–08; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Information Card Foundation

Notice is hereby given that, on August 18, 2008, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Information Card Foundation has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Wave Systems, Lee, MA; IDology, Inc., Atlanta, GA; ooTao, Berkeley, CA; FuGen, Sunnyvale, CA; fun communications, Karlsruhe, GERMANY; IP Commerce, Denver, CO; Fraunhofer FOKUS, Berlin, GERMANY; Ping Identity, Denver, CO; e-backgroundchecks.com, Inc., Dallas, TX; A.T.E. Software, Frankfurt, GERMANY; Parity Communications, Needham, MA; Daniel Bartholomew (individual member), Kirrawee, NSW, AUSTRALIA; Privo, Vienna, VA; Gemalto, Austin, TX; and Kim Cameron (individual member), Bellvue, WA have been added as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and Information Card Foundation intends to file additional written notifications disclosing all changes in membership.

On June 2, 2008, Information Card Foundation filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on July 16, 2008 (73 FR 40883).

Patricia A. Brink,

Deputy Director of Operations, Antitrust Division.

[FR Doc. E8–21740 Filed 9–17–08; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—PXI Systems Alliance, Inc.

Notice is hereby given that, on August 20, 2008, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), PXI Systems Alliance, Inc. has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, EADS North America Test & Services, Irvine, CA; DAQTron, Inc., Roswell, GA; and Integrated Device Technology, Inc. San Jose, CA have been added as parties to this venture. Also, Nextronic Engineering Corp., Taipei TAIWAN; and OpenSystems Publishing LLC, St. Clair Shores, MI have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and PXI Systems Alliance, Inc. intends to file additional written notifications disclosing all changes in membership.

On November 22, 2000, PXI Systems Alliance, Inc. filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on March 8, 2001 (66 FR 13971).

The last notification was filed with the Department on June 4, 2008. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on July 11, 2008 (73 FR 39987).

Patricia A. Brink,

Deputy Director of Operations, Antitrust Division.

[FR Doc. E8–21743 Filed 9–17–08; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Semiconductor Test Consortium, Inc.

Notice is hereby given that, on August 20, 2008, pursuant to Section 6(a) of the

National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 et seq. (''the Act''), Semiconductor Test Consortium, Inc. has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, National Instruments, Austin, TX has been added as a party to this venture. Also, SEPT.Europe, Munich, GERMANY; Reid-Ashman Mfg., St. George, UT; Q–Star Test, HR Erugge, BELGUIM; Rood Technology GmbH Co., Nordlingen, GERMANY; BitifEye Digital Solutions GmbH, Boeblingen, GERMANY; Manufacturing Technology Center Semiconductor Company, Nagaolcakyo City, Kyoto, JAPAN; and Zhou Feng (individual member) Hougang, SINGAPORE have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and Semiconductor Test Consortium, Inc. intends to file additional written notifications disclosing all changes in membership.

On May 27, 2003, Semiconductor Test Consortium, Inc. filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on June 17, 2003 (68 FR 35913).

The last notification was filed with the Department on June 4, 2008. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on July 16, 2008 (73 FR 40883).

Patricia A. Brink,

Deputy Director of Operations, Antitrust Division.

[FR Doc. E8–21741 Filed 9–17–08; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993 Wireless Industrial Technology Konsortium Inc.

Notice is hereby given that, on August August 8, 2008, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 5 4301 *et seq.* (''the Act''), Wireless Industrial Technology Konsortium Inc. (''WITK'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identities of the parties to the venture and (2) the nature and objectives of the venture. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Pursuant to Section 6(b) of the Act, the identities of the parties to the venture are: Airsprite Technologies, Inc., Marlborough, MA; Freescale Semiconductor, Inc., Austin, TX; Pepperl + Fuchs GmbH, Mannheim, GERMANY; Emerson Process Management LLLP, Eden Prairie, MN; Endress + Hauser Process Solutions AG, Reinach, SWITZERLAND; Software Technologies Group, Westchester, IL; Siemens AG, Karisruhe, GERMANY; and ABE Automation Products GmbH, Alzenau, GERMANY.

The general areas of WITK's planned activity are to develop, implement, promote and distribute on a nonprofit basis one or more software communication stacks and supporting products, the first of which will be the WirelessHART Specification (HART 7) published by the HART Communication Foundation, and to encourage the use of such communications stacks and products on a standardized basis within, for example, the process control and factory automation communities worldwide, provided, however, WITK shall not carry on any activity not permitted to be carried on by a corporation that is exempt from federal income tax under Section 501(a) of the Code as an organization described in Section 501(c)(6) of the Internal Revenue Code.

Patricia A. Brink,

Deputy Director of Operations, Antitrust Division.

[FR Doc. E8–21742 Filed 9–17–08; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review: Comment Request

September 12, 2008.

The Department of Labor (DOL) hereby announces the submission of 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 Amy Hobby on 202–693–4553 (this is not a toll-free number)/e-mail: *DOL_PRA_PUBLIC@dol.gov*.

Interested parties are encouraged to send comments to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Employment Standards Administration (ESA), Office of Management and Budget, Room 10235, Washington, DC 20503, Telephone: 202–395–7316/Fax: 202–395–6974 (these are not toll-free numbers), Email: *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: Employment Standards Administration.

Type of Review: Extension without change of an existing OMB Control Number.

Title of Collection: Payment of Compensation without Award.

OMB Control Number: 1215–0022.

Agency Form Number(s): LS–206.

Affected Public: Businesses or other for-profits.

Total Estimated Number of Respondents: 600.

Total Estimated Annual Burden Hours: 5,250.

Total Estimated Annual Costs Burden: $10,395.

Description: The LS–206 is used by insurance carriers and self-insurers to report the initial payment of compensation benefits to injured claimants as required by the Longshore and Harbor Workers' Compensation Act. For additional information, see related notice published at 73 FR 31888 on June 4, 2008.

Darrin A. King,

Departmental Clearance Officer.

[FR Doc. E8–21819 Filed 9–17–08; 8:45 am]

BILLING CODE 4510–CF–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–63,130]

Sea Gull Lighting Products LLC, Riverside, NJ; Notice of Affirmative Determination Regarding Application for Reconsideration

By application submitted via facsimile on August 28, 2008, a petitioner requested administrative reconsideration of the negative determination regarding workers' eligibility to apply for Trade Adjustment Assistance (TAA) and Alternative Trade Adjustment Assistance (ATAA) applicable to workers and former workers of the subject firm. The determination was issued on July 28, 2008. The Notice of Determination was published in the **Federal Register** on August 12, 2008 (73 FR 46924).

The initial investigation resulted in a negative determination based on the finding that imports of residential lighting fixtures did not contribute importantly to worker separations at the subject firm and no shift of production to a foreign source occurred.

In the request for reconsideration, the petitioner provided additional information pertaining to the imports of lighting fixtures and the impact it has on subject firm production.

The Department has carefully reviewed the request for reconsideration and the existing record and has determined that the Department will conduct further investigation to determine if the workers meet the eligibility requirements of the Trade Act of 1974.

Conclusion

After careful review of the application, I conclude that the claim is of sufficient weight to justify reconsideration of the U.S. Department of Labor's prior decision. The application is, therefore, granted.

Signed at Washington, DC, this 5th day of September 2008.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E8–21842 Filed 9–17–08; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–63,295]

Visteon Corporation Regional Assembly & Manufacturing LLC; Fuel Delivery—Climate Group Division Concordia, MO; Notice of Affirmative Determination Regarding Application for Reconsideration

By application dated August 12, 2008, United Automobile, Aerospace & Agricultural Implement Workers of America, International Union, Local 710 requested administrative reconsideration of the negative determination regarding workers' eligibility to apply for Trade Adjustment Assistance (TAA) and Alternative Trade Adjustment Assistance (ATAA) applicable to workers and former workers of the subject firm. The determination was issued on July 23, 2008. The Notice of determination was published in the **Federal Register** on August 12, 2008 (73 FR 46924).

The determination was based on the Department's findings that imports of automotive fuel tanks did not contribute importantly to worker separations at the subject firm and no shift of production to a foreign source occurred.

In the request for reconsideration the petitioner provided additional information regarding the subject firm's customers indicating some customers have been certified for TAA and requested the Department of Labor investigate for secondary impact as a supplier of a component to a TAA certified firm.

The Department has carefully reviewed the request for reconsideration and the existing record and has determined that the Department will conduct further investigation to determine if the workers meet the eligibility requirements of the Trade Act as secondary impact workers.

Conclusion

After careful review of the application, I conclude that the claim is of sufficient weight to justify reconsideration of the U.S. Department of Labor's prior decision. The application is, therefore, granted.

Signed at Washington, DC, this 2nd day of September 2008.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E8–21843 Filed 9–17–08; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–63,589]

Delfingen US, Inc. Formerly Known as M&Q Plastics Products Also Known as Safanou, Inc., San Antonio, Texas; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273), and section 246 of the Trade Act of 1974 (26 U.S.C. 2813), as amended, the Department of Labor issued a Certification Regarding Eligibility to Apply for Worker Adjustment Assistance and a Negative Determination Regarding Eligibility to Apply for Alternative Trade Adjustment Assistance on July 16, 2008, applicable to workers of Delfingen US, Inc., San Antonio, Texas. The notice was published in the **Federal Register** on July 30, 2008 (73 FR 44283).

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. The workers were engaged in employment related to the production of convoluted protective plastic covers for wire harnesses.

New information shows that in March 2008, Delfingen US, Inc. purchased M&Q Plastic Products. Currently some of the workers wages at the subject firm are being reported under several Unemployment Insurance (UI) tax accounts for Delfingen US, Inc., formerly known as M&Q Plastic Products, also known as Safanou, Inc.

Accordingly, the Department is amending this certification to properly reflect this matter.

The intent of the Department's certification is to include all workers of Delfingen US, Inc., formerly known as M&Q Plastic Products, also known as Safanou, Inc. who were adversely affected by a shift in production of convoluted protective plastic covers for wire harnesses to Mexico.

The amended notice applicable to TA–W–63,589 is hereby issued as follows:

''All workers of Delfingen US, Inc., formerly known as M&Q Plastic Products, also known as Safanou, Inc., San Antonio, Texas, who became totally or partially separated from employment on or after June 24, 2007, through July 16, 2010, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.''

I further determine that all workers of Delfingen US, Inc., formerly known as M&Q Plastic Products, also known as Safanou, Inc., San Antonio, Texas, are denied eligibility to apply for alternative trade adjustment assistance under Section 246 of the Trade Act of 1974.

Signed at Washington, DC, this 4th day of September 2008

Richard Church,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E8–21844 Filed 9–17–08; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–63,766]

Federal Mogul Corporation Lighting Products Division, Boyertown, PA; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273), and section 246 of the Trade Act of 1974 (26 U.S.C. 2813), as amended, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance on August 27, 2008, applicable to workers of Federal Mogul Corporation, Lighting Products Division, Boyertown, Pennsylvania. The notice will be published soon in the **Federal Register** .

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. The workers are engaged in the production of sealed beam forward lighting products.

Findings show that there was a previous certification, TA–W–58,721, issued on March 6, 2006, for the workers of the Boyertown, Pennsylvania location of the subject firm. That certification expired March 6, 2008. To avoid an overlap in worker group coverage for the workers of the Boyertown, Pennsylvania location, the certification is being amended to change the impact date from July 24, 2007 to March 7, 2008.

Accordingly, the Department is amending the certification to properly reflect this matter.

The intent of the Department's certification is to include all workers of Federal Mogul Corporation who were adversely affected by increased imports of sealed beam forward lighting.

The amended notice applicable to TA–W–63,766 is hereby issued as follows:

''All workers of Federal Mogul Corporation, Lighting Products Division, Boyertown, Pennsylvania, who became totally or partially separated from employment on or after March 7, 2008, through August 27, 2010, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974, and are also eligible to apply for alternative trade adjustment assistance under Section 246 of the Trade Act of 1974.''

Signed at Washington, DC, this 10th day of September 2008.

Richard Church,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E8–21845 Filed 9–17–08; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–62,022]

Irwin Industrial Tools Including On-Site Leased Workers From Work-A-While, Advance Services, Inc. and Oasis Staffing Dewitt, Nebraska; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273), and section 246 of the Trade Act of 1974 (26 U.S.C. 2813), as amended, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance on August 31, 2007, applicable to workers of Irwin Industrial Tools, including on-site leased workers from Work-A-While and Advance Services, Inc., Dewitt, Nebraska. The notice was published in the **Federal Register** on September 11, 2007 (72 FR 51845).

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. The workers are engaged in the production of VISE–GRIP locking pliers and clamps.

New information shows that leased workers of Oasis Staffing were employed on-site at the Dewitt, Nebraska location of Irwin Industrial Tools.

The Department has determined that these workers were sufficiently under the control of the subject firm to be considered leased workers.

Based on these findings, the Department is amending this certification to include leased workers of Oasis Staffing working on-site at the Dewitt, Nebraska location of the subject firm.

The intent of the Department's certification is to include all workers employed at Irwin Industrial who were adversely affected by a shift in production of VISE-GRIP locking pliers and clamps to China.

The amended notice applicable to TA–W–62,022 is hereby issued as follows:

''All workers of Irwin Industrial Tools, including on-site leased workers from Work-A-While, Advance Services, Inc. and Oasis Staffing, Dewitt, Nebraska, who became totally or partially separated from employment on or after August 21, 2006, through August 31, 2009, are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974, and are also eligible to apply for alternative trade adjustment assistance under Section 246 of the Trade Act of 1974.''

Signed at Washington, DC this 10th day of September 2008.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E8–21840 Filed 9–17–08; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (19 U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers (TA–W) number and alternative trade adjustment assistance (ATAA) by (TA–W) number issued during the period of September 1 through September 5, 2008.

In order for an affirmative determination to be made for workers of a primary firm and a certification issued regarding eligibility to apply for worker

adjustment assistance, each of the group eligibility requirements of Section 222(a) of the Act must be met.

I. Section (a)(2)(A) all of the following must be satisfied:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. The sales or production, or both, of such firm or subdivision have decreased absolutely; and

C. Increased imports of articles like or directly competitive with articles produced by such firm or subdivision have contributed importantly to such workers' separation or threat of separation and to the decline in sales or production of such firm or subdivision; or

II. Section (a)(2)(B) both of the following must be satisfied:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. There has been a shift in production by such workers' firm or subdivision to a foreign country of articles like or directly competitive with articles which are produced by such firm or subdivision; and

C. One of the following must be satisfied:

1. The country to which the workers' firm has shifted production of the articles is a party to a free trade agreement with the United States;

2. The country to which the workers' firm has shifted production of the articles to a beneficiary country under the Andean Trade Preference Act, African Growth and Opportunity Act, or the Caribbean Basin Economic Recovery Act; or

3. There has been or is likely to be an increase in imports of articles that are like or directly competitive with articles which are or were produced by such firm or subdivision.

Also, in order for an affirmative determination to be made for secondarily affected workers of a firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(b) of the Act must be met.

(1) Significant number or proportion of the workers in the workers' firm or an appropriate subdivision of the firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The workers' firm (or subdivision) is a supplier or downstream producer to a firm (or subdivision) that employed a group of workers who received a certification of eligibility to apply for trade adjustment assistance benefits and such supply or production is related to the article that was the basis for such certification; and

(3) Either—

(A) The workers' firm is a supplier and the component parts it supplied for the firm (or subdivision) described in paragraph (2) accounted for at least 20 percent of the production or sales of the workers' firm; or

(B) A loss or business by the workers' firm with the firm (or subdivision) described in paragraph (2) contributed importantly to the workers' separation or threat of separation.

In order for the Division of Trade Adjustment Assistance to issue a certification of eligibility to apply for Alternative Trade Adjustment Assistance (ATAA) for older workers, the group eligibility requirements of Section 246(a)(3)(A)(ii) of the Trade Act must be met.

1. Whether a significant number of workers in the workers' firm are 50 years of age or older.

2. Whether the workers in the workers' firm possess skills that are not easily transferable.

3. The competitive conditions within the workers' industry (i.e., conditions within the industry are adverse).

Affirmative Determinations for Worker Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of Section 222(a)(2)(A) (increased imports) of the Trade Act have been met.

None.

The following certifications have been issued. The requirements of Section 222(a)(2)(B) (shift in production) of the Trade Act have been met.

TA–W–63,944; Norma Products (US), Inc., Wixom, MI: August 19, 2007.

The following certifications have been issued. The requirements of Section 222(b) (supplier to a firm whose workers are certified eligible to apply for TAA) of the Trade Act have been met.

None.

The following certifications have been issued. The requirements of Section 222(b) (downstream producer for a firm whose workers are certified eligible to apply for TAA based on increased imports from or a shift in production to Mexico or Canada) of the Trade Act have been met.

None.

Affirmative Determinations for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of Section 222(a)(2)(A) (increased imports) and Section 246(a)(3)(A)(ii) of the Trade Act have been met.

TA–W–63,744; Alexvale Furniture Company, Kincaid Furniture Co., Plant 1, Upholstery, Mulberry, Taylorsville, NC: July 8, 2008.

TA–W–63,725; Superior Sample Company, Rochester, IN: July 11, 2007.

TA–W–63,733; Center Manufacturing Company, Inc., Bellevue, OH: July 23, 2007.

TA–W–63,873; Century Furniture, Highland House Division, Subsidiary of CV Industrial, Hickory, NC: August 13, 2007.

TA–W–63,977; Easy Garment, Inc., New York, NY: August 29, 2007.

The following certifications have been issued. The requirements of Section 222(a)(2)(B) (shift in production) and Section 246(a)(3)(A)(ii) of the Trade Act have been met.

TA–W–63,721A; Hutchinson FTS, Inc., High Pressure Plant 2, Placement Pros, Livingston, TN: July 17, 2007.

TA–W–63,721B; Hutchinson FTS, Inc., Central Warehouse, Livingston, TN: July 17, 2007.

TA–W–63,721; Hutchinson FTS, Inc., High Pressure Plant 1, Placement Pros, Livingston, TN: July 17, 2007.

TA–W–63,825; Accuride International, Inc., Santa Fe Springs, CA: August 5, 2007.

TA–W–63,839; Blue Water Automotive Systems, Inc., Howell, MI: August 7, 2007.

TA–W–63,882; Kohler Company, Searcy, AR: August 15, 2007.

TA–W–63,927; Delfingen US, Inc., El Paso Division, El Paso, TX: August 22, 2007.

TA–W–63,929; Superior Industries International Incorporated, Pittsburg, KS: August 22, 2007.

TA–W–63,773; McAllister Corporation, dba Environmental Power Coating, Caledonia, MI: July 29, 2007.

TA–W–63,752; San Francisco Network, San Rafael, CA: July 18, 2007.

TA–W–63,769; TSI Graphics, Effingham, IL: July 28, 2007.
TA–W–63,906; Bel Power, Inc., Kelly Services, Westboro, MA: August 19, 2007.
TA–W–63,782; Whirlpool Corporation, LaVergne Division, LaVergne, TN: September 16, 2008.

The following certifications have been issued. The requirements of Section 222(b) (supplier to a firm whose workers are certified eligible to apply for TAA) and Section 246(a)(3)(A)(ii) of the Trade Act have been met.

TA–W–63,723; General Motors Corporation, GMNA Powetrain Masena, Massena, NY: July 16, 2007.

The following certifications have been issued. The requirements of Section 222(b) (downstream producer for a firm whose workers are certified eligible to apply for TAA based on increased imports from or a shift in production to Mexico or Canada) and Section 246(a)(3)(A)(ii) of the Trade Act have been met.

None.

Negative Determinations for Alternative Trade Adjustment Assistance

In the following cases, it has been determined that the requirements of 246(a)(3)(A)(ii) have not been met for the reasons specified.

The Department has determined that criterion (1) of Section 246 has not been met. The firm does not have a significant number of workers 50 years of age or older.

TA–W–63,944; Norma Products (US), Inc., Wixom, MI.

The Department has determined that criterion (2) of Section 246 has not been met. Workers at the firm possess skills that are easily transferable.

None.

The Department has determined that criterion (3) of Section 246 has not been met. Competition conditions within the workers' industry are not adverse.

None.

Negative Determinations for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In the following cases, the investigation revealed that the eligibility criteria for worker adjustment assistance have not been met for the reasons specified.

Because the workers of the firm are not eligible to apply for TAA, the workers cannot be certified eligible for ATAA.

The investigation revealed that criteria (a)(2)(A)(I.A.) and (a)(2)(B)(II.A.) (employment decline) have not been met.

TA–W–63,786; International Automotive Components, Group North America, Inc., Rochester Hills, MI.
TA–W–63,865; SFO Apparel, Inc., Brisbane, CA.
TA–W–63,930; Liberty Molds, Inc., Portage, MI.

The investigation revealed that criteria (a)(2)(A)(I.B.) (Sales or production, or both, did not decline) and (a)(2)(B)(II.B.) (shift in production to a foreign country) have not been met.

TA–W–63,896; Neoconix, Inc., Sunnyvale, CA.

The investigation revealed that criteria (a)(2)(A)(I.C.) (increased imports) and (a)(2)(B)(II.B.) (shift in production to a foreign country) have not been met.

TA–W–63,567; Huber Engineered Woods, LLC, Broken Bow, OK.
TA–W–63,719; 3M Precision Optics, Inc., Cincinnati, OH.
TA–W–63,722; California Professional Dyework, City of Industry,CA.
TA–W–63,806; Core Molding Technologies, Gaffney, SC.
TA–W–63,910; Magna Services of America, Inc., Magna Aftermarket, Inc., Greenville, MI.

The workers' firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

TA–W–63,831; OTC International Ltd., Long Island City, NY.
TA–W–63,905; ConAgra Foods, Omaha, NE.
TA–W–63,936; Emerson Power Transmission, Frontline CustomerService Div., Maysville, KY.

The investigation revealed that criteria of Section 222(b)(2) has not been met. The workers' firm (or subdivision) is not a supplier to or a downstream producer for a firm whose workers were certified eligible to apply for TAA.

None.

I hereby certify that the aforementioned determinations were issued during the period of September 1 through September 5, 2008. Copies of these determinations are available for inspection in Room C–5311, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 During normal business hours or will be mailed to persons who write to the above address.

Dated: September 11, 2008.

Erin Fitzgerald,

Director, Division of Trade Adjustment Assistance.

[FR Doc. E8–21839 Filed 9–17–08; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–62,955]

Pitney Bowes Tech Central Infrastructure & Support Services, Danbury, CT; Notice of Negative Determination on Reconsideration

On July 15, 2008, the Department issued an Affirmative Determination Regarding Application for Reconsideration for the workers and former workers of the subject firm. The notice was published in the **Federal Register** on July 21, 2008 (73 FR 42368).

The initial investigation resulted in a negative determination based on the finding that worker group does not produce an article within the meaning of section 222 for the Trade Act of 1974. The investigation revealed that workers of Pitney Bowes, Tech Central Infrastructure & Support Services, Danbury, Connecticut performed IT technical support for Pitney Bowes, Inc., which included tech support for the mainframe, network, and supporting software, including upgrades, installs, patches, maintenance, help desk support and repair.

In the request for reconsideration the petitioner stated that workers of Tech Central Infrastructure & Support Services are Computer Operations Management and Staff, Server Engineering and Support, Network Engineering and Support, Telecommunications Engineering and Support and various Application Support group (HR, SAP, Lotus Notes, etc.) The petitioner further alleged that the workers of the subject firm supported production of Postage Meters by building custom servers, applications and infrastructure, ''built the physical equipment that allows Pitney Bowes to offer additional products and services'' and ''supported production of custom stamps by designing, implementation, storage and support of this product.''

On reconsideration, the Department contacted a company official and requested additional information regarding the production of various products by Pitney Bowes and whether workers of the subject firm supported production of the above mentioned products.

The company official stated that Pitney Bowes, Inc. bought servers from a third-party vendor and in no sense built these servers or develop applications or code. Furthermore, the company official stated that the workers of the subject firm neither built physical equipment nor designed or created the

Stamp products. The company official stated that some of the petitioning workers may have loaded software of the Stamp Expressions product on the servers and/or connected the software to the network.

The petitioner further alleged that production of the above-mentioned articles has been shifted to India and thus workers of the Tech Central Infrastructure & Support Services, Danbury, Connecticut should be eligible for TAA.

The company official denied this allegation and stated that production of postage meters, custom stamps, and similar Pitney Bowes equipment is continuing to be produced in the United States and that there was no shift in production of these articles to India or any other foreign country.

The company official stated that some information support functions have been outsourced to a third party vendor, both in the United States and India. However, this outsourcing does not include any outsourcing in production.

The allegation of a shift to another country might be relevant if it was determined that workers of the subject firm produced an article. Since the investigation determined that workers of Pitney Bowes, Tech Central Infrastructure & Support Services, Danbury, Connecticut do not produce an article, there can not be imports nor a shift in production of an ''article'' abroad within the meaning of the Trade Act of 1974 in this instance.

Conclusion

After reconsideration, I affirm the original notice of negative determination of eligibility to apply for worker adjustment assistance for workers and former workers of Pitney Bowes, Tech Central Infrastructure & Support Services, Danbury, Connecticut.

Signed at Washington, DC, this 9th day of September, 2008.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E8–21841 Filed 9–17–08; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–63,819]

Jakel, Inc., Murray, KY; Notice of Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, as amended, an investigation was initiated on August 6, 2008 in response to a petition filed by workers of Jakel, Inc., Murray, Kentucky. The subject firm stopped production on September 30, 2007.

The petitioning group of workers is covered by a previous certification (TA–W–59,714) which expired on September 2, 2008. The date of separation of the worker group was within the time period covered by this certification. Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed at Washington, DC, this 8th day of September 2008.

Richard Church,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E8–21836 Filed 9–17–08; 8:45 am]

BILLING CODE 4510–FN–P

NUCLEAR REGULATORY COMMISSION

Agency Information Collection Activities: Submission for the Office of Management and Budget (OMB) Review; Comment Request

AGENCY: U. S. Nuclear Regulatory Commission (NRC).

ACTION: Notice of the OMB review of information collection and solicitation of public comment.

SUMMARY: The NRC has recently submitted to OMB for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The NRC published a **Federal Register** Notice with a 60-day comment period on this information collection on May 30, 2008.

1. *Type of submission, new, revision, or extension:* Extension.

2. *The title of the information collection:* 10 CFR Part 33—Specific Domestic Licenses of Broad Scope for Byproduct Material.

3. *Current OMB approval number:* 3150–0015.

4. *The form number if applicable:* N/A.

5. *How often the collection is required:* There is a one-time submittal of information to receive a license. Once a specific license has been issued, there is a 10-year resubmittal of the information for renewal of the license.

6. *Who will be required or asked to report:* All applicants requesting a license of broad scope for byproduct material and all current licensees requesting renewal of a broad scope license.

7. *An estimate of the number of annual responses:* All of the information collections in Part 33 are captured under OMB clearance number 3150–0120 for NRC Form 313.

8. *The estimated number of annual respondents:* See Item 7.

9. *An estimate of the total number of hours needed annually to complete the requirement or request:* See Item 7.

10. *Abstract:* 10 CFR Part 33 contains mandatory requirements for the issuance of a broad scope license authorizing the use of byproduct material. The subparts cover specific requirements for obtaining a license of broad scope. These requirements include equipment, facilities, personnel, and procedures adequate to protect health and minimize danger to life or property.

A copy of the final supporting statement may be viewed free of charge at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O–1 F21, Rockville, MD 20852. OMB clearance requests are available at the NRC worldwide Web site: *http://www.nrc.gov/public-involve/doc-comment/omb/index.html*. The document will be available on the NRC home page site for 60 days after the signature date of this notice.

Comments and questions should be directed to the OMB reviewer listed below by October 20, 2008. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date.

Nathan J. Frey, Office of Information and Regulatory Affairs (3150–0121), NEOB–10202, Office of Management and Budget, Washington, DC 20503.

Comments can also be e-mailed to *Nathan_J._Frey@omb.eop.gov* or submitted by telephone at (202) 395–7345.

The NRC Clearance Officer is Russell Nichols, (301) 415–6874.

Dated at Rockville, Maryland, this 10th day of September, 2008.

For the Nuclear Regulatory Commission.

Gregory Trussell,

Acting NRC Clearance Officer, Office of Information Services.

[FR Doc. E8–21799 Filed 9–17–08; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 030–33261]

Notice of Availability of Environmental Assessment and Finding of No Significant Impact for License Amendment Request to Byproduct Materials License 37–30062–01 for the Defense Logistics Agency/Defense Distribution Center, New Cumberland, PA

AGENCY: Nuclear Regulatory Commission.

ACTION: Issuance of Environmental Assessment and Finding of No Significant Impact for License Amendment.

FOR FURTHER INFORMATION CONTACT: Thomas Thompson, Senior Health Physicist, Commercial and R&D Branch, Division of Nuclear Materials Safety, Region I, 475 Allendale Road, King of Prussia, PA 19406. Telephone: (610) 337–5303; fax number: (610) 337–5269; e-mail: *TKT@nrc.gov*.

SUPPLEMENTARY INFORMATION:

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is considering the issuance of a license renewal to Byproduct Materials License No. 37–30062–01. This license is held by the Defense Logistics Agency/Defense Distribution Center (Licensee), located in New Cumberland, Pennsylvania. As part of its license renewal, the Licensee has requested an exemption from the requirement in 10 CFR 30.32(g) to list sealed sources by their manufacturer and model number 4 as registered under the provisions of 10 CFR 32.210. The Licensee requested this exemption in a letter dated October 26, 2005. The NRC has prepared an Environmental Assessment (EA) in support of this proposed action in accordance with the requirements of Title 10, Code of Federal Regulations (CFR), Part 51 (10 CFR Part 51). Based on the EA, the NRC has concluded that a Finding of No Significant Impact (FONSI) is appropriate with respect to the proposed action. The license renewal, including the approval of the exemption request, will be issued to the Licensee following the publication of this FONSI and EA in the **Federal Register**.

II. Environmental Assessment

Identification of Proposed Action

The proposed action would renew License No. 37–30062–01, including approval of the Licensee's request for exemption submitted on October 26, 2005. License No. 37–30062–01 was issued on January 27, 1995, pursuant to 10 CFR Parts 30, 40, and 70, and has been amended periodically since that time. This license authorized the Licensee for the receipt, storage and packaging of serviceable Department of Defense commodity items containing licensed material and distribution of these items to any Department of Defense persons authorized to receive the licensed material, pursuant to the items and conditions of specific licenses issued by the U.S. Nuclear Regulatory Commission; and for use in calibration and verification of the licensee's instruments.

On December 21, 2004, the Licensee submitted its renewal application for License No. 37–30062–01. In a letter dated June 27, 2005, submitted in response to a Request for Additional Information from the NRC dated May 20, 2005, requesting that the Licensee identify all sealed sources by radionuclide, manufacturer, and model number, the Licensee described its need for flexibility in its authorization, stating that the listing of broad categories of materials on the license was intentional to allow the Licensee the flexibility to receive, store and transfer all items authorized to either of the branches of service by their NRC License. The Licensee also stated that maintaining a current list of all sealed sources is contingent on what items the military services wish to possess and is subject to change independent from the Licensee's authorization. The Licensee stated that ensuring that each sealed source is registered as an approved sealed source or device by the NRC or an Agreement State is the responsibility of each of the military services. In its follow-up letter dated October 26, 2005, the Licensee explicitly requested an exemption from the requirement in 10 CFR 30.32(g) to list sealed sources by their manufacturer and model number as registered under the provisions of 10 CFR 32.210. In requesting this exemption, the Licensee stated the use of the radioactive materials authorized under the License is in the context of distribution operations. The initial procurement, storage period and distribution of these sources are at the direction of the item manager assigned by the specific military service. The procuring service is responsible for ensuring the radioactive sources used in items of military supply are properly registered with the NRC or an appropriate Agreement State. As such, each of the military services has a variety of NRC licenses that authorize the use and possession of each item that could be processed through the Licensee. The Licensee stated further that the requested exemption is especially important given increased operational tempo that the current war on terrorism demands.

Need for the Proposed Action

This exemption is needed to authorize the Licensee to continue to receive, store, and distribute these sources and devices needed by the military services.

Technical Analysis of the Proposed Action

10 CFR 30.11(a) states that the Commission may grant such exemptions from the requirements of the regulations as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest. The NRC staff has analyzed the Licensee's request to be authorized to receive and take possession of sealed sources and devices which have not been registered with the NRC under 10 CFR 32.210 or with an Agreement State. The NRC staff considered that the Licensee is qualified by sufficient training and experience and has sufficient facilities and equipment to handle these sources and devices. Furthermore, NRC inspections have evaluated the Licensee's performance and determined that the Licensee has safely handled these unregistered sources for many years. Accordingly, the NRC staff has concluded that granting this exemption is authorized by law, will not endanger life or property or the common defense and security, and is in the public interest.

Environmental Impacts of the Proposed Action

The proposed action is largely administrative in nature. Approving this exemption will have no environmental impact.

Environmental Impacts of the Alternatives to the Proposed Action

Due to the largely administrative nature of the proposed action, its environmental impacts are small. Additionally, denying the exemption request would result in no change in current environmental impacts. The environmental impacts of the proposed action and the no-action alternative are therefore similar, and the no-action alternative is accordingly not further considered.

Conclusion

The NRC staff has concluded that the proposed action will not significantly impact the quality of the human

environment; the NRC staff concludes that the proposed action is the preferred alternative.

Agencies and Persons Consulted

The NRC staff has determined that the proposed action is of a procedural nature, and will not affect listed species or critical habitat. Therefore, no further consultation is required under section 7 of the Endangered Species Act. The NRC staff has also determined that the proposed action is not the type of activity that has the potential to cause effects on historic properties. Therefore, no further consultation is required under section 106 of the National Historic Preservation Act.

III. Finding of No Significant Impact

The NRC staff has prepared this EA in support of the proposed action. On the basis of this EA, the NRC finds that there are no significant environmental impacts from the proposed action, and that preparation of an environmental impact statement is not warranted. Accordingly, the NRC has determined that a Finding of No Significant Impact is appropriate.

IV. Further Information

Documents related to this action, including the application for exemption and supporting documentation, are available electronically at the NRC's Electronic Reading Room at *http://www.nrc.gov/reading-rm/adams.html*. From this site, you can access the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. The documents related to this action are listed below, along with their ADAMS accession numbers.

1. Licensee letter dated June 27, 2005 [ML051870315].

2. Licensee letter dated October 26, 2005 [ML053010281].

If you do not have access to ADAMS, or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1–800–397–4209, 301–415–4737, or by e-mail to *pdr@nrc.gov*. These documents may also be viewed electronically on the public computers located at the NRC's PDR, O 1 F21, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852. The PDR reproduction contractor will copy documents for a fee.

Dated at Region I, 475 Allendale Road, King of Prussia, PA this 8th day of September 2008.

For the Nuclear Regulatory Commission.

James P. Dwyer,

Chief, Commercial and R&D Branch, Division of Nuclear Materials Safety, Region I.

[FR Doc. E8–21803 Filed 9–17–08; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 030–29879]

Notice of Availability of Environmental Assessment and Finding of No Significant Impact for License Amendment Request to Byproduct Materials License 29–28005–01 for the Sarnoff Corporation, Princeton, NJ

AGENCY: Nuclear Regulatory Commission.

ACTION: Issuance of Environmental Assessment and Finding of No Significant Impact for License Amendment.

FOR FURTHER INFORMATION CONTACT: Dennis Lawyer, Health Physicist, Commercial and R&D Branch, Division of Nuclear Materials Safety, Region I, 475 Allendale Road, King of Prussia, PA 19406. Telephone: (610) 337–5303; fax number: (610) 337–5366; e-mail: *Dennis.Lawyer@nrc.gov*.

SUPPLEMENTARY INFORMATION:

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is considering the issuance of a license renewal to Byproduct Materials License No. 29–28005–01. This license is held by The Sarnoff Corporation (Licensee) in Princeton, New Jersey. As part of its license renewal, the Licensee has requested an exemption from the requirement in 10 CFR 30.32(g) to list sealed sources by their manufacturer and model number as registered under the provisions of 10 CFR 32.210. The Licensee requested this exemption in a letter dated June 2, 2006. The NRC has prepared an Environmental Assessment (EA) in support of this proposed action in accordance with the requirements of Title 10, Code of Federal Regulations (CFR), Part 51 (10 CFR Part 51). Based on the EA, the NRC has concluded that a Finding of No Significant Impact (FONSI) is appropriate with respect to the proposed action. The license renewal, including the approval of the exemption request, will be issued to the Licensee following the publication of this FONSI and EA in the **Federal Register**.

II. Environmental Assessment

Identification of Proposed Action

The proposed action would renew License No. 29–28005–01, including approval of the Licensee's request for exemption submitted on June 2, 2006. License No. 29–28005–01 was issued on June 16, 1987, pursuant to 10 CFR Part 30, and has been amended periodically since that time. This license authorized the Licensee for research and development as defined in 10 CFR 30.4.

On June 24, 2005, the Licensee submitted its renewal application for License No. 29–28005–01. In a letter dated February 1, 2006, discussing its unregistered americium-241 source, the Licensee referenced the guidance in NUREG 1556, Volume 3 (Revision 1) which states that that sealed sources containing 10 microcuries or less of alpha-emitting radioactive material and 100 microcuries or less of beta and/or gamma emitting materials were not required to be registered. In a letter dated June 2, 2006, in response to NRC questions contained in an e-mail dated May 16, 2006, the Licensee explicitly requested an exemption from the requirement in 10 CFR 30.32(g) to list its americium-241 source by a manufacturer and model number as registered under the provisions of 10 CFR 32.210. The unregistered americium-241 sealed source (a gamma emitting source of approximately 11 microcuries) possessed by the Licensee meets the criterion in NUREG 1556, Volume 3 (Revision 1) which states that that sealed sources containing 100 microcuries or less of gamma emitting materials were not required to be registered. In addition, the Licensee stated that granting this exemption will enable the Licensee to continue to make calibrations of its equipment in a timely manner, avoiding the need to send equipment out for calibration. The Licensee further stated that granting this exemption would avoid the need and risk of bringing a calibration source to the site for instruments that cannot be moved. The Licensee also stated that a replacement americium-241 source that would meet the current registration requirements would likely be a larger source with an increased risk of handling.

Need for the Proposed Action

The Licensee has used this source for many years without incident. This exemption is needed to authorize the Licensee to continue to possess this source.

Technical Analysis of the Proposed Action

10 CFR 30.11(a) states that the Commission may grant such exemptions from the requirements of the regulations as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest. The NRC staff has analyzed the Licensee's request to be authorized to receive and take possession of sealed sources and devices which have not been registered with the NRC under 10 CFR 32.210 or with an Agreement State. The NRC staff considered that the Licensee is qualified by sufficient training and experience and has sufficient facilities and equipment to handle these sources and devices. Furthermore, NRC inspections have evaluated the Licensee's performance and determined that the Licensee has safely handled these unregistered sources for many years. Accordingly, the NRC staff has concluded that granting this exemption is authorized by law, will not endanger life or property or the common defense and security, and is in the public interest.

Environmental Impacts of the Proposed Action

The proposed action is largely administrative in nature. The Licensee has handled sources and devices which have not been registered by the NRC under 10 CFR 32.210, or by an Agreement State, for many years. The Licensee is qualified by sufficient training and experience and has sufficient facilities and equipment to handle these sources and devices. Approving this exemption will have no environmental impact.

Environmental Impacts of the Alternatives to the Proposed Action

Due to the largely administrative nature of the proposed action, its environmental impacts are small. Additionally, denying the exemption request would result in no change in current environmental impacts. The environmental impacts of the proposed action and the no-action alternative are therefore similar, and the no-action alternative is accordingly not further considered.

Conclusion

The NRC staff has concluded that the proposed action will not significantly impact the quality of the human environment; the NRC staff concludes that the proposed action is the preferred alternative.

Agencies and Persons Consulted

The NRC staff has determined that the proposed action is of a procedural nature, and will not affect listed species or critical habitat. Therefore, no further consultation is required under section 7 of the Endangered Species Act. The NRC staff has also determined that the proposed action is not the type of activity that has the potential to cause effects on historic properties. Therefore, no further consultation is required under section 106 of the National Historic Preservation Act.

III. Finding of No Significant Impact

The NRC staff has prepared this EA in support of the proposed action. On the basis of this EA, the NRC finds that there are no significant environmental impacts from the proposed action, and that preparation of an environmental impact statement is not warranted. Accordingly, the NRC has determined that a Finding of No Significant Impact is appropriate.

IV. Further Information

Documents related to this action, including the application for exemption and supporting documentation, are available electronically at the NRC's Electronic Reading Room at *http://www.nrc.gov/reading-rm/adams.html*. From this site, you can access the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. The documents related to this action are listed below, along with their ADAMS accession numbers.

1. Licensee renewal application dated June 24, 2005 [ML051890490].

2. Licensee letter dated February 1, 2006 [ML060590605].

3. Licensee letter dated June 2, 2006 [ML061560252].

If you do not have access to ADAMS, or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1–800–397–4209, 301–415–4737, or by e-mail to *pdr@nrc.gov*. These documents may also be viewed electronically on the public computers located at the NRC's PDR, O 1 F21, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852. The PDR reproduction contractor will copy documents for a fee.

Dated at Region I, 475 Allendale Road, King of Prussia, this 10th day of September 2008.

For the Nuclear Regulatory Commission.

James P. Dwyer,

Chief, Commercial and R&D Branch, Division of Nuclear Materials Safety Region I.

[FR Doc. E8–21802 Filed 9–17–08; 8:45 am]

BILLING CODE 7590–01–P

UNITED STATES POSTAL SERVICE

Board of Governors; Sunshine Act Meeting

DATE AND TIME: Tuesday, September 23, 2008, at 12:30 p.m.; and Wednesday, September 24, 2008, at 8:30 a.m. and 11 a.m.

PLACE: Washington, DC, at U.S. Postal Service Headquarters, 475 L'Enfant Plaza, SW., in the Benjamin Franklin Room.

STATUS: September 23—12:30 p.m.—Closed; September 24—8:30 a.m.—Open; September 24—11 a.m.—Closed.

MATTERS TO BE CONSIDERED:

Tuesday, September 23 at 12:30 p.m. (Closed)

1. Financial Update.
2. Fiscal Year 2009 Integrated Financial Plan Briefing.
3. Fiscal Year 2009 Goals and Performance Assessment.
4. Product Pricing.
5. Strategic Issues.
6. Personnel Matters and Compensation Issues.
7. Governors' Executive Session—Discussion of prior agenda items and Board Governance.

Wednesday, September 24 at 8:30 a.m. (Open)

1. Minutes of the Previous Meetings, May 6–7, and July 28–29, 2008.
2. Remarks of the Chairman of the Board.
3. Remarks of the Postmaster General and CEO.
4. Committee Reports.
5. Financial Update.
6. Preliminary Fiscal Year 2010 Appropriation Request.
7. Capital Investments.
a. Distribution Quality Improvement (DQI) Program.
b. San Francisco, California, Townsend Carrier Annex.
8. Vision 2013—Five-Year Strategic Plan.
9. Board of Governors Bylaw Amendments.
10. National Identity Crimes Law Enforcement Network.
11. Tentative Agenda for the November 12–13, 2008, meeting in Washington, DC.

Wednesday, September 24 at 11:00 a.m. (Closed)—If Needed

1. Continuation of Tuesday's closed session agenda.

CONTACT PERSON FOR MORE INFORMATION: Julie S. Moore, Secretary of the Board, U.S. Postal Service, 475 L'Enfant Plaza, SW., Washington, DC 20260–1000. Telephone (202) 268–4800.

Julie S. Moore,

Secretary.

[FR Doc. E8–21904 Filed 9–16–08; 11:15 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549.

Extension:

Form N–2; SEC File No. 270–21; OMB Control No. 3235–0026.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) the Securities and Exchange Commission (the ''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

The title for the collection of information is ''Form N–2 (17 CFR 239.14 and 274.11a–1) under the Securities Act of 1933 and under the Investment Company Act of 1940, Registration Statement of Closed-End Management Investment Companies.'' Form N–2 is the form used by closed-end management investment companies (''closed-end funds'') to register as investment companies under the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.*) (''Investment Company Act'') and to register their securities under the Securities Act of 1933 (15 U.S.C. 77a *et seq.*) (''Securities Act''). The primary purpose of the registration process is to provide disclosure of financial and other information to investors and potential investors for the purpose of evaluating an investment in a security. Form N–2 also permits closed-end funds to provide investors with a prospectus containing information required in a registration statement prior to the sale or at the time of confirmation of delivery of securities. The form also may be used by the Commission in its regulatory review, inspection, and policy-making roles.

The Commission estimates that there are 140 initial registration statements and 60 post-effective amendments to initial registration statements filed on Form N–2 annually and that the average number of portfolios referenced in each initial filing and post-effective amendment is 1. The Commission further estimates that the hour burden for preparing and filing a post-effective amendment on Form N–2 is 116.5 hours per portfolio. The total annual hour burden for preparing and filing post-effective amendments is 6,990 hours (60 post-effective amendments × 1 portfolios × 116.5 hours per portfolio). The estimated annual hour burden for preparing and filing initial registration statements is 79,478 hours (140 initial registration statements × 1 portfolios × 567.7 hours per portfolio). The total annual hour burden for Form N–2, therefore, is estimated to be 86,468 hours (6,990 hours + 79,478 hours).

The information collection requirements imposed by Form N–2 are mandatory. Responses to the collection of information will not be kept confidential. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid control number.

Written 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 collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to Lewis W. Walker, Acting Director/CIO, Securities and Exchange Commission, C/O Shirley Martinson, 6432 General Green Way, Alexandria, VA 22312; or send an e-mail to: *PRA_Mailbox@sec.gov*.

Dated: September 10, 2008.

Florence E. Harmon,

Acting Secretary.

[FR Doc. E8–21764 Filed 9–17–08; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 28379; 812–13483]

Rafferty Asset Management, LLC, et al.; Notice of Application

September 12, 2008.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of an application for an order under section 6(c) of the Investment Company Act of 1940 (the ''Act'') for an exemption from sections 2(a)(32), 5(a)(1), 22(d), 22(e), and 24(d) of the Act and rule 22c–1 under the Act, and under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act.

Summary of Application: Applicants request an order that would permit (a) an open-end management investment company and its series to issue shares (''ETS'') that can be redeemed only in large aggregations (''Creation Units''); (b) secondary market transactions in ETS to occur at negotiated prices; (c) dealers to sell ETS to purchasers in the secondary market unaccompanied by a prospectus when prospectus delivery is not required by the Securities Act of 1933 (''Securities Act''); (d) certain series to pay redemption proceeds, under certain circumstances, more than seven days after the tender of ETS for redemption and; (e) certain affiliated persons of the series to deposit securities into, and receive securities from, the series in connection with the purchase and redemption of Creation Units.

Applicants: Rafferty Asset Management, LLC (''Adviser'') and Direxion Shares ETF Trust (''Trust'').

Filing Dates: The application was filed on January 23, 2008 and amended on May 8, 2008, August 21, 2008 and September 12, 2008.

Hearing or Notification of Hearing: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on October 3, 2008, and should be accompanied by proof of service on applicants, in the form of an affidavit, or for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090; Applicants, 33 Whitehall Street, 10th Floor, New York, New York 10004.

FOR FURTHER INFORMATION CONTACT: Emerson S. Davis, Sr., Senior Counsel at (202) 551–6868, or Julia Kim Gilmer, Branch Chief, at (202) 551–6821 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the Public Reference Branch, U.S. Securities and Exchange Commission, 100 F Street, NE., Washington DC 20549–1520, telephone (202) 551–5850.

Applicants' Representations

1. The Trust is an open-end management investment company registered under the Act and organized as a Delaware statutory trust. The Trust is authorized to offer an unlimited number of series (the ''Funds''). The Adviser is registered as an investment adviser under the Investment Advisers Act of 1940 (''Advisers Act''). The Trust will initially offer thirty-two series (''Initial Funds'') with different types of investment objectives as further described below.[1] Applicants may offer additional Funds in the future (''Future Funds'' and included in the term Funds).[2] Each Fund will be advised by the Adviser. The Adviser may enter into subadvisory agreements with additional investment advisers to act as subadvisers to the Trust and any of the Funds. Any subadviser to the Trust or a Fund will be registered under the Advisers Act. A broker-dealer registered under the Securities Exchange Act of 1934 (''Exchange Act'') will act as the distributor and principal underwriter of each Fund's Creation Units of ETS (''Distributor'').

2. The Funds will seek daily investment results, before fees and expenses, that: (a) Correspond to the return of particular foreign equity indices (''Underlying Foreign Indices''), domestic equity indices (''Underlying Domestic Indices'') or fixed income securities indices (''Underlying Fixed Income Indices'' together with the Underlying Foreign Indices and the Underlying Domestic Indices, the ''Underlying Indices'')[3] (such Funds are referred to as the ''Conventional Funds''); (b) provide up to 400% of the return of their Underlying Indices (''Leveraged Funds''); or (c) provide up to 400% of the inverse performance of their Underlying Indices (''Inverse Funds'').[4]

3. Conventional Funds and Leveraged Funds based on Underlying Domestic Indices will invest at least 95% and 80%, respectively, of their total assets in the equity securities contained in the relevant Underlying Domestic Index. Conventional Funds and Leveraged Funds based on Underlying Fixed Income Indices will invest at least 80% of their total assets in the securities that comprise the relevant Underlying Fixed Income Index. Conventional Funds and Leveraged Funds based on Underlying Foreign Indices will invest at least 80% of their total assets in the equity securities contained in the relevant Underlying Foreign Index and depositary receipts representing such securities.[5]

4. Additionally, the Funds may invest in short-term debt instruments that meet the definition of ''Eligible Security'' in rule 2a–7 under the Act (''Money Market Instruments''), and in futures contracts, options, equity caps, collars and floors, swap agreements, forward contracts, and reverse repurchase agreements (collectively, ''Financial Instruments'') in order to meet their investment objectives. The Inverse Funds will only invest in Financial Instruments and Money Market Instruments; they will not invest in the component securities of their Underlying Indices.

5. A Conventional Fund will utilize either a replication or representative sampling strategy. A Conventional Fund using a ''replication'' strategy will invest in substantially all of the Component Securities in its Underlying Index in approximately the same proportions as in the Underlying Index. A Conventional Fund using a representative sampling strategy will invest in some, but not all, of the relevant Component Securities. The Adviser will seek to achieve the investment objectives of the Leveraged Funds and the Inverse Funds by using a mathematical model that takes into account a variety of specified criteria, the most important of which are: (a) The net assets in each Fund's portfolio at the end of each trading day; (b) the amount of required exposure to the Underlying Index; and (c) the positions in equity and fixed income securities, Financial Instruments and Money Market Instruments at the beginning of each trading day. On each day that a Fund is required to be open under section 22(e) of the Act (''Business Day'') the full portfolio holdings of each Fund will be disclosed on the website of the Trust and/or the Exchange on which ETS are primarily listed (''Primary Listing Exchange''). The portfolio holdings information disclosed each Business Day will form the basis for that Fund's net asset value (''NAV'') calculation as of 4:00 pm Eastern Time that day and will reflect portfolio trades made on the immediately preceding Business Day. Intra-day values of each Underlying Domestic Index and Underlying Foreign Index will be disseminated every 15 seconds throughout the trading day. The value of Underlying Fixed Income Indices will be calculated and published once per day.

6. Applicants expect that each Conventional Fund will have an annual tracking error of less than 5% over the course of the year (excluding the impact of expenses and interest, if any) to the performance of its Underlying Index. For Leveraged Funds and Inverse Funds, applicants expect a tracking error of less than 5% over the course of a year (excluding the impact of expenses and interest, if any) to the specified multiple or inverse multiple, respectively, of the performance of the relevant Underlying Index.

7. Each Fund will issue Creation Units of approximately 25,000 to 100,000 ETS. Applicants expect the initial offering price of a Creation Unit to be a minimum of $1 million. All orders to purchase Creation Units must be placed on a Business Day with the Distributor by or through a party that has entered into a participant agreement with the Distributor (an ''Authorized Participant''). An Authorized Participant must be either (a) a broker-dealer or other participant in the continuous net settlement system of the National Securities Clearing Corporation, a clearing agency that is registered with the Commission, or (b) a participant in the Depository Trust Company (''DTC'') system. The Distributor also will be responsible for delivering the Prospectus to those persons purchasing Creation Units and for maintaining records of the orders

[1] The underlying indices for the Initial Funds are identified in the application.

[2] All existing entities that intend to rely on the requested order have been named as applicants. Any Future Fund that relies on the requested order will comply with the terms and conditions of the application.

[3] An entity that creates, compiles, sponsors or maintains an Underlying Index is not and will not be an affiliated person, as defined in section 2(a)(3) of the Act, or an affiliated person of an affiliated person of the Trust, a Fund, the Distributor, the Adviser, or any subadviser or promoter of any Fund.

[4] Sixteen of the Initial Funds are Leveraged Funds and the remainder are Inverse Funds.

[5] ''Depositary Receipts'' include American Depositary Receipts, Global Depositary Receipts and European Depositary Receipts.

and acknowledgements of acceptance for orders.

8. Creation Units of Conventional and Leveraged Funds generally will be purchased and redeemed in exchange for an ''in-kind'' transfer of securities (''In-Kind Payment'') and cash. Inverse Funds will generally be purchased and redeemed entirely for cash because of the limited transferability of Financial Instruments.[6] An investor making an In-Kind Payment will be required to transfer to the Trust a ''Deposit Basket'' consisting of: (a) A basket of securities consisting of some or all of the securities in the relevant Underlying Index or other securities selected by the Adviser to correspond to the performance of the Underlying Index (the ''Deposit Securities''); and (b) a ''Balancing Amount.'' The Balancing Amount will be equal to the differential, if any, between the total aggregate market value of the Deposit Securities, or in the case of redemptions, the Redemption Securities (defined below), and the NAV per Creation Unit.[7] An investor purchasing or redeeming a Creation Unit from a Fund will be charged a fee (''Transaction Fee'') to prevent the dilution of the interests of the remaining shareholders resulting from the Fund incurring costs in connection with the purchase and redemption of the Creation Units.[8] The maximum Transaction Fee and any variations or waivers of the Transaction Fee will be disclosed in the prospectus for ETS (''Prospectus'') and the method of determining the Transaction Fees will be disclosed in the Prospectus and/or statement of additional information (''SAI'').

9. Persons purchasing Creation Units from a Fund may hold the ETS or sell some or all of them in the secondary market. ETS of the Funds will be listed on an Exchange and trade in the secondary market in the same manner as other exchange-traded funds. It is expected that one or more Exchange member firms will act as a specialist (''Exchange Specialist'') or market maker (''Market Maker'') and maintain a market on the Primary Listing Exchange for ETS. The price of ETS traded on an Exchange will be based on a current bid/offer market. The initial trading price for ETS of each Fund will fall in the range of $50 to $250. Transactions involving the sale of ETS in the secondary market will be subject to customary brokerage commissions and charges.

10. Applicants expect that purchasers of Creation Units will include institutional and retail investors, arbitrageurs, traders, financial advisors, portfolio managers and other market participants.[9] An Exchange Specialist or Market Maker, in providing for a fair and orderly secondary market for ETS, also may purchase or redeem Creation Units for use in its market-making activities. Applicants expect that the market price of ETS will be disciplined by arbitrage opportunities created by the ability to purchase or redeem Creation Units at their NAV, which should ensure that the market price of ETS at or close to 4 p.m. stays close to the NAV on that Business Day.

11. ETS will not be individually redeemable. ETS will only be redeemable in Creation Units through the Distributor, which will act as the Trust's agent for redemption. To redeem, an investor must accumulate enough ETS to constitute a Creation Unit. An investor redeeming a Creation Unit of a Conventional or Leveraged Fund generally will receive an In-Kind Payment of securities published by the Trust's index receipt agent (the ''Redemption Securities''), the Balancing Amount in effect on the date a request for redemption is made, minus any Transaction Fee.

12. Applicants state that in accepting Deposit Securities and satisfying redemptions with Redemption Securities,[10] the relevant Funds will comply with the federal securities laws, including that the Deposit Securities and Fund Securities are sold in transactions that would be exempt from registration under the Securities Act.[11] As a general matter, the Deposit Securities and Redemption Securities will correspond pro rata to the securities held by each Conventional Fund and Leveraged Fund, but Redemption Securities received on redemption may not always be identical to Deposit Securities deposited in connection with the purchase of Creation units for the same day.

13. Applicants state that neither the Trust nor any Fund will be advertised, marketed or otherwise held out as a ''mutual fund.'' The term ''mutual fund'' will not be used in the Prospectus except to compare and contrast the Trust or a Fund with conventional mutual funds. In all marketing materials where the features or methods of obtaining, buying, or selling Creation Units are described or where there is reference to redeemability, applicants will include a prominent statement to the effect that individual ETS are not redeemable except in Creation Units. The same approach will be followed in connection with reports and other communications to shareholders, as well as any other investor education materials issued or circulated in connection with ETS. The Trust will provide copies of its annual and semi-annual shareholder reports to DTC participants for distribution to beneficial holders of ETS.

Applicants' Legal Analysis

1. Applicants request an order under section 6(c) of the Act for an exemption from sections 2(a)(32), 5(a)(1), 22(d), 22(e), and 24(d) of the Act and rule 22c–

[6] The Trust may also accept and deliver all-cash payments for the purchase and redemption of Creation Units of any Fund in certain limited circumstances.

[7] On each Business Day, prior to the opening of trading on the New York Stock Exchange, the Trust's index receipt agent will make available the list of the names and the required number of shares of each security included in the current Deposit Basket and the Balancing Amount for each Fund. Such Deposit Basket will apply to all purchases of Creation Units until a new Deposit Basket for a Fund is announced. The Primary Listing Exchange will disseminate every 15 seconds during regular trading hours, through the facilities of the Consolidated Tape Association, an amount representing on a per ETS basis the sum of the current value of the Deposit Securities, and the estimated amount of cash and Money Market Instruments held in the portfolio of a Conventional or Leveraged Fund. For Leveraged Funds, the amount would also include, on a per share basis, the marked-to-market gains or losses of the Financial Instruments held by the Fund. For Inverse Funds, the Primary Listing Exchange will disseminate an amount representing, on a per share basis, the estimated amount of cash and Money Market Instruments, and the marked-to-market gains or losses of the Fund's Financial Instruments.

[8] A purchaser permitted to substitute cash for certain Deposit Securities may be assessed a higher Transaction Fee to cover the cost of purchasing such securities, including operational processing and brokerage costs, and part or all of the spread between the expected bid and offer side of the market relating to such securities.

[9] ETS will be registered in book-entry form only. DTC or its nominee will be the record or registered owner of all outstanding ETS. DTC or its participants will maintain records reflecting the beneficial owners of ETS.

[10] Applicants state that a cash-in-lieu amount will replace any ''to-be-announced'' (''TBA'') transaction that is listed as a Deposit Security or Redemption Security of any Fund. A TBA transaction is a method of trading mortgage-backed securities where the buyer and seller agree upon general trade parameters such as agency, settlement date, par amount and price. The actual pools delivered generally are determined two days prior to the settlement date. The amount of substituted cash in the case of TBA transactions will be equivalent to the value of the TBA transaction listed as a Deposit Security or Redemption Security.

[11] In accepting Deposit Securities and satisfying redemptions with Redemption Securities that are restricted securities eligible for resale pursuant to rule 144A under the Securities Act, the relevant Funds will comply with the conditions of rule 144A, including in satisfying redemptions with such rule 144A eligible restricted Redemption Securities. The Prospectus will also state that an Authorized Participant that is not a ''Qualified Institutional Buyer'' as defined in rule 144A under the Securities Act will not be able to receive, as part of a redemption, restricted securities eligible for resale under rule 144A.

1 under the Act, and under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act.

2. Section 6(c) of the Act provides that the Commission may exempt any person, security or transaction, or any class of persons, securities or transactions, from any provision of the Act, if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

Sections 5(a)(1) and 2(a)(32) of the Act

3. Section 5(a)(1) of the Act defines an ''open-end company'' as a management investment company that is offering for sale or has outstanding any redeemable security of which it is the issuer. Section 2(a)(32) of the Act defines a redeemable security as any security, other than short-term paper, under the terms of which the owner, upon its presentation to the issuer, is entitled to receive approximately his proportionate share of the issuer's current net assets, or the cash equivalent. Because ETS will not be individually redeemable, applicants request an order that would permit the Trust to issue ETS that are redeemable in Creation Units only. Applicants state that investors may purchase ETS of a Fund in Creation Units and redeem Creation Units from the Trust. Applicants further state that because the market price of ETS will be disciplined by arbitrage opportunities, investors should be able to sell ETS in the secondary market at or close to 4:00 p.m. on a Business Day at prices that do not vary substantially from the NAV on that Business Day.

Section 22(d) of the Act and Rule 22c–1 Under the Act

4. Section 22(d) of the Act, among other things, prohibits a dealer from selling a redeemable security, which is currently being offered to the public by or through a principal underwriter, except at a current public offering price described in the prospectus. Rule 22c–1 under the Act generally requires that a dealer selling, redeeming or repurchasing a redeemable security do so only at a price based on its NAV. Applicants state that secondary market trading in ETS will take place at negotiated prices, not at a current offering price described in a Fund's Prospectus as required by section 22(d) of the Act, and not at a price based on NAV as required by rule 22c–1 under the Act. Applicants request an exemption under section 6(c) from these provisions.

5. Applicants assert that the concerns sought to be addressed by section 22(d) of the Act and rule 22c–1 under the Act with respect to pricing are equally satisfied by the proposed method of pricing ETS. Applicants maintain that while there is little legislative history regarding section 22(d), its provisions, as well as those of rule 22c–1, appear to have been intended to (a) prevent dilution caused by certain riskless-trading schemes by principal underwriters and contract dealers, (b) prevent unjust discrimination or preferential treatment among buyers, and (c) ensure an orderly distribution of investment company shares by eliminating price competition from dealers offering shares at less than the published sales price and repurchasing shares at more than the published redemption price.

6. Applicants believe that none of these purposes will be thwarted by permitting ETS to trade in the secondary market at negotiated prices. Applicants state that (a) secondary market trading in ETS does not directly involve Trust assets and (b) to the extent different prices exist during a given trading day, or from day to day, such variances occur as a result of third-party market forces, such as supply and demand, not as a result of unjust or discriminatory manipulation. Therefore, applicants assert that secondary market transactions in ETS will not lead to discrimination or preferential treatment among purchasers. Finally, applicants contend that the proposed distribution system will be orderly because competitive forces in the marketplace will ensure that the difference between the market price of ETS and their NAV remains narrow.

Section 24(d) of the Act

7. Section 24(d) of the Act provides, in relevant part, that the prospectus delivery exemption provided to dealer transactions by section 4(3) of the Securities Act does not apply to any transaction in a redeemable security issued by an open-end investment company. Applicants seek relief from section 24(d) to permit dealers selling ETS in the secondary markets to rely on the prospectus delivery exemption provided by section 4(3) of the Securities Act.[12]

8. Applicants state that secondary market investors will regard ETS in a manner similar to other securities, including closed-end fund shares that are listed, bought and sold on an Exchange. Applicants note that shares of closed-end fund investment companies are sold in the secondary market unaccompanied by a prospectus.

9. Applicants contend that ETS, as a listed security, merit a reduction in the compliance costs and regulatory burdens resulting from the imposition of prospectus delivery obligations in the secondary market. Because ETS will be exchange-listed, prospective investors will have access to several types of market information about ETS. Applicants state that information regarding market price and volume will be continually available on a real-time basis throughout the day from the relevant Exchange, automated quotation systems, published or other public sources or on-line information services. Applicants expect that the previous day's closing price and volume information for ETS also will be published daily in the financial section of newspapers. In addition, the Trust expects to maintain a website that includes quantitative information updated on a daily basis, including, for each Fund, daily trading volume, the NAV and the reported closing price. The website will also include, for each Fund, a calculation of the premium or discount of the reported closing price against NAV, and data in chart format displaying the frequency distribution of discounts and premiums of the reported closing price against the NAV, within appropriate ranges, for each of the four previous calendar quarters.

10. Applicants will make available for distribution to secondary market purchasers of ETS a product description (''Product Description'') that describes, in plain English, the Trust, relevant Fund and its ETS. Applicants state that,

[12] Applicants state that they are not seeking relief from the prospectus delivery requirement for non-secondary market transactions, such as transactions in which an investor purchases ETS from the Funds or an underwriter. Applicants further state that each Fund's Prospectus will caution broker-dealers and others that some activities on their part, depending on the circumstances, may result in their being deemed statutory underwriters and subject them to the prospectus delivery and liability provisions of the Securities Act. For example, a broker-dealer firm and/or its client may be deemed a statutory underwriter if it takes Creation Units after placing an order with the Distributor, breaks them down into the constituent ETS, and sells those ETS directly to customers, or if it chooses to couple the creation of a supply of new ETS with an active selling effort involving solicitation of secondary market demand for ETS. Each Fund's Prospectus will state that whether a person is an underwriter depends upon all of the facts and circumstances pertaining to that person's activities. The Prospectus also will state that dealers who are not ''underwriters'' but are participating in a distribution (as contrasted to ordinary secondary market trading transactions), and thus dealing with ETS that are part of an ''unsold allotment'' within the meaning of section 4(3)(C) of the Securities Act, would be unable to take advantage of the prospectus delivery exemption provided by section 4(3) of the Securities Act.

while not intended as a substitute for a Prospectus, the Product Description will contain information about ETS that is tailored to meet the needs of investors purchasing ETS in the secondary market. The Product Description will also disclose the potential for deviation over time between the return of the Leveraged Funds or Inverse Funds and the multiple return of the corresponding Underlying Index and provide an example of this deviation in returns over time in the same manner as in the Prospectus.

Section 22(e)

11. Section 22(e) of the Act generally prohibits a registered investment company from suspending the right of redemption or postponing the date of payment of redemption proceeds for more than seven days after the tender of a security for redemption. Applicants state that settlement of redemptions for Funds based on Underlying Foreign Indices (''Foreign Funds'') is contingent not only on the settlement cycle of the United States market, but also on delivery cycles in local markets for underlying foreign securities held by the Foreign Funds. Applicants state that local market delivery cycles for transferring Redemption Securities to redeeming investors, coupled with local market holiday schedules, will, under certain circumstances, require a delivery process longer than seven calendar days for Foreign Funds. Applicants request relief under section 6(c) of the Act from section 22(e) to allow Foreign Funds to pay redemption proceeds up to 14 calendar days after the tender of a Creation Unit for redemption. Except as disclosed in the relevant Foreign Fund's Prospectus, Product Description and/or SAI, applicants expect that each Foreign Fund will be able to deliver redemption proceeds within seven days.[13] With respect to future Foreign Funds, applicants seek the same relief from section 22(e) only to the extent that circumstances similar to those described in the application exist.

12. Applicants state that section 22(e) was designed to prevent unreasonable, undisclosed and unforeseen delays in the payment of redemption proceeds. Applicants assert that the requested relief will not lead to the problems that section 22(e) was designed to prevent. Applicants state that the SAI will disclose those local holidays (over the period of at least one year following the date of the SAI), if any, that are expected to prevent the delivery of redemption proceeds in seven calendar days, and the maximum number of days needed to deliver the proceeds for each Foreign Fund. Applicants are not seeking relief from section 22(e) with respect to Foreign Funds that do not effect creations and redemptions of Creation Units in-kind.

Sections 17(a)(1) and 17(a)(2) of the Act

13. Section 17(a) of the Act generally prohibits an affiliated person of a registered investment company, or an affiliated person of such a person (''Second-Tier Affiliate''), from selling any security to or purchasing any security from the company. Section 2(a)(3) of the Act defines ''affiliated person'' to include (a) any person directly or indirectly owning, controlling or holding with power to vote 5% or more of the outstanding voting securities of the other person, (b) any person 5% or more of whose outstanding voting securities are directly or indirectly owned, controlled or held with the power to vote by the other person, and (c) any person directly or indirectly controlling, controlled by or under common control with the other person. Section 2(a)(9) of the Act provides that a control relationship will be presumed where one person owns more than 25% of another person's voting securities.

14. Applicants request an exemption from section 17(a) of the Act pursuant to sections 17(b) and 6(c) of the Act to permit persons to effectuate in-kind purchases and redemptions with a Fund when they are affiliated persons of the Fund or Second-Tier Affiliates solely by virtue of one or more of the following: (a) Holding 5% or more, or more than 25%, of the outstanding ETS of one or more Funds; (b) having an affiliation with a person with an ownership interest described in (a); or (c) holding 5% or more, or more than 25%, of the shares of one or more other registered investment companies (or series thereof) advised by the Adviser or an entity, controlling, controlled by or under common control with the Adviser.

15. Section 17(b) of the Act authorizes the Commission to exempt a proposed transaction from section 17(a) of the Act if evidence establishes that the terms of the transaction, including the consideration to be paid or received, are reasonable and fair and do not involve overreaching on the part of any person concerned, and the proposed transaction is consistent with the policies of the registered investment company and the general provisions of the Act. Applicants assert that no useful purpose would be served by prohibiting these types of affiliated persons from purchasing or redeeming Creation Units through ''in-kind'' transactions. The deposit procedures for both in-kind purchases and in-kind redemptions of Creation Units will be the same for all purchases and redemptions. Deposit Securities and Redemption Securities will be valued in the same manner as the securities held by the Funds. Therefore, applicants state that in-kind purchases and redemptions will afford no opportunity for the affiliated persons described above to effect a transaction detrimental to other holders of ETS. Applicants also believe that in-kind purchases and redemptions will not result in self-dealing or overreaching of the Fund.

Applicants' Conditions

Applicants agree that any order of granting the requested relief will be subject to the following conditions:

1. The Prospectus and Product Description will clearly disclose that, for purposes of the Act, ETS are issued by the Funds and the acquisition of ETS by investment companies is subject to the restrictions of section 12(d)(1) of the Act, except as permitted by an exemptive order that permits registered investment companies to invest in a Fund beyond the limits in section 12(d)(1), subject to certain terms and conditions, including that the registered investment company enter into an agreement with the Fund regarding the terms of the investment.

2. As long as the Trust operates in reliance on the requested order, the ETS will be listed on an Exchange.

3. Neither the Trust nor any Fund will be advertised or marketed as an open-end investment company or a mutual fund. The Prospectus will prominently disclose that ETS are not individually redeemable shares and will disclose that the owners of ETS may acquire those ETS from a Fund and tender those ETS for redemption to a Fund in Creation Units only. Any advertising material that describes the purchase or sale of Creation Units or refers to redeemability will prominently disclose that ETS are not individually redeemable, and that owners of ETS may acquire those ETS from a Fund and tender those ETS for redemption to a Fund in Creation Units only.

4. Before a Fund may rely on the order, the Commission will have approved, pursuant to rule 19b–4 under the Exchange Act, an Exchange rule or an amendment thereto, requiring Exchange members and member organizations effecting transactions in

[13] Rule 15c6–1 under the Exchange Act requires that most securities transactions be settled within three business days of the trade. Applicants acknowledge that no relief obtained from the requirements of section 22(e) will affect any obligations applicants may have under rule 15c6–1.

ETS to deliver a Product Description to purchasers of ETS.

5. The Trust's Web site, which will be publicly accessible at no charge, will contain the following information, on a per ETS basis, for each Fund: (a) The prior Business Day's NAV and the reported closing price, and a calculation of the premium or discount of such price against such NAV; and (b) data in chart format displaying the frequency distribution of discounts and premiums of the daily closing price against the NAV, within appropriate ranges, for each of the four previous calendar quarters (or the life of the Fund, if shorter). In addition, the Product Description for each Fund will state that the Trust's Web site has information about the premiums and discounts at which the ETS have traded.

6. The Prospectus and annual report for each Fund also will include: (a) The information listed in condition 5(b), (i) in the case of the Prospectus, for the most recently completed year (and the most recently completed quarter or quarters, as applicable) and (ii) in the case of the annual report, for the immediately preceding five years (or the life of the Fund, if shorter); and (b) the following data, calculated on a per ETS basis for one, five and ten year periods (or life of the Fund, if shorter), (i) the cumulative total return and the average annual total return based on NAV and closing price, and (ii) the cumulative total return of the relevant Underlying Index.

7. The requested relief to permit ETF operations will expire on the effective date of any Commission rule under the Act that provides relief permitting the operation of index-based exchange-traded funds and exchange-traded funds that seek to return a multiple, the inverse or an inverse multiple of an index.

For the Commission, by the Division of Investment Management, under delegated authority.

Florence E. Harmon,

Acting Secretary.

[FR Doc. E8–21763 Filed 9–17–08; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

In the Matter of Cadema Corp. and Caredata.com, Inc.; Order of Suspension of Trading

September 16, 2008.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Cadema Corp. because it has not filed any periodic reports since the period ended September 30, 2002.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Caredata.com, Inc. because it has not filed any periodic reports since the period ended September 30, 2000.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above-listed companies.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of Cadema Corp. and Caredata.com, Inc. is suspended for the period from 9:30 a.m. EDT on September 16, 2008, through 11:59 p.m. EDT on September 29, 2008.

By the Commission.

Florence E. Harmon,

Acting Secretary.

[FR Doc. E8–21938 Filed 9–16–08; 4:15 pm]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–58516; File No. SR–Amex–2008–69]

Self-Regulatory Organizations; American Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Related to the Listing and Trading of Options on Section 107 Securities

September 11, 2008.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 3, 2008, the American Stock Exchange LLC (''Amex'' or ''Exchange''), filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. Amex filed the proposal pursuant to Section 19(b)(3)(A) of the Act [3] and Rule 19b–4(f)(6) thereunder,[4] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6).

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to add new Commentary .11 to Rule 915 and new Commentary .12 to Rule 916 to enable the listing and trading of options on securities meeting the requirements of Sections 107D, 107E, 107F, 107G, 107H or 107I of the Amex *Company Guide* (the ''*Company Guide*'').

The text of the proposed rule change is available on the Amex's Web site at *http://www.amex.com,* the Office of the Secretary, the Amex and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to adopt new Commentary .11 to Rule 915 and new Commentary .12 to Rule 916 to enable the listing and trading of options on index-linked securities (''Index-Linked Securities''), commodity-linked securities (''Commodity-Linked Securities''), currency-linked securities (''Currency-Linked Securities''), fixed income-linked securities (''Fixed Income-Linked Securities''), futures-linked securities (''Futures-Linked Securities'') and combination-linked securities (''Combination-Linked Securities'') (collectively known as ''Section 107 Securities'' as defined in Sections 107D, 107E, 107F, 107G, 107H and 107I, respectively, of the *Company Guide*) that are principally traded on a national securities exchange and an ''NMS Stock'' (as defined in Rule 600 of Regulation NMS under the Securities Exchange Act of 1934 (the ''1934 Act'')).

Section 107 Securities are designed for investors who desire to participate in a specific market segment by providing

exposure to one or more identifiable underlying securities, commodities, currencies, derivative instruments or market indexes of the foregoing (''Underlying Index'' or ''underlying Indexes''). Section 107 Securities are the non-convertible debt of an issuer that have a term of at least one (1) year but not greater than thirty (30) years. Despite the fact that Section 107 Securities are linked to an underlying index, each trades as a single, exchange-listed security. Accordingly, rules pertaining to the listing and trading of standard equity options will apply to Section 107 Securities. The Exchange does not propose any changes to rules pertaining to Stock Index Options.

Listing Criteria

The Exchange will consider listing and trading options on Section 107 Securities provided the Section 107 Securities meet the criteria for underlying securities set forth in Commentary .01 to Rule 915. The Exchange proposes that Section 107 Securities deemed appropriate for options trading represent ownership of a security that provides for the payment at maturity, as described below.

- *Index-Linked Securities* are securities that provide for the payment at maturity of a cash amount based on the performance of an underlying index or indexes of equity securities (''Equity Reference Asset'').
- *Commodity-Linked Securities* are securities that provide for the payment at maturity of a cash amount based on the performance of one or more physical commodities or commodity futures, options or other commodity derivatives or Commodity-Based Trust Shares or a basket or index of any of the foregoing (''Commodity Reference Asset'').
- *Currency-Linked Securities* are securities that provide for the payment at maturity of a cash amount based on the performance of one or more currencies, or options or currency futures or other currency derivatives or Currency Trust Shares [5] or a basket or index of any of the foregoing (''Currency Reference Asset'').
- *Fixed Income-Linked Securities* are securities that provide for the payment at maturity of a cash amount based on the performance of one or more notes, bonds, debentures or evidence of indebtedness that include, but are not limited to, U.S. Department of the Treasury securities (''Treasury Securities''), government-sponsored entity securities (''GSE Securities''), municipal securities, trust preferred securities, supranational debt and debt of a foreign country or a subdivision thereof or a basket or index of any of the foregoing (''Fixed Income Reference Asset'');
- *Futures-Linked Securities* are securities that provide for the payment at maturity of a cash amount based on the performance of an index of (a) futures on Treasury Securities, GSE Securities, supranational debt and debt of a foreign country or a subdivision thereof, or options or other derivatives on any of the foregoing; or (b) interest rate futures or options or derivatives on the foregoing in this subparagraph (b) (''Futures Reference Asset''); and
- *Combination-Linked Securities* are securities that provide for the payment at maturity of a cash amount based on the performance of any combination of two or more Equity Reference Assets, Commodity Reference Assets, Currency Reference Assets, Fixed Income Reference Assets or Futures Reference Assets (''Combination Reference Asset'').

For the purposes of Commentary .11 to Rule 915, Equity Reference Assets, Commodity Reference Assets, Currency Reference Assets, Fixed Income Reference Assets, Futures Reference Assets and Combination Reference Assets, will be collectively referred to as ''Reference Assets,'' as defined in Sections 107D, 107E, 107F, 107G, 107H and 107I, respectively, of the *Company Guide.* Section 107 Securities must meet the criteria and guidelines for underlying securities set forth in Commentary .01 to Rule 915, or the Section 107 Securities must be redeemable at the option of the holder at least on a weekly basis through the issuer at a price related to the applicable underlying Reference Asset. In addition, the issuing company is obligated to issue or repurchase the securities in aggregation units for cash or cash equivalents satisfactory to the issuer of Section 107 Securities which underlie the option as described in the Section 107 Securities prospectus.

Continued Listing Requirements

Options on Section 107 Securities will be subject to all Exchange rules governing the trading of equity options. The current continuing or maintenance listing standards for options traded on the Amex will continue to apply.

The Exchange proposes to establish Commentary .12 to Rule 916 which will include criteria related to the continued listing of options on Section 107 Securities.

Under the applicable continued listing criteria in proposed Commentary .12 to Rule 916, options on Section 107 Securities initially approved for trading pursuant to proposed Commentary .11 to Rule 915 may be subject to the suspension of opening transactions as follows: (1) Non-compliance with the terms of proposed Commentary .11 to Rule 915; (2) non-compliance with the terms of Commentary .01 to Rule 916, except that in the case of options covering Section 107 Securities approved pursuant to proposed Commentary .11(c)(2) to Rule 915 that are redeemable at the option of the holder at least on a weekly basis, then option contracts of the class covering such Securities may only continue to be open for trading as long as the Securities are listed on a national securities exchange and are an ''NMS stock'' as defined in Rule 600 of Regulation NMS; (3) in the case of any Section 107 Security trading pursuant to Commentary .11 to Rule 915, the value of the Reference Asset is no longer calculated or available; or (4) such other event shall occur or condition exist that in the opinion of the Exchange makes further dealing in such options on the Exchange inadvisable.

The Exchange represents that the listing and trading of options on Section 107 Securities pursuant to proposed Commentary .11 to Rule 915 will not have any effect on the rules pertaining to position and exercise limits [6] or margin.[7]

The Exchange will implement surveillance procedures for options on Section 107 Securities, including adequate comprehensive surveillance sharing agreements with markets trading in non-U.S. components, as applicable. The Amex represents that these procedures will be adequate to properly monitor Exchange trading of options on these securities and to deter and detect violations of Exchange rules.

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6 of the Act,[8] in general, and furthers the objectives of Section 6(b)(5),[9] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with

[5] *See* Amex Rule 1200B–AEMI(b). The term ''Currency Trust Shares'' means a security that (i) is issued by a trust that holds a specified non-U.S. currency deposited with the trust; (ii) when aggregated in some specified minimum number may be surrendered to the trust by the beneficial owner to receive the specified non-U.S. currency; and (iii) pays beneficial owners interest and other distributions on the deposited non-U.S. currency, if any, declared and paid by the trust.

[6] *See* Amex Rules 904 and 905.

[7] *See* Amex Rules 462.

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Exchange submits that the instant proposal to adopt generic initial and continued listing criteria for options on Section 107 Securities will serve to provide enhanced risk management tools for investors that, to date, have been absent in connection with Section 107 Securities. In addition, the Exchange further believes that the proposed listing criteria together with the Exchange's surveillance procedures will serve to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited nor received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change: (1) Does not significantly affect the protection of investors or the public interest; (2) does not impose any significant burden on competition; and (3) by its terms does not become operative for 30 days after the date of this filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [10] and Rule 19b–4(f)(6) thereunder.[11]

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative for 30 days after the date of filing. However, Rule 19b–4(f)(6)(iii) permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange requests that the Commission waive the 30-day operative delay so that the Exchange is able to compete with other options exchanges that are currently permitted to list and trade options on Section 107 Securities. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest.[12] The Commission notes the proposal is substantively identical to proposals that were recently approved by the Commission, and does not raise any new regulatory issues.[13] For these reasons, the Commission designates the proposed rule change as operative upon filing.

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–Amex–2008–69 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–Amex–2008–69. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Amex–2008–69 and should be submitted on or before October 9, 2008.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Florence E. Harmon,

Acting Secretary.

[FR Doc. E8–21761 Filed 9–17–08; 8:45 am]

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[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to provide the Commission with written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has fulfilled this requirement.

[12] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[13] *See* Securities Exchange Act Release Nos. 58203 (July 22, 2008), 73 FR 43812 (July 28, 2008) (SR–NYSEArca–2008–57) and 58204 (July 22, 2008), 73 FR 43807 (July 28, 2008) (SR–CBOE–2008–64).

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–58513; File No. SR–CBOE–2008–92]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Hybrid Electronic Quoting Fee

September 11, 2008.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 29, 2008, the Chicago Board Options Exchange, Incorporated (''Exchange'' or ''CBOE'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the CBOE. The Commission is publishing this notice to solicit

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

CBOE is proposing to amend its Hybrid Electronic Quoting Fee. The text of the proposed rule change is available on the Exchange's Web site (*http://www.cboe.org/Legal*), at the Exchange's Office of the Secretary and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, CBOE included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The CBOE has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this proposed rule change is to amend CBOE's Hybrid Electronic Quoting Fee (''Quoting Fee''), which is applicable to all Market-Makers, DPMs, and e-DPMs (collectively ''liquidity providers'') in order to promote and encourage more efficient quoting.

Under the current Quoting Fee, CBOE assesses all liquidity providers who are submitting electronic quotations to CBOE in Hybrid option classes a monthly amount of $450 per membership utilized.[3] CBOE also assesses or credits fees on liquidity providers that vary depending on: (i) the quality of the liquidity provider's quotation (a quotation is a bid and an offer); and (ii) the value of the underlying security and CBOE's bid in the option series. The Quoting Fee provides that a liquidity provider's total credits cannot exceed the total debits assessed. If the total credits were to exceed the total debits, the Quoting Fee assessed to that liquidity provider would be $450.

CBOE now proposes to amend the Quoting Fee and establish a cap of $50,000 on the amount a liquidity provider's total credits can exceed the total debits assessed. If the liquidity provider is a member organization utilizing more than one membership, the $50,000 cap is applied per member organization. CBOE believes that establishing a cap of $50,000 will serve as an incentive to liquidity providers to submit competitive quotations, and that the Quoting Fee will continue to promote and encourage more efficient quoting and help to reduce quote traffic.

Additionally, CBOE proposes to make a technical change to Section 17 and delete the reference to ''Hybrid 2.0,'' which CBOE recently deleted from its rules.[4]

The Exchange intends to implement this revised Quoting Fee effective September 1, 2008.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934 (''Act'')[5], in general, and furthers the objectives of Section 6(b)(4)[6] of the Act in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges among CBOE members. In particular, CBOE believes the establishment of a $50,000 cap on the amount a liquidity provider's total credits can exceed the total debits assessed is an equitable allocation of reasonable dues and fees in that it will serve as an incentive to liquidity providers to submit competitive quotations. CBOE also believes that the Quoting Fee will continue to promote and encourage more efficient quoting and help to reduce quote traffic.

B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposal.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[7] and subparagraph (f)(2) of Rule 19b–4[8] thereunder. At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–CBOE–2008–92 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2008–92. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m.

[3] *See* Securities Exchange Act Release No. 34–56927 (12/7/07), 72 FR 70912 (12/13/07), granting immediate effectiveness to SR–CBOE–2007–145.

[4] *See* Securities Exchange Act Release No. 34–58153 (7/14/08), 73 FR 41386 (7/18/08), granting immediate effectiveness to SR–CBOE–2008–67.

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(4).

[7] 15 U.S.C. 78s(b)(3)(A).

[8] 17 CFR 240.19b–4(f)(2).

Copies of such filing also will be available for inspection and copying at the principal office of the CBOE. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2008–92 and should be submitted on or before October 9, 2008.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

Florence E. Harmon,

Acting Secretary.

[FR Doc. E8–21759 Filed 9–17–08; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–58519; File No. SR–CBOE–2008–84]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 8.3A Pertaining to Class Quoting Limits

September 11, 2008.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 8, 2008, the Chicago Board Options Exchange, Incorporated (''Exchange'' or ''CBOE'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend CBOE Rule 8.3A pertaining to Class Quoting Limits. The text of the proposed rule change is available on the Exchange's Web site (*http://www.cboe.org/Legal*), at the Exchange's Office of the Secretary and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

CBOE Rule 8.3A establishes the upper limit, *i.e.*, Class Quoting Limit (''CQL''), on the number of members that may quote electronically in a particular product traded on CBOE's Hybrid Trading System. The purpose of this rule change is to amend Interpretations .01 and .03 of CBOE Rule 8.3A.

First, CBOE proposes to amend Interpretation .01(b) which generally provides that CBOE's President may increase the CQL when ''exceptional circumstances'' warrant. Interpretation .01(b) states that ''exceptional circumstances'' refers to substantial trading volume, whether actual or expected (*e.g.*, in the case of a new product or a major news announcement). Interpretation .01(b) also provides that when the ''exceptional circumstances'' cease, the President can reduce the CQL, and includes fair procedures for how such a reduction would occur. CBOE believes that there may be circumstances in which it would be appropriate to increase the CQL in a particular product even though it may not be apparent that there has been, or will be, a substantial change in trading volume in the product. For example, there may be circumstances in which a product is not experiencing a substantial change in trading volume and yet additional members may want to quote electronically in the product. Provided CBOE's trading systems can handle the increase and CBOE's President determines that it would be appropriate, CBOE should be permitted to increase the CQL in that product.[5] Similarly, CBOE believes that the President should be allowed to decrease the CQL in appropriate circumstances, particularly in those cases where the CQL previously has been increased and provided such increase is no longer needed.

Accordingly, CBOE proposes to amend Interpretation .01(b) to provide that CBOE's President (or his designee) can increase or decrease the CQL in an existing or new product when he/she determines it would be appropriate. One of the factors that would be considered is the trading volume of the product. CBOE believes that amending Interpretation .01(b) as proposed is procompetitive, as it provides more flexibility in determining when to increase the CQL and thus allow more electronic quoters in a particular product. It is also consistent with the purpose of maintaining a CQL, which is to limit the number of members that are quoting electronically in a particular product to ensure that the Exchange has the ability to effectively handle all quotes generated by members. CBOE's President certainly can determine whether CBOE's systems can effectively handle the increase in quote message traffic caused by an increase in the CQL when the President determines that the increase would be appropriate. CBOE is not proposing to change the procedures for decreasing a CQL that are currently contained in Interpretation .01(b).

Second, CBOE proposes to clarify and amend Interpretation .03, which provides that in the event a Market-Maker has not submitted any electronic quotations in an appointed option class during the preceding 30 calendar days, then the Market-Maker's appointment in that option class will be terminated effective immediately. Interpretation .03 expressly states that it only applies to those option classes in which the CQL for the option class is full and there is a wait-list of member(s) requesting the ability to quote electronically in the option class, and that CBOE will notify the Market-Maker prior to terminating its appointment.

In adopting the interpretation, it was not CBOE's intention to allow a Market-Maker, who has chosen not to submit any electronic quotations in an appointed option class during the preceding 30 calendar days, to be able to preserve the Market-Maker's appointment in the option class by submitting one or more electronic quotes and then to discontinue quoting, thereby avoiding the termination.

[9] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] CBOE notes that it increases the CQL in products infrequently, and when it does, members on the wait-list have first priority.

Accordingly, CBOE proposes to amend Interpretation .03 to provide that CBOE will notify the Market-Maker that the Market-Maker's appointment has been terminated, as opposed to providing notification prior to termination. The rule text itself provides effective notification to Market-Makers that their appointment in an option class will be terminated if they have not submitted any electronic quotations in the appointed option class during the preceding 30 calendar days. CBOE notes that the circumstances giving rise to this Interpretation do not occur frequently. CBOE also believes that amending Interpretation .03 as proposed promotes competition, as it would allow other members who are ready and willing to provide competitive quotations and liquidity in an option class, in the place of a Market-Maker who chooses not to submit any electronic quotations in the option class for at least 30 calendar days.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations under the Act applicable to a national securities exchange and, in particular, the requirements of Section 6(b) of the Act. Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) Act[6] requirements that the rules of an exchange be designed to promote just and equitable principles of trade, to prevent fraudulent and manipulative acts and, in general, to protect investors and the public interest. Granting CBOE's President the authority to increase or decrease the CQL in an option class when he deems it appropriate promotes competition and also ensures that the integrity of CBOE's trading systems are protected. Similarly, terminating a Market-Maker's appointment when the Market-Maker has elected not to submit electronic quotations in an option class for 30 calendar days also promotes competition in that it will provide an opportunity to other Market-Makers who are ready and willing to provide competitive quotations and liquidity in the option class.

B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

[6] 15 U.S.C. 78f(b)(5).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposal.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing rule does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, provided that the self-regulatory organization has given the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change or such shorter time as designated by the Commission,[7] the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[8] and Rule 19b–4(f)(6) thereunder.[9] At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–CBOE–2008–84 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2008–84. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the CBOE. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2008–84 and should be submitted on or before October 9, 2008.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Florence E. Harmon,

Acting Secretary.

[FR Doc. E8–21766 Filed 9–17–08; 8:45 am]

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[7] CBOE fulfilled this requirement.

[8] 15 U.S.C. 78s(b)(3)(A).

[9] 17 CFR 240.19b–4(f)(6).

[10] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–58514; File No. SR–FINRA–2008–039]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Order Approving the Proposed Rule Change To Adopt FINRA Rules 5110 (Corporate Financing Rule), 5190 (Notification Requirements for Offering Participants) and 6470 (Withdrawal of Quotations in an OTC Equity Security in Compliance With SEC Regulation M) in the Consolidated FINRA Rulebook

September 11, 2008.

I. Introduction

On July 16, 2008, the Financial Industry Regulatory Authority, Inc. (''FINRA'') (f/k/a National Association of Securities Dealers, Inc. (''NASD'')) filed with the Securities and Exchange Commission (''Commission'' or ''SEC''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'' or ''Act'') [1] and Rule 19b–4 thereunder,[2] a proposal to adopt most of NASD Rule 2710 (Corporate Financing Rule) as FINRA Rule 5110 in the consolidated FINRA rulebook, consolidating the rules in FINRA's jurisdiction relating to Regulation M as new Rules 5190 and 6470 in the consolidated FINRA rulebook, and make conforming changes to the rules related to Regulation M applicable to the Alternative Display Facility (''ADF''). This proposal was published for comment in the **Federal Register** on August 11, 2008.[3] The Commission received no comments on the proposal. This order approves this proposed rule change.

II. Description of the Proposed Rule Change

As part of the process of developing the new consolidated rulebook (''Consolidated FINRA Rulebook''),[4] FINRA is proposing to (1) adopt NASD Rule 2710 as FINRA Rule 5110, with the exception of paragraphs (b)(10) and (11); (2) adopt new FINRA Rule 5190, which would house the Regulation M-related notice requirements applicable to members participating in securities offerings (including paragraphs (b)(10) and (11) of NASD Rule 2710 and paragraph (a) of Incorporated NYSE Rule 392); (3) adopt new FINRA Rule 6470, which would house certain Regulation M-related requirements that are currently in the Over-the-counter (''OTC'') Bulletin Board (''OTCBB'') rules and would apply to all OTC Equity Securities; [5] and (4) make conforming amendments to the Regulation M-related rules applicable to the ADF.

A. Corporate Financing Rule

NASD Rule 2710, except paragraphs (b)(10) and (11) (which are discussed below), regulates the underwriting terms and arrangements of most public offerings (including shelf offerings) of securities sold through FINRA members. NASD Rule 2710 requires members to file with FINRA's Corporate Financing Department (the ''Corporate Financing Department'') information regarding initial public offerings and certain secondary offerings and to submit pertinent documentation, including registration statements. The Corporate Financing Department reviews this information prior to commencement of the offering to determine whether the underwriting compensation and other terms and arrangements meet the requirements of applicable FINRA rules. Members are required to receive the Corporate Financing Department's opinion of no-objections to the offering terms prior to participating in the offering.

FINRA proposed to adopt NASD Rule 2710 as FINRA Rule 5110 in the Consolidated FINRA Rulebook. With the exception of the deletion of paragraphs (b)(10) and (11) as discussed below, FINRA proposed to make only technical non-substantive changes to Rule 2710 such as replacing references to ''NASD'' or ''the Association'' with ''FINRA'' and certain conforming changes to references in Rule 2710 to, *e.g.*, the Exchange Act, SEA Rules, the Securities Act and Securities Act Rules.

B. Regulation M-Related Requirements

Regulation M is designed to prevent manipulation by persons with an interest in the outcome of an offering and generally prohibits activities and conduct that could artificially influence the market for an offered security.[6] In this regard, Regulation M generally prohibits underwriters, broker-dealers, issuers and other persons participating in a distribution from directly or indirectly bidding for or purchasing the offered security (or inducing another person to do so) during the ''restricted period,'' which commences on the later of either one or five business days prior to the determination of the offering price or such time that a person becomes a distribution participant.[7] For purposes of determining whether a one or five-day or no restricted period applies under Regulation M, the SEC has adopted a dual standard of world-wide average daily trading volume (''ADTV'') and public float value. Regulation M also governs certain market activities, usually undertaken by the managing underwriter or underwriting group (*i.e.*, stabilizing bids, syndicate covering transactions and penalty bids) [8] in connection with an offering and requires that notice of such activity be provided to the relevant self-regulatory organization or, in the case of stabilizing bids, the market where the stabilizing bid is to be posted. Finally, Regulation M generally prohibits any person from selling short a security that is the subject of a public offering and purchasing the security in the offering if such short sale was effected during the restricted period (which, for purposes of the short sale restrictions, generally is the five-day period prior to pricing).[9]

As part of FINRA's program to monitor for member compliance with Regulation M, FINRA's Market Regulation Department (the ''Market Regulation Department'') reviews members' OTC trading and quoting activity for prohibited purchases and/or bids during the applicable restricted period and short sales during the five-day period prior to pricing the offering. FINRA rules must ensure that FINRA receives pertinent distribution-related information in a timely fashion to facilitate this component of FINRA's Regulation M compliance program.

1. Existing FINRA Rules

FINRA's current Regulation M-related rules comprise notice requirements set forth in NASD Rule 2710(b)(10) and (11) and Incorporated NYSE Rule 392

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 58302 (August 4, 2008), 73 FR 46657 (August 11, 2008) (SR–FINRA–2008–039).

[4] The current FINRA rulebook consists of two sets of rules: (1) NASD Rules and (2) rules incorporated from NYSE (''Incorporated NYSE Rules'') (together referred to as the ''Transitional Rulebook''). The Incorporated NYSE Rules apply only to those members of FINRA that are also members of the NYSE (''Dual Members''). Dual Members also must comply with NASD Rules. For more information about the rulebook consolidation process, *see* FINRA *Information Notice*, March 12, 2008 (Rulebook Consolidation Process).

[5] NASD Rule 6610(d) defines OTC Equity Security as ''any non-exchange-listed security and certain exchange-listed securities that do not otherwise qualify for real-time trade reporting.''

[6] *See* Securities Exchange Act Release No. 38067 (December 20, 1996), 62 FR 520 (January 3, 1997).

[7] 17 CFR 242.100, definition of ''restricted period.''

[8] 17 CFR 242.100, definitions of ''stabilizing,'' ''syndicate covering transaction,'' and ''penalty bid.''

[9] *See* Securities Exchange Act Release No. 56206 (August 6, 2007), 72 FR 45094 (August 10, 2007).

(Notification Requirements for Offerings of Listed Securities), as well as marketplace-specific requirements in the OTCBB and ADF rules. NASD Rule 2710(b)(10) requires members that are acting as manager (or in a similar capacity) of a distribution of unlisted securities that are considered a subject or reference security subject to Rule 101 of Regulation M or an ''actively traded'' security under Rule 101 of Regulation M to submit a request for an Underwriting Activity Report (''UAR'') from the Market Regulation Department. The request for a UAR, which is the mechanism by which FINRA currently receives notice of prospective distributions, must be submitted at the time a registration statement or similar offering document is filed with the Corporate Financing Department, the Commission, or other regulatory agency and if not filed with any regulatory agency, at least two business days prior to commencement of the restricted period. Such request must include a copy of the registration statement or similar offering document. If no member is acting as manager, then each member that is a distribution participant or affiliated purchaser shall submit the request for a UAR, unless another member has assumed responsibility for compliance.

NASD Rule 2710(b)(11) requires members that are acting as manager (or in a similar capacity) of a distribution of securities that are listed on a national securities exchange and considered a subject security or reference security subject to Rule 101 of Regulation M or an ''actively traded'' security under Rule 101 of Regulation M to provide notice to the Market Regulation Department of the pricing of the distribution, including the date and time of pricing, the offering price and the time the distribution terminated. Such notice must be provided no later than the close of business the day the offering terminates and may be submitted on the UAR.

Incorporated NYSE Rule 392(a) requires that Dual Members provide notice of pricing and related information (including the restricted period, if any, the offering price and the basis for pricing) in connection with an offering of an NYSE-listed security. Incorporated NYSE Rule 392(b) requires that Dual Members provide notice of syndicate covering transactions and penalty bids and stabilizing bids in connection with an offering of an NYSE-listed security.

FINRA's OTCBB and ADF-related marketplace rules also include certain Regulation M-related requirements. Any member that is a distribution participant or affiliated purchaser in a distribution of an OTCBB-eligible security must provide notice to the Corporate Financing Department of its intention to impose a penalty bid or conduct a syndicate covering transaction pursuant to Rule 104 of Regulation M.[10]

In addition, members are required to withdraw their quotations in the OTCBB (in OTCBB-eligible securities) and the ADF (in NMS stocks) to comply with applicable restricted periods under Regulation M. Specifically, a member that is a distribution participant or affiliated purchaser in a distribution of an OTCBB-eligible security must withdraw its quotations in the offered security,[11] and provide notice to FINRA's Operations Department prior to pricing.[12] The member must also provide notice to the Market Regulation Department upon the pricing of the distribution.[13] Additionally, members are prohibited from entering stabilizing bids pursuant to Rule 104 of Regulation M in the OTCBB.[14]

With respect to quotations in the ADF, FINRA's Operations Department may grant excused withdrawal status to a Registered Reporting ADF Market Maker, as defined in NASD Rule 4200A(a)(14), that is a distribution participant or affiliated purchaser in a distribution of an NMS stock in order to comply with the applicable restricted period under Regulation M.[15] A member acting as manager (or in a similar capacity), or any member that is a distribution participant or affiliated purchaser in a distribution that does not have a manager, must notify FINRA's ADF Operations and the Market Regulation Department of a prospective distribution and request a withdrawal of each market maker's quotations.[16] Members also must submit a written request to ADF Operations and the Market Regulation Department to rescind the market maker's excused withdrawal status and provide notice of the date and time of the pricing of the offering, the offering price, and the time the offering terminated.[17]

2. Proposed New FINRA Rule 5190

FINRA proposed to consolidate and house all of its Regulation M-related notice requirements in a single rule, proposed new FINRA Rule 5190 (Notification Requirements for Offering Participants). The scope of the current rules and information required would be expanded, as necessary, to impose consistent notice requirements relating to distributions of listed and unlisted securities. FINRA believes that the proposed rule change would ensure that FINRA receives from its members pertinent distribution-related information in a timely fashion.

Proposed Rule 5190(c) sets forth the notice requirements applicable to distributions of listed and unlisted securities that are ''covered securities'' subject to a restricted period under Rule 101 or 102 of Regulation M.[18] Specifically, proposed Rule 5190(c)(1)(A) would require members to determine, in accordance with Regulation M, whether a distribution is subject to a one-day or five-day restricted period under Rule 101 of Regulation M, and provide written notice to FINRA of the member's determination and the basis for such determination.[19] Additionally, pursuant to proposed Rule 5190(c)(1)(A), members would be required to include in the written notice the contemplated date and time of commencement of the restricted period, identifying the distribution participants and affiliated purchasers.

Members would be required to provide such notice no later than the business day prior to the first complete trading session of the applicable restricted period, unless later notification is necessary under specific circumstances.[20] FINRA notes that where the principal market closes early, for example for a holiday, the shortened session would constitute a complete

[10] *See* NASD Rule 6540(d)(1)(D)(iii).

[11] *See* NASD Rule 6540(d)(1)(D)(ii).

[12] *See* NASD Rule 6540(d)(1)(D)(i).

[13] *See* NASD Rule 6540(d)(1)(D)(iv).

[14] *See* NASD Rule 6540(d)(1)(D)(ii).

[15] *See* NASD Rule 4619A(f).

[16] *See* NASD Rule 4619A(f)(1).

[17] *See* NASD Rule 4619A(f)(3).

[18] 17 CFR 242.100, definition of ''covered securities.''

[19] While the proposed rule change would place the onus of determining the applicable restricted period on the member for all distributions, as a practical matter, FINRA represented that it would accept notification by a member that the maximum five-day restricted period applies to a prospective distribution, without providing the basis for that determination. If, on the other hand, a member were to assert that a one day or no restricted period applied to a particular distribution, FINRA represented that it would require that the member demonstrate the basis for that determination.

[20] In most instances, FINRA represented it would expect to receive notification within the prescribed time frame, but may permit later notification in limited circumstances. Such determination would be made by the Market Regulation Department on a case-by-case basis. For example, there may be instances where the nature of the transaction has made it impossible to provide timely notice (*e.g.*, a private investment in public equity (''PIPE'') offering is commenced and priced on the same day, and thus the member could not have provided notice on the business day prior to the first complete trading session of the applicable restricted period). NASD Rule 4619A(f)(1), which sets forth the notice and withdrawal of quotations requirements applicable to ADF participants for purposes of compliance with Regulation M, similarly contemplates later notification where necessary under the specific circumstances.

trading session for purposes of proposed Rule 5190. NASD Rule 2710(b)(10) requires that notice be provided at the time of filing the registration statement. However, for some distributions, particularly shelf offerings, the registration statement may be filed well in advance of commencement of the distribution. As a result, by the time the distribution takes place, the information previously provided by the member could be out-of-date or the ADTV or public float levels could have changed, in which case a different restricted period would apply.

The proposed rule change would eliminate the express requirement under FINRA rules that members request a UAR and would instead permit FINRA to prescribe the form in which notice and the required information must be submitted to FINRA (including, as discussed above, notice of the member's independent determination regarding whether a restricted period applies).[21] The proposed rule change also would eliminate the requirement in NASD Rule 2710(b)(10) that members submit a copy of the registration statement. FINRA represented that the Market Regulation Department does not rely on the registration statement in monitoring member quoting and trading activity for purposes of Regulation M compliance. Moreover, FINRA believes that this requirement could potentially suggest that the Regulation M-related requirements are applicable only to registered offerings when, in fact, certain unregistered offerings, *e.g.*, private placements and PIPEs, are subject to Regulation M and FINRA's notice requirements.

Proposed Rule 5190(c)(1)(B) would require that upon pricing a distribution that is subject to a restricted period under Rule 101 of Regulation M, members provide written notice to FINRA and the following information: (1) The security name and symbol; (2) the type of security; (3) the number of shares offered; (4) the offering price; (5) the last sale before the distribution; (6) the pricing basis (*e.g.*, the prior day closing price, a negotiated price, last sale, etc.); (7) the SEC effective date and time; (8) the trade date; and (9) the restricted period. Consistent with proposed paragraph (c)(1)(A), members also would be required to identify the distribution participants and affiliated purchasers.

The notice under proposed Rule 5190(c)(1)(B) would be required to be submitted no later than the close of business the next business day following the pricing of the distribution, unless later notification is necessary under specific circumstances. NASD Rule 2710(b)(11) requires that notice of pricing be provided no later than the close of business the day the offering terminates. However, FINRA represented that current practice is for most members to provide immediate notice of pricing. FINRA believes that, in addition to being consistent with current practice, the proposed rule change would ensure that FINRA gets timely pricing information in instances where a distribution does not terminate for weeks or even months after pricing.

Proposed Rule 5190(c)(1)(C) would require that members provide written notice of the cancellation or postponement of any distribution for which prior notice of commencement of the restricted period has been provided to FINRA. Members would be required to provide such notice immediately upon the cancellation or postponement of the distribution.

Proposed Rule 5190(c)(2) would require that any member that is an issuer or selling security holder in a distribution of any security that is a covered security subject to a restricted period under Rule 102 of Regulation M comply with the notice requirements of proposed Rule 5190(c)(1), unless another member has assumed responsibility in writing for compliance therewith. FINRA believes that the proposed provision would ensure that FINRA receives notice of any distribution in which a member is participating as an issuer or selling security holder, to the extent that notice of such distribution has not already been provided under proposed Rule 5190.

Proposed Rule 5190(d) sets forth the notice requirements applicable to distributions of listed and unlisted securities that are considered ''actively traded'' securities and thus are not subject to a restricted period under Rule 101 of Regulation M.[22] In connection with such distributions, pursuant to proposed Rule 5190(d)(1), members would be required to provide written notice to FINRA of the member's determination that no restricted period applies and the basis for such determination. Proposed Rule 5190(d)(1) would require that such notice be provided at least one business day prior to the pricing of the distribution, unless later notification is necessary under specific circumstances.

Proposed Rule 5190(d)(2) would require that upon pricing a distribution of a security that is considered ''actively traded'' under Rule 101 of Regulation M, members provide written notice to FINRA and the same pricing-related information that would be required under proposed paragraph (c)(1)(B) as discussed above. Also consistent with proposed paragraph (c)(1)(B), proposed Rule 5190(d)(2) would require members to identify the distribution participants and affiliated purchasers, and provide the required notice no later than the close of business the next business day following the pricing of the distribution, unless later notification is necessary under specific circumstances.[23]

Under paragraphs (c)(1) and (d) of proposed Rule 5190, a member acting as manager (or in a similar capacity) of the distribution would have the obligation to submit the requisite notice to FINRA. However, if no member is acting as manager (or in a similar capacity), then each member that is a distribution participant or affiliated purchaser would be required to provide notice to FINRA, unless another FINRA member has assumed responsibility in writing for compliance with the notice requirement. This is consistent with the current approach under NASD Rule 2710(b)(10).[24]

Finally, proposed Rule 5190(e) would require members to provide notice to FINRA of penalty bids or syndicate covering transactions in connection with an offering of an OTC Equity Security. Members would be required to provide notice to FINRA of their intention to conduct such activity prior to imposing the penalty bid or engaging

[21] FINRA represented that it will announce the form and method of transmission in a *Notice* to be published on its Web site. For example, such form could include the request for a UAR in connection with distributions of Nasdaq-listed securities.

Additionally, FINRA notes that the Market Regulation Department monitors for purposes of compliance with Regulation M on behalf of the Nasdaq Exchange pursuant to a Regulatory Services Agreement (RSA). The Market Regulation Department will continue to generate UARs on behalf of the Nasdaq Exchange under the RSA to assist firms in determining the applicable restricted period, as well as applicable Nasdaq passive market making limits, under Regulation M with respect to Nasdaq-listed securities pursuant to Nasdaq Exchange rules.

[22] The rule text for Proposed Rule 5190(d)(1) states that members must make a determination that ''no restricted period applies under Rule 101.'' The Commission notes, however, that although distribution participants may rely on the actively-traded securities exception of Rule 101(c)(1) if applicable, a restricted period would otherwise apply. For example, the actively-traded securities exception is not available in Rule 102.

[23] FINRA represented that a member that is an issuer or selling security holder in a distribution of an actively traded security that is subject to a restricted period under Rule 102 of Regulation M would be required to comply with the notice requirements under proposed Rule 5190(c)(2).

[24] Members would be required to update the notice required under proposed Rule 5190, as necessary (*e.g.*, a manager would update the notice where distribution participants are added after commencement of the restricted period).

in the first syndicate covering transaction, as well as other pertinent information, such as identification of the security, its symbol, and the date such activity will occur. In addition, members would be required to subsequently confirm such activity within one business day of completion, including identification of the security and its symbol, the total number of shares and the date(s) of such activity. The proposed provision is substantially similar to NASD Rule 6540(d)(1)(D)(iii). FINRA believes that by including these notice requirements in proposed Rule 5190, the proposed rule change would clarify that they apply to distributions of all OTC Equity Securities and are not limited to distributions of OTCBB-eligible securities.

In light of the foregoing, FINRA proposed to delete paragraphs (b)(10) and (11) from NASD Rule 2710 and Incorporated NYSE Rule 392 in its entirety. FINRA represented that the notice requirements of NASD Rule 2710(b)(10) and (11) and Incorporated NYSE Rule 392(a) largely would be incorporated in proposed Rule 5190. Because Incorporated NYSE Rule 392(b) is specific to the NYSE marketplace, FINRA did not propose that these requirements become part of the Consolidated FINRA Rulebook.

3. Proposed Amendments to Marketplace Rules

FINRA also proposed to clarify the scope and application of the Regulation M-related requirements that are in the current OTCBB and ADF marketplace rules. FINRA proposed to adopt new FINRA Rule 6470 (Withdrawal of Quotations in an OTC Equity Security in Compliance with SEC Regulation M), which would: (1) require a member that is a distribution participant, affiliated purchaser, selling security holder or issuer in a distribution of an OTC Equity Security that is a covered security subject to Rule 101 or Rule 102 of Regulation M to withdraw all quotations in the security during the restricted period; and (2) prohibit the entry of stabilizing bids for the OTC Equity Security pursuant to Rule 104 of Regulation M. FINRA represented that proposed Rule 6470 is substantially similar to NASD Rule 6540(d)(1)(D)(ii) and would clarify that the requirements apply not only to OTCBB-eligible securities, but to all OTC Equity Securities quoted in any inter-dealer quotation system (*i.e.*, OTCBB and Pink Sheets). Thus, under the proposed rule change, the Regulation M-related provisions would be deleted from the OTCBB rules (specifically, paragraphs (d)(1)(D), (E) and (F) would be deleted from NASD Rule 6540) and comparable requirements would be housed in either proposed Rule 5190, as discussed above, or proposed Rule 6470.

FINRA also proposed to make certain conforming changes to the Regulation M-related rules applicable to the ADF. Specifically, FINRA proposed to amend NASD Rule 4619A(f) to conform to the language and structure of proposed Rule 6470. Thus, a Registered Reporting ADF Market Maker that is a distribution participant, affiliated purchaser, selling security holder or issuer in a distribution of an NMS stock that is a covered security subject to Rule 101 or 102 of Regulation M would be required to request an excused withdrawal of its quotations in the ADF in the offered security. FINRA believes that it is more appropriate to impose such obligation on the member that is posting the quotation, rather than require the manager of the distribution to do so on behalf of each member. FINRA further proposed to amend NASD Rule 4200A, which sets forth the definitions applicable to the ADF rules, to make technical and conforming changes such as adding necessary references to Regulation M and deleting definitions that are currently not used in the ADF rules.

FINRA believes that the proposed rule change will significantly improve the clarity of the current rules and enhance the information FINRA receives, which will better enable FINRA to monitor member OTC quoting and trading for purposes of Regulation M compliance.

FINRA will announce the implementation date of the proposed rule change in a *Regulatory Notice* to be published no later than 60 days following Commission approval.

III. Discussion and Findings

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of the Act, and the rules and regulations thereunder that are applicable to a national securities association.[25] In particular, the Commission believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[26] which requires, among other things, that FINRA rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. The Commission believes that moving the Regulation M-related provisions of the rules under FINRA's jurisdiction in the manner proposed will provide greater clarity to members and aid in compliance. The Commission also notes that it has previously approved the portions of NASD Rule 2710 to be adopted as FINRA Rule 5110,[27] and the proposal merely moves that portion of Rule 2710 nearly verbatim from the NASD rulebook to the Consolidated FINRA Rulebook. The Commission believes that this move is primarily ministerial and only aids FINRA members in complying with existing obligations.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[28] that the proposed rule change (File No. SR–FINRA–2008–039) be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[29]

Florence E. Harmon,

Acting Secretary.

[FR Doc. E8–21760 Filed 9–17–08; 8:45 am]

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[25] In approving this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[26] 15 U.S.C. 78o–3(b)(6).

[27] *See, e.g.*, Securities Exchange Act Release No. 48989 (December 23, 2003), 68 FR 75684 (December 31, 2003).

[28] 15 U.S.C. 78s(b)(2).

[29] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–58520; File No. SR–FINRA–2008–040]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Order Approving Proposed Rule Change To Eliminate the Requirement To Report Yield to TRACE and for FINRA To Calculate and Disseminate a Standard Yield

September 11, 2008.

I. Introduction

On July 17, 2008, the Financial Industry Regulatory Authority, Inc. (''FINRA'') 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 proposal to eliminate the requirement for members to report yield to the Trade Reporting and Compliance Engine (''TRACE'') in connection with a transaction in a TRACE-eligible security, and instead for TRACE to calculate and disseminate a ''standard

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

yield.'' The proposal was published for comment in the **Federal Register** on August 7, 2008.[3] The Commission received no comments on the proposal. This order approves the proposed rule change.

II. Background

NASD Rule 6230(c) currently requires a member, in connection with a transaction in a TRACE-eligible security, to report various pieces of information to TRACE, including, for most transactions, the lower of yield to call or yield to maturity.[4] Upon receipt of that trade report, TRACE disseminates certain information about the transaction (except if it is a Rule 144A transaction), including the yield as reported by the member. TRACE calculates the standard yield [5] but generally does not disseminate it.[6]

FINRA has proposed (1) to eliminate the requirement for members to report yield; and (2) to disseminate the standard yield in most cases.[7] FINRA stated that there currently is no uniformity in the manner by which members calculate yield, and that disseminating standard yield—calculated according to a single formula and with a uniform set of assumptions—will provide more useful information to market participants. Moreover, FINRA believes that it may be useful for customers to compare the standard yield in a transaction as reported by TRACE against the member-calculated yield that the member provides on the customer confirmation required by Rule 10b-10 under the Act.[8]

Vendors. FINRA also has proposed to require that data vendors and redistributors that provide TRACE information display the yield. However, certain vendors desire to disseminate a yield calculated by the vendor, rather than the standard yield. FINRA would permit this flexibility, provided that a vendor displaying a yield other than the standard yield disclose that fact.

Effective Date. FINRA will announce the effective date of the proposed rule change in a *Regulatory Notice* to be published no later than 60 days following Commission approval. The effective date would be no later than 90 days following publication of that *Regulatory Notice*.

III. Discussion and Findings

After careful consideration, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities association.[9] In particular, the Commission finds that the proposed rule change is consistent with section 15A(b)(6) of the Act,[10] which requires, among other things, that FINRA rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and in general to protect investors and the public interest. The Commission believes that the proposal will likely improve transparency in the corporate debt markets by making available a standard yield for most transactions that is calculated using an industry-recognized formula with a uniform set of assumptions. At the same time, the proposal reduces regulatory burdens by relieving FINRA members of the obligation to calculate and report yield for each transaction in a TRACE-eligible security.

IV. Conclusion

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[11] that the proposed rule change (File No. SR–FINRA–2008–040) be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant delegated authority.[12]

Florence E. Harmon,

Acting Secretary.

[FR Doc. E8–21762 Filed 9–17–08; 8:45 am]

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[3] Securities Exchange Act Release No. 58283 (August 1, 2008), 73 FR 46108 (August 7, 2008) (SR–FINRA–2008–040).

[4] The member is not required to report yield if the TRACE-eligible security is in default; the interest rate on the security floats; the interest rate will or may be ''stepped-up'' or ''stepped-down'', and the amount of increase or decrease is an unknown variable; the security is a pay-in-kind (''PIK'') security; the principal or interest to be paid is an unknown variable or is an amount that is not currently ascertainable; or if FINRA determines that reporting yield would provide inaccurate or misleading information concerning the price of, or trading in, the security. *See* NASD Rule 6230(c)(13).

[5] FINRA stated that the standard yield in TRACE: (1) Is calculated as the internal rate of return according to a discounted cash flow model; (2) is calculated, in a principal trade, on the reported price, which includes the mark-up/mark-down, and in an agency trade, on the reported price and reported commission; (3) does not include any fees or charges that are not included, in a principal trade, as part of the reported price, and in an agency trade, in the reported commission; (4) is calculated as the lower of yield to call (if the bond is callable) and yield to maturity, or so-called ''yield-to-worst;'' and (5) is calculated utilizing a methodology that is widely used by professionals in the securities industry.

[6] Standard yield is included in the disseminated TRACE data when the member is required to report yield but fails to do so.

[7] TRACE would not disseminate a standard yield for any transaction where a member currently is not required to report yield under NASD Rule 6230(c)(13). *See supra* note 4.

[8] 17 CFR 240.10b–10.

[9] In approving this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[10] 15 U.S.C. 78o–3(b)(6).

[11] 15 U.S.C. 78s(b)(2).

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–58502; File No. SR–NYSEArca–2008–93]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Change Relating to the Listing of the iShares Lehman Agency Bond Fund

September 10, 2008.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 25, 2008, NYSE Arca, Inc. (''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons and approves the proposed rule change on an accelerated basis.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange, through its wholly-owned subsidiary NYSE Arca Equities, Inc. (''NYSE Arca Equities''), proposes to list and trade shares (''Shares'') of the following fund of iShares Lehman Agency Bond Fund. The text of the proposed rule change is available on the Exchange's Web site at *http://www.nyse.com*, at the Exchange's principal office and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

places specified in Item III below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to list and trade the Shares of the following fund under NYSE Arca Equities Rule 5.2(j)(3), the Exchange's listing standards for Investment Company Units (''ICUs''): [3] iShares Lehman Agency Bond Fund (the ''Fund''), a series of the iShares Trust (''Trust'').

The Fund seeks investment results that correspond generally to the price and yield, before fees and expenses, of the agency sector of the U.S. government bond market as defined by the Lehman Brothers U.S. Agency Index (''Index''). The Index measures the performance of the agency sector of the U.S. government bond market and is comprised of investment grade U.S. dollar-denominated debentures issued by government and government-related agencies.

The Exchange is submitting this proposed rule change because the Index for the Fund does not meet all of the ''generic'' listing requirements of Commentary .02 to NYSE Arca Equities Rule 5.2(j)(3) applicable to listing of ICUs based on Fixed Income Securities.[4] The Index meets all such requirements except for those set forth in Commentary .02(a)(5).[5] The Exchange represents that: (1) Except for the requirement under Commentary .02(a)(5) to NYSE Arca Equities Rule 5.2(j)(3) that an underlying index or portfolio (excluding one consisting entirely of exempted securities) must include a minimum of 13 non-affiliated issuers, the Shares of the Fund currently satisfy all of the applicable generic listing standards under NYSE Arca Equities Rule 5.2(j)(3); (2) the continued listing standards under NYSE Arca Equities Rules 5.2(j)(3) and 5.5(g)(2) applicable to ICUs shall apply to the Shares; and (3) the Trust is required to comply with Rule 10A–3 [6] under the Act for the initial and continued listing of the Shares. In addition, the Exchange represents that the Shares will comply with all other requirements applicable to ICUs including, but not limited to, requirements relating to the dissemination of key information such as the Index value and Intraday Indicative Value, rules governing the trading of equity securities, trading hours, trading halts, surveillance, firewalls and Information Bulletin to ETP Holders, as set forth in prior Commission orders approving the generic listing rules applicable to the listing and trading of ICUs.[7]

Detailed descriptions of the Fund, the Index, procedures for creating and redeeming Shares, transaction fees and expenses, dividends, distributions, taxes, and reports to be distributed to beneficial owners of the Shares can be found in the Trust's Registration Statement [8] or on the Web site for the Fund (*http://www.ishares.com*), as applicable.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) [9] of the Act, in general, and furthers the objectives of Section 6(b)(5),[10] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanisms of a free and open market and a national market system. The Exchange believes that the proposed rule change will facilitate the listing and trading of an additional type of exchange-traded product that will enhance competition among market participants, to the benefit of investors and the marketplace.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File No. SR–NYSEArca–2008–93 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2008–93. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the

[3] An Investment Company Unit is a security that represents an interest in a registered investment company that holds securities comprising, or otherwise based on or representing an interest in, an index or portfolio of securities (or holds securities in another registered investment company that holds securities comprising, or otherwise based on or representing an interest in, an index or portfolio of securities). *See* NYSE Arca Equities Rule 5.2(j)(3)(A).

[4] Fixed Income Securities are described in NYSE Arca Equities Rule 5.2(j)(3), Commentary .02 as debt securities that are notes, bonds, debentures or evidence of indebtedness that include, but are not limited to, U.S. Department of Treasury securities, government-sponsored entity securities, municipal securities, trust preferred securities, supranational debt and debt of a foreign country or a subdivision thereof.

[5] The Exchange states that, as of August 8, 2008, the Index included securities of 10 non-affiliated issuers. Approximately 0.59% of the Index weight consisted of non-exempted securities. The Exchange notes that all 10 non-affiliated issuers of issues in the Index are U.S. government or government-related agencies. The Exchange believes that, under these circumstances, having 10 non-affiliated issuers rather than 13 non-affiliated issuers, as required by Commentary .02(a)(5) to NYSE Arca Equities Rule 5.2(j)(3), will have no negative impact on investor protection or on competition among market participants. E-mail from Tim Malinowski, Director, NYSE Euronext, Exchange, to Edward Cho, Special Counsel, Division of Trading and Markets, Commission, dated September 3, 2008.

[6] 17 CFR 240.10A–3.

[7] *See, e.g.*, Securities Exchange Act Release No. 55783 (May 17, 2007), 72 FR 29194 (May 24, 2007) (SR–NYSEArca–2007–36) (order approving generic listing standards for ICUs based on fixed income indexes); Securities Exchange Act Release No. 44551 (July 12, 2001), 66 FR 37716 (July 19, 2001) (SR–PCX–2001–14) (order approving generic listing standards for ICUs and Portfolio Depositary Receipts); Securities Exchange Act Release No. 41983 (October 6, 1999), 64 FR 56008 (October 15, 1999) (SR–PCX–98–29) (order approving rules for listing and trading of ICUs).

[8] *See* the Trust's Registration Statement on Form N–1A, dated July 16, 2008 (File Nos. 333–92935 and 811–09729).

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2008–93 and should be submitted on or before October 9, 2008.

IV. Commission's Findings and Order Granting Accelerated Approval of the Proposed Rule Change

After careful consideration, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[11] In particular, the Commission believes that the proposal is consistent with Section 6(b)(5) of the Act,[12] which requires, among other things, that the rules of a national securities exchange be designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and in general, to protect investors and the public interest.

Although NYSE Arca Equities Rule 5.2(j)(3) permits the Exchange to list ICUs based on Fixed Income Securities pursuant to Rule 19b–4(e) under the Act,[13] the Index for the Fund does not meet all of the generic listing requirements applicable to ICUs based on Fixed Income Securities. Specifically, the Index does not satisfy Commentary .02(a)(5) to NYSE Arca Equities Rule 5.2(j)(3), which requires that an underlying index or portfolio (excluding one consisting entirely of exempted securities) include a minimum of 13 non-affiliated issuers. According to the Exchange, as of August 8, 2008, the Index included securities of only 10 non-affiliated issuers, all of which are U.S. government or government-related agencies. The Exchange has noted that approximately 0.59% of the weight of the Index consists of non-exempted securities.[14]

The Commission believes that the listing and trading of the Shares is consistent with the Act. The Commission notes that all of the issuers of the Fixed Income Securities comprising the Index are either U.S. government or other government-related agencies. In addition, the Commission notes that, based on the Exchange's representations: (1) the Shares will meet all of the applicable generic listing standards under NYSE Arca Equities Rule 5.2(j)(3), except for the requirement under Commentary .02(a)(5) thereto that the Index include a minimum of 13 non-affiliated issuers; (2) the Shares will be subject to all of the continued listing standards under NYSE Arca Equities Rules 5.2(j)(3) and 5.5(g)(2) applicable to ICUs; and (3) the Trust is required to comply with Rule 10A–3 under the Act.[15] The Commission also notes that Shares of the Fund will comply with all other requirements of NYSE Arca Equities Rule 5.2(j)(3), applicable to ICUs including, but not limited to, requirements relating to the dissemination of key information such as the Index value and Intraday Indicative Value and rules governing the trading of equity securities, trading hours, trading halts, surveillance, firewalls, and Information Bulletins to ETP Holders, as set forth in prior Commission orders approving the generic listing rules applicable to the listing and trading of ICUs.[16]

The Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[17] for approving the proposal prior to the thirtieth day after the date of publication of the Notice in the **Federal Register**. The Commission notes that, because the Shares comply with all of NYSE Arca Equities' generic listing standards for ICUs based on Fixed Income Securities (except for the requirement relating to the minimum number of non-affiliated issuers), the listing and trading of the Shares by the Exchange does not appear to present any novel or significant regulatory issues, significantly affect the protection of investors or the public interest, or impose any significant burden on competition. The Commission further notes that it has previously approved the listing and trading of derivative securities products based on underlying assets that did not meet certain quantitative generic listing criteria[18] and, more specifically, the listing and trading of an exchange-traded fund based on an underlying index of Fixed Income Securities, which similarly did not satisfy the generic listing requirement relating to minimum number of non-affiliated issuers.[19] The Commission believes that accelerating approval of this proposal should benefit investors by creating, without undue delay, additional competition in the market for ICUs. Therefore, the Commission finds good cause, consistent with Section 19(b)(2) of the Act, to approve the proposed rule change on an accelerated basis. This order is based on the Exchange's representations.

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[20] that the proposed rule change (SR–NYSEArca–2008–93) be, and it hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

Florence E. Harmon,

Acting Secretary.

[FR Doc. E8–21758 Filed 9–17–08; 8:45 am]

BILLING CODE 8010–01–P

[11] In approving this rule change, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[12] 15 U.S.C. 78f(b)(5).

[13] *See* 17 CFR 240.19b–4(e). *See also* Commentary .02 to NYSE Arca Equities Rule 5.2(j)(3).

[14] *See supra* note 5.

[15] *See* 17 CFR 240.10A–3.

[16] *See, e.g.*, Securities Exchange Act Release Nos. 41983 (October 6, 1999), 64 FR 56008 (October 15, 1999) (SR–PCX–98–29) (approving the adoption of rules governing the listing and trading of ICUs); 44551 (July 12, 2001), 66 FR 37716 (July 19, 2001) (SR–PCX–2001–14) (approving generic listing standards for ICUs and portfolio depositary receipts); 55783 (May 17, 2007), 72 FR 29194 (May 24, 2007) (SR–NYSEArca–2007–36) (approving generic listing standards for ICUs based on fixed income indexes); and 56625 (October 5, 2007), 72 FR 58144 (October 12, 2007) (SR–NYSEArca–2007–73) (approving a proposal relating to extended hours trading for ICUs and portfolio depository receipts).

[17] 15 U.S.C. 78s(b)(2).

[18] *See, e.g.*, Securities Exchange Act Release Nos. 58437 (August 28, 2008), 73 FR 51684 (September 4, 2008) (SR–NYSEArca–2008–77); 57349 (February 19, 2008), 73 FR 10084 (February 25, 2008) (SR–NYSEArca–2008–22); 55953 (June 25, 2007), 72 FR 36084 (July 2, 2007) (SR–NYSE–2007–46); and 56695 (October 24, 2007), 72 FR 61413 (October 30, 2007) (SR–NYSEArca–2007–111).

[19] *See* Securities Exchange Act Release No. 57356 (February 20, 2008), 73 FR 10314 (February 26, 2008) (SR–Amex–2007–115) (approving the listing and trading of shares of the SPDR® Barclays Capital Global Inflation Linked Exchange-Traded Fund).

[20] 15 U.S.C. 78s(b)(2).

[21] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[License No. 06/76–0330]

SunTx Fulcrum Fund II—SBIC, L.P.; Notice Seeking Exemption Under Section 312 of the Small Business Investment Act, Conflicts of Interest

Notice is hereby given that SunTx Fulcrum Fund II—SBIC, L.P., Two Lincoln Centre, 5420 LBJ Freeway, Suite 1000, Dallas, TX 75240, a Federal Licensee under the Small Business Investment Act of 1958, as amended (''the Act''), in connection with the financing of a small concern, has sought an exemption under section 312 of the Act and section 107.730, Financings which Constitute Conflicts of Interest of the Small Business Administration (''SBA'') rules and regulations (13 CFR 107.730 (2002)). SunTx Fulcrum Fund II—SBIC, L.P. proposes to provide preferred equity security financing to Interface Security Holdings, Inc., 3773 Corporate Center Drive, Earth City, MO 63045. The financing is contemplated to provide the company with the necessary capital to purchase the interest of GAC's founders.

The financing is brought within the purview of Sec. 107.730(a)(1) of the Regulations because SunTx Fulcrum Fund, L.P. and SunTx Fulcrum Dutch Investors, L.P., an Associate of SunTx Fulcrum Fund II—SBIC, L.P., own in the aggregate 47% of the outstanding ownership of Interface. Therefore, this transaction is considered a financing of an Associate requiring prior SBA approval.

Notice is hereby given that any interested person may submit written comments on the transaction, within 15 days of the date of this publication, to the Associate Administrator for Investment, U.S. Small Business Administration, 409 Third Street, SW., Washington, DC 20416.

Dated: September 5, 2008.

A. Joseph Shepard,

Associate Administrator for Investment.

[FR Doc. E8–21898 Filed 9–17–08; 8:45 am]

BILLING CODE 8025–01–P

SOCIAL SECURITY ADMINISTRATION

[Docket No. SSA 2008–0040]

Privacy Act of 1974 as Amended; Computer Matching Program (SSA/Bureau of the Public Debt (BPD)—Match Number 1304)

AGENCY: Social Security Administration (SSA).

ACTION: Notice of the renewal of an existing computer matching program which is scheduled to expire on September 30, 2008.

SUMMARY: In accordance with the provisions of the Privacy Act, as amended, this notice announces the renewal of an existing computer matching program that SSA is currently conducting with BPD.

DATES: SSA will file a report of the subject matching program with the Committee on Homeland Security and Governmental Affairs of the Senate; the Committee on Oversight and Government Reform of the House of Representatives; and the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). The renewal of the matching program will be effective as indicated below.

ADDRESSES: Interested parties may comment on this notice by either telefaxing to (410) 965–0201 or writing to the Deputy Commissioner for Budget, Finance and Management, 800 Altmeyer Building, 6401 Security Boulevard, Baltimore, MD 21235–6401. All comments received will be available for public inspection at this address.

FOR FURTHER INFORMATION CONTACT: The Deputy Commissioner for Budget, Finance and Management as shown above.

SUPPLEMENTARY INFORMATION:

A. General

The Computer Matching and Privacy Protection Act of 1988 (Pub. L.100–503), amended the Privacy Act (5 U.S.C. 552a) by describing the conditions under which computer matching involving the Federal government could be performed and adding certain protections for individuals applying for, and receiving Federal benefits. Section 7201 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508) further amended the Privacy Act regarding protections for such individuals.

The Privacy Act, as amended, regulates the use of computer matching by Federal agencies when records in a system of records are matched with other Federal, State or local government records. It requires Federal agencies involved in computer matching programs to:

(1) Negotiate written agreements with the other agency or agencies participating in the matching programs;

(2) Obtain the approval of the matching agreement by the Data Integrity Boards (DIB) of the participating Federal agencies;

(3) Publish notice of the computer matching program in the **Federal Register**;

(4) Furnish detailed reports about matching programs to Congress and OMB;

(5) Notify applicants and beneficiaries that their records are subject to matching; and

(6) Verify match findings before reducing, suspending, terminating or denying an individual's benefits or payments.

B. SSA Computer Matches Subject to the Privacy Act

We have taken action to ensure that all of SSA's computer matching programs comply with the requirements of the Privacy Act, as amended.

Dated: July 31, 2008.

Mary Glenn-Croft,

Deputy Commissioner for Budget, Finance and Management.

Notice of Computer Matching Program, Social Security Administration (SSA) With the Bureau of the Public Debt (BPD)

A. Participating Agencies

SSA and BPD.

B. Purpose of the Matching Program

The purpose of this agreement is to establish the conditions, terms and safeguards under which BPD, the Source Agency, agrees to disclose ownership of Savings Securities to SSA, the Recipient Agency. This disclosure will provide SSA with information necessary to verify an individual's self-certification of eligibility for prescription drug subsidy assistance under Public Law 108–173, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA).

C. Authority for Conducting the Matching Program

The legal authority for SSA to conduct this matching activity is contained in section 1860D–14 (42 U.S.C.1395w–114) of the Social Security Act. Section 1860D–14 of the Act requires the Commissioner of SSA to verify the eligibility of an individual who seeks to be considered as a subsidy eligible individual for Part D of Medicare under the MMA, and who self-certifies his/her income, resources and family size. Pursuant to section 1860D–14(a)(3) of the Act (42 U.S.C.1395w–114(a)(3)), SSA shall determine whether a Part D eligible individual residing in a state is a subsidy eligible individual and whether the individual is an individual as described in section 1860D–14.

D. Categories of Records and Individuals Covered by the Matching Program

SSA will provide BPD with a finder file containing SSNs extracted from the Medicare database. BPD will match the SSNs in the finder file with the SSNs in its Savings Securities registration systems. This file will be formatted as stated in the attached Appendix. These records are included under the systems of records Treasury/BPD.002, United States Savings-Type Securities, and Treasury/BPD.008, Retail Treasury Securities Access Application, last published on July 23, 2008 at 73 FR 42906 and 42918, respectively. SSA will then match the BPD data with the new Medicare Part D and Part D Subsidy File system of records, SSA/ORSIS 60–0321, published at 69 FR 248 (December 28, 2004). As required by the Privacy Act, the Medicare Part D and Part D Subsidy File system of records was published in the **Federal Register** (Vol. 69, No. 248, pp. 77816–77822 [04–28302]) on Tuesday, December 28, 2004.

The number of records matched each year is determined in part by the number of people who file for subsidy for Part D. (In July 2007, there were 1,921,207 records matched.) BPD will perform the automated matching with its computer systems and provide the response file to SSA as soon as possible. This agreement covers the following matches:

(1) Screening for Potential Recipients

An ongoing monthly match of less than 200,000 potential applicants and those recipients who notify SSA of a change.

(2) Screening To Confirm Eligibility

Ongoing yearly matches of approximately two million recipients each year for confirming eligibility of individuals receiving Medicare Part D subsidy. SSA will substitute the yearly match file for the ongoing monthly match files and will not be a separate submission.

E. Inclusive Dates of the Matching Program

The matching program will become effective no sooner than 40 days after notice of the matching program is sent to Congress and OMB, or 30 days after publication of this notice in the **Federal Register**, whichever date is later. The matching program will continue for 18 months from the effective date and may be extended for an additional 12 months thereafter, if certain conditions are met.

[FR Doc. E8–21817 Filed 9–17–08; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Notice of Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart B (formerly Subpart Q) During the Week Ending September 5, 2008

The following Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits were filed under Subpart B (formerly Subpart Q) of the Department of Transportation's Procedural Regulations (See 14 CFR 301.201 *et seq.*). The due date for Answers, Conforming Applications, or Motions to Modify Scope are set forth below for each application. Following the Answer period DOT may process the application by expedited procedures. Such procedures may consist of the adoption of a show-cause order, a tentative order, or in appropriate cases a final order without further proceedings.

Docket Number: DOT–OST–2008–0274.

Date Filed: September 5, 2008.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: September 26, 2008.

Description: Joint Application of TradeWinds Airlines, Inc. (''TW'') and Sky Lease I, Inc. (''Sky Lease'') requesting the Department transfer TW's certificates of public convenience and necessity (and certain other exemption authority) to Sky Lease.

Docket Number: DOT–OST–2008–0277.

Date Filed: September 4, 2008.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: September 25, 2008.

Description: Application of TUIfly Nordic A.B. (''TUIfly'') requesting an exemption and an amended foreign air carrier permit authorizing TUIfly to conduct operations to and from the United States to the full extent authorized by the United States-European Union Air Transport Agreement (''U.S.-E.U. Agreement''), including authority to engage in: (i) Charter foreign air transportation of persons, property and mail from any point(s) behind any Member State(s) of the European Community via any point(s) in any Member State(s) and intermediate points to any point(s) in the United States and beyond; (ii) charter foreign air transportation of persons, property and mail between any point(s) in the United States and any points(s) in any member of the European Common Aviation Area; (iii) charter foreign cargo air transportation between any point(s) in the United States and any other point(s); (iv) other charter pursuant to the prior approval requirements; and (v) transportation authorized by any additional route or other right(s) made available to European Community carrier in the future.

Renee V. Wright,

Program Manager, Docket Operations, Federal Register Liaison.

[FR Doc. E8–21815 Filed 9–17–08; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Aviation Proceedings, Agreements Filed the Week Ending September 5, 2008

The following Agreements were filed with the Department of Transportation under the Sections 412 and 414 of the Federal Aviation Act, as amended (49 U.S.C. 1383 and 1384) and procedures governing proceedings to enforce these provisions. Answers may be filed within 21 days after the filing of the application.

Docket Number: DOT–OST–2008–0276.

Date Filed: September 4, 2008.

Parties: Members of the International Air Transport Association.

Subject: PTC COMP Mail Vote 575 Amending Composite Resolutions (Memo 1477). Intended effective date: 1 April 2009.

Renee V. Wright,

Program Manager, Docket Operations, Federal Register Liaison.

[FR Doc. E8–21818 Filed 9–17–08; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA–2008–0128]

Credit Assistance for Surface Transportation Projects; Expedited Process for Execution of TIFIA Loans

AGENCIES: Federal Highway Administration (FHWA), (DOT).

ACTION: Announcement of template term sheet and template loan agreement for an expedited TIFIA loan process; notice and request for comments.

SUMMARY: In order to more efficiently facilitate innovative financing transactions, the DOT intends to develop an expedited process for

execution of TIFIA loans for certain eligible highway projects developed pursuant to concession agreements with senior bank and/or bond debt facilities. To the extent applicants choose to take advantage of the expedited process, utilizing standardized documents and terms, as well as meet standard closing conditions, the DOT will commit to execute a final loan agreement within 45 days of the applicant's agreement to all of the terms and conditions contained in a template term sheet and a template loan agreement, drafts of which are published for comment on the docket for this notice and at the TIFIA Web site listed below. In addition, the DOT seeks comment regarding which term sheet and loan terms would need to be amended to provide an expedited process and which terms need to be amended for eligible transit projects developed pursuant to concession agreements.

DATES: Comments must be received on or before October 20, 2008.

ADDRESSES: The template term sheet and template loan agreement for the expedited TIFIA loan process which are the subject of this notice can be viewed electronically at the docket established for this rulemaking at *http://www.regulations.gov* or on the TIFIA Web site at *http://tifia.fhwa.dot.gov*. Hard copies of the documents will also be available for viewing at the DOT address listed below.

Mail or hand deliver comments to the U.S. Department of Transportation, Dockets Management Facility, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, or submit comments electronically at *http://www.regulations.gov*, or fax comments to (202) 493–2251. Alternatively, comments may be submitted via the Federal eRulemaking Portal at *http://www.regulations.gov* (follow the on-line instructions for submitting comments). All comments should include the docket number that appears in the heading of this document. All comments received will be available for examination and copying at the above address from 9 a.m. to 5 p.m., *e.t.*, Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped postcard or you may print the acknowledgment page that appears after submitting comments electronically. All comments received into any docket may be searched in electronic format by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). Persons making comments may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70, Pages 19477–78), or you may view the statement at *http://dms.dot.gov*.

FOR FURTHER INFORMATION CONTACT: Mr. Mark Sullivan, TIFIA Joint Program Office (202) 366–5785, Mr. Marcus J. Lemon, Chief Counsel (202) 366–0740, or Mr. Steven Rochlis, Office of the Chief Counsel (202) 366–1395, Federal Highway Administration; 1200 New Jersey Avenue, SE., Washington, DC 20590. Office hours for the FHWA are from 7:45 a.m. to 4:15 p.m., *e.t.*, Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

You may submit or retrieve comments online through the Federal eRulemaking portal at: *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 Office of the Federal Register's home page at: *http://www.archives.gov/federal_register* and the Government Printing Office's Web page at: *http://www.gpoaccess.gov*.

Background

TIFIA was enacted in 1998 as part of the Transportation Equity Act for the 21st Century (TEA–21) (Pub. L. 105–178, June 1998). TIFIA established a Federal credit program which provides Federal credit assistance to major surface transportation projects of regional or national significance. In 1999, the DOT promulgated a rule implementing TIFIA (64 FR 29742, June 2, 1999), and amended the rule in 2000 (65 FR 44936, July 19, 2000). Subsequently, in 2005, Congress enacted the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU) (Pub. L. 109–59, Aug. 10, 2005), which made a number of amendments to TIFIA.

In enacting the original TIFIA legislation, Congress found that ''a well-developed system of transportation infrastructure is critical'' to the nation's economy, and it sought to ''attract new investment capital'' to transportation infrastructure projects. Congress further found that TIFIA could complement existing funding resources by filling ''market gaps,'' thereby leveraging substantial private co-investment.

To date, the DOT has provided almost $4.8 billion in TIFIA credit assistance to 15 projects representing almost $18.6 billion of infrastructure investment. Four TIFIA loans, including the three most recent TIFIA loans, have been executed with private companies for eligible highway projects developed pursuant to concession agreements with a public entity. In addition, TIFIA has recently experienced a sharp growth in demand for credit assistance, in large part because it has received several applications for highway projects developed pursuant to concession agreements as a result of State implementation of public-private partnership initiatives. The pipeline of expected TIFIA applications, which demonstrates that this demand is not likely to subside in the foreseeable future, is also dominated by these types of projects. In response to recurring concerns over the length of time associated with executing and closing loans for these types of projects, the DOT intends to offer certain borrowers the option of an expedited loan process or ''fast track,'' which would require such borrowers to accept certain standard loan terms set forth in template loan documents.

Expedited Loan Process and Template Loan Documents

The statutory and regulatory requirements applicable to the TIFIA program will not be modified, amended, or supplemented for purposes of the expedited loan process. If an applicant wishes to take advantage of the expedited loan process, the applicant would be required to agree to the standard terms and conditions contained in a template term sheet (subject to negotiation of certain project specific terms, which must be separately negotiated for each transaction). The DOT would then commit to execute a loan agreement substantially similar to the template loan agreement, which is maintained on the TIFIA Web site, within 45 days of the applicant's signature accepting the term sheet. The expedited loan process will be subject to the DOT Credit Council and Secretary approving the loan. An applicant's decision to seek an expedited process will not affect the Department's decision to approve or disapprove credit assistance. Applicants are strongly encouraged to make use of this innovative process.

For purposes of the expedited process, the DOT has developed a template term sheet for applicants requesting secured loans for eligible highway projects being developed pursuant to a concession agreement with senior bank and/or bond debt facilities. The template term sheet contains the key business terms to

which the DOT would require the borrower to agree and certain project specific terms that must be separately negotiated for each transaction. The DOT expects that these terms may be modified periodically to reflect changes in TIFIA policies and practices. The DOT seeks public comment regarding the terms contained in the template term sheet. The template term sheet can be viewed at the docket established for this notice or at the TIFIA Web site at *http://tifia.fhwa.dot.gov*.

The DOT has also developed a template loan agreement. In order to receive the DOT's commitment to an expedited process, an applicant must agree that the standard template loan agreement is acceptable in form and substance, subject only to modifications required to conform the agreement to the terms and conditions of the agreed upon term sheet. The DOT expects that these terms may be modified periodically to reflect changes in TIFIA policies and practices. The DOT seeks public comment regarding the terms contained in the template loan agreement. The template loan agreement can be viewed at the docket established for this notice or at the TIFIA Web site at *http://tifia.fhwa.dot.gov*.

The DOT is aware that some of the terms in the template term sheet and template loan agreement may be unsuitable for transactions involving eligible transit projects. The DOT seeks public comment regarding which terms would need to be amended for transactions involving eligible transit projects developed pursuant to a concession agreement with senior bank and/or bond debt facilities.

Should an applicant seek terms that deviate from those in the template term sheet or the template loan agreement, the DOT may still commit to an expedited process, but only after the revised terms have been agreed to by the DOT. Items that require the TIFIA JPO's due diligence review (*e.g.*, traffic and revenue studies, senior loan documents, inter-creditor agreements, rating letters, etc.) do not need to be in final form for DOT to commit to the expedited process; however, DOT's commitment will be subject to receipt and due diligence analysis of final versions similar in every material respect to the draft versions reviewed by the JPO prior to the commitment.

Projects that require material deviations from the terms in the template term sheet or the template loan agreement, as determined by the DOT in its sole discretion, would not be eligible for the expedited process. In these circumstances, the DOT will maintain the same approach to loan negotiations that has always characterized the TIFIA program.

Authority: 23 U.S.C 315 and 23 U.S.C. 601–609; 49 CFR 1.48(b)(6), 49 CFR Part 80.

Issued on: September 12, 2008.

Thomas J. Madison, Jr.,

Federal Highway Administrator.

[FR Doc. E8–21783 Filed 9–17–08; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Highway in Delaware

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Limitation on Claims for Judicial Review of Actions by FHWA and Other Federal Agencies.

SUMMARY: This notice announces actions taken by the FHWA and other Federal agencies that are final within the meaning of 23 U.S.C. 139(l)(1). The actions relate to: a proposed highway project, the U.S. 301: MD/DE Line to SR1, South of the C&D Canal, New Castle County, Delaware, including the new 13 mile long U.S. 301 mainline on new alignment between the Delaware/Maryland state line and State Route (SR) 1, and the new 3.5 mile long Spur Road, on new alignment from proposed U.S. 301 in the vicinity of Armstrong Corner Road to the Summit Bridge, south of the Chesapeake and Delaware (C&D) Canal, State of Delaware. Those actions grant approvals for both parts of the proposed project.

DATES: By this notice, the FHWA is advising the public of final agency actions subject to 23 U.S.C. 139(l)(1). A claim seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filed on or before *March 17, 2009*. If the Federal law that authorizes judicial review of a claim provides a time period of less than 180 days for filing such a claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: Daniel Montag, Project Manager, Federal Highway Administration, 300 South New Street, Suite 2101,Dover DE 19904; weekdays 8 a.m. to 4 p.m.; telephone 302–734–1719; e-mail: *Daniel.Montag@fhwa.dot.gov.* Mark Tudor, Project Director, Delaware Department of Transportation, 800 Bay Road, Dover DE 19903; weekdays 8 a.m. to 4 p.m.; telephone 302–760–2275; e-mail: *Mark.Tudor@state.de.us.*

SUPPLEMENTARY INFORMATION: Notice is hereby given that the FHWA and other Federal agencies have taken final agency actions by issuing licenses, permits and approvals for the proposed construction of new U.S. 301 in the State of Delaware that is described below. The actions by the Federal agencies on the project, and the laws under which such actions were taken, are described in the Final Environmental Impact Statement (FEIS) for the project approved on November 30, 2007 and issued on December 14, 2007 (FR Vol. 72, No. 240, p. 71138) and in the FHWA Record of Decision (ROD) issued on April 30, 2008, and in other project records. The FEIS, ROD, and other records for the project are available by contacting the FHWA or the Delaware Department of Transportation at the addresses provided above. In addition, the FEIS and ROD can be viewed and downloaded electronically from the project Web site, *http://www.deldot.gov/information/projects/us301/*, or viewed at public libraries and other public venues in the relevant project area.

This notice applies to all Federal agency decisions on the listed project as of the issuance date of this notice and all laws under which such actions were taken. The laws under which Federal agency decisions were made on the project include, but are not limited to:

1. *General:* National Environmental Policy Act (NEPA) [42 U.S.C. 4321–4351]; Federal-Aid Highway Act [23 U.S.C. 109].

2. *Wetlands and Water Resources:* Clean Water Act [33 U.S.C. 1251–1377] (Section 404, Section 401, Section 319); TEA–21 Wetlands Mitigation [23 U.S.C. 103(b)(6)(m), 133(b)(11)]; Coastal Zone Management Act [16 U.S.C. 1451–1465].

3. *Air:* Clean Air Act [42 U.S.C. 7401–7671(q) and applicable regulations promulgated under 40 CFR 93.

4. *Wildlife:* Endangered Species Act [16 U.S.C. 1531–1544 and Section 1536]; Bald Eagle Protection Act [16 U.S.C. 668–668d]; Migratory Bird Treaty Act [16 U.S.C. 703–712].

5. *Historic and Cultural Resources*: Section 106 of the National Historic Preservation Act of 1966, as amended [16 U.S.C. 470(f) *et seq.*]; Archaeological Resources Protection Act of 1977 [16 U.S.C. 470(aa)–(ii)]; Archaeological and Historic Preservation Act [16 U.S.C. 469–469(c)]; Native American Grave Protection and Repatriation Act (NAGPRA) [25 U.S.C. 3001–3013].

6. *Land:* Farmland Protection Policy Act (FPPA) [7 U.S.C. 4201–4209]; Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303].

7. *Social and Economic:* Civil Rights Act of 1964 [42 U.S.C. 2000(d)–2000(d)(1)]; The Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970, as amended [23 CFR 450.318].

8. *Executive Orders:* Executive Order (E.O.) 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations; E.O. 11593, Protection and Enhancement of Cultural Resources; E.O. 13175, Consultation and Coordination with Indian Tribal Governments; E.O. 11514, Protection and Enhancement of Environmental Quality; E.O. 11990, Protection of Wetlands; E.O. 11988, Floodplain Management; E.O. 13112, Invasive Species.

The project subject to this notice is: U.S. 301: MD/DE Line to SR1, South of the C&D Canal. Project Location: New Castle County, Delaware. Project Reference number: 52–0599112.

Project Type: The Selected Alternative will provide a four-lane, tolled, limited access roadway on a new location, extending generally northward from the Maryland/Delaware state line, west of Middletown, to the vicinity of Armstrong Corner Road, where the new U.S. 301 mainline alignment will curve and extend northeast, crossing over existing U.S. 301, the Norfolk Southern Railroad, and existing SR 896 (Boyds Corner Road) before curving and extending east and tying into SR 1, north of the Biddles Corner Toll Plaza and south of the C&D Canal. Near Armstrong Corner Road, a two-lane, limited access, tolled Spur Road will extend north from new U.S. 301, on a new location to interchange with SR 15/SR 896 south of Summit Bridge and the C&D Canal. The U.S. 301 portion of the Selected Alternative will provide two 12-foot wide lanes in each direction and interchanges with: Levels Road, existing U.S. 301 north of Armstrong Corner Road, Jamison Corner Road, and SR 1 north of the Biddles Toll Plaza and south of the C&D Canal. The Spur Road portion of the Selected Alternative will provide one 12-foot lane in each direction and interchanges with new U.S. 301 near Armstrong Corner Road and SR 896/Bethel Church Road Extended (toll free), south of Summit Bridge. The Selected Alternative includes interchange Option 2A at existing U.S. 301, north of Armstrong Corner Road, Interchange Option 3B at SR 896/Bethel Church Road Extended, south of Summit Bridge, Alignment Option 4B Modified in the Ratledge Road/Boyds Corner Road area, and Alignment Option 1 Modified for the local road connection between Strawberry Lane and existing U.S. 301. Tolls will be collected utilizing electronic toll collection at highway speeds at the U.S. 301 mainline toll barrier near the Maryland/Delaware state line and at the interchange ramps to and from the north at Levels Road, existing U.S. 301 near Armstrong Corner Road, and Jamison Corner Road. The ramps to and from the north at the Spur Road interchange with SR 896/Bethel Church Road Extended will be toll free. Traditional cash lanes may also be provided at the toll barriers.

(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.)

Authority: 23 U.S.C. 139(l)(1).

Issued on September 12, 2008.

Hassan Raza,

Division Administrator Dover, Delaware.

[FR Doc. E8–21855 Filed 9–17–08; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Docket No. AB–55 (Sub–No. 689X)]

CSX Transportation, Inc.—Abandonment Exemption—in Logan County, WV

CSX Transportation, Inc. (CSXT) has filed a verified notice of exemption under 49 CFR 1152 Subpart F—*Exempt Abandonments* to abandon a 1.16-mile line of railroad on its Southern Region, Huntington Division East, Logan Subdivision, known as the Snap Creek Industrial Track, extending from milepost CLV 2.0 to the end of the line at milepost CLV 3.16 near Don, Logan County, WV. The line traverses United States Postal Service Zip Code 25632.

CSXT has certified that: (1) No local traffic has moved over the line for at least 2 years; (2) any overhead traffic on the line can be rerouted over other lines; (3) no formal complaint filed by a user of rail service on the line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Surface Transportation Board or with any U.S. District Court or has been decided in favor of complainant within the 2-year period; and (4) the requirements at 49 CFR 1105.7 (environmental report), 49 CFR 1105.8 (historic report), 49 CFR 1105.11 (transmittal letter), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line R. Co.—Abandonment-Goshen,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on October 18, 2008, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[1] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),[2] and trail use/rail banking requests under 49 CFR 1152.29 must be filed by September 29, 2008. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by October 8, 2008, with the Surface Transportation Board, 395 E Street, SW., Washington, DC 20423–0001.

A copy of any petition filed with the Board should be sent to CSXT's representative: Kathryn R. Barney, CSX Transportation, Inc., 500 Water Street, J–150, Jacksonville, FL 32202.

If the verified notice contains false or misleading information, the exemption is void *ab initio.*

CSXT has filed an environmental and historic report addressing the effects, if any, of the abandonment on the environment and historic resources. SEA will issue an environmental assessment (EA) by September 23, 2008. Interested persons may obtain a copy of the EA by writing to SEA (Room 1100, Surface Transportation Board, Washington, DC 20423–0001) or by calling SEA, at (202) 245–0305. [Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1–800–877–8339.] Comments on environmental and historic preservation matters must be filed within 15 days

[1] The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Section of Environmental Analysis (SEA) in its independent investigation) cannot be made before the exemption's effective date. *See Exemption of Out-of-Service Rail Lines,* 5 I.C.C.2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

[2] Effective July 18, 2008, the filing fee for an OFA increased to $1,500. *See Regulations Governing Fees for Services Performed in Connection with Licensing and Related Services—2008 Update,* STB Ex Parte No. 542 (Sub-No. 15) (STB served June 18, 2008).

after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), CSXT shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the line. If consummation has not been effected by CSXT's filing of a notice of consummation by September 18, 2009, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Board decisions and notices are available on our Web site at ''*http://www.stb.dot.gov.*''

Decided: September 5, 2008.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Anne K. Quinlan,

Acting Secretary.

[FR Doc. E8–21128 Filed 9–17–08; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Docket No. AB–43 (Sub-No. 184X)]

Illinois Central Railroad Company—Abandonment Exemption—in Cook County, IL

On August 29, 2008, Illinois Central Railroad Company (IC) filed with the Board a petition under 49 U.S.C. 10502 for exemption from the provisions of 49 U.S.C. 10903 to permit IC to abandon approximately 1.1 miles of rail line, beginning from the point of switch at Station 0+00 (mainline MP 3.00–Throop Street) and extending northeasterly 5,863 feet to the end of the track at Station 58+63 (mainline MP 2.00–Cermak Road), where it stub-ends, all in Chicago, Cook County, IL.[1] The line traverses U.S. Postal Service Zip Code 60616 and includes no stations.

The line does not contain Federally granted rights-of-way. Any documentation in IC's possession will be made available promptly to those requesting it.

The interest of railroad employees will be protected by the conditions set forth in *Oregon Short Line R. Co.—Abandonment—Goshen*, 360 I.C.C. 91 (1979).

By issuance of this notice, the Board is instituting an exemption proceeding pursuant to 49 U.S.C. 10502(b). A final decision will be issued by December 17, 2008.

Any offer of financial assistance (OFA) under 49 CFR 1152.27(b)(2) will be due no later than 10 days after service of a decision granting the petition for exemption. Each OFA must be accompanied by a $1,500 filing fee. *See* 49 CFR 1002.2(f)(25).[2]

All interested persons should be aware that, following abandonment of rail service and salvage of the line, the line may be suitable for other public use, including interim trail use. Any request for a public use condition under 49 CFR 1152.28 or trail use/rail banking under 49 CFR 1152.29 will be due no later than October 8, 2008. Each trail use request must be accompanied by a $200 filing fee. *See* 49 CFR 1002.2(f)(27).

All filings in response to this notice must refer to STB Docket No. AB–43 (Sub-No. 184X), and must be sent to: (1) Surface Transportation Board, 395 E Street, SW., Washington, DC 20423–0001; and (2) Michael J. Barron, Jr., Fletcher & Sippel LLC, 29 North Wacker Drive, Suite 920, Chicago, IL 60606–2832. Replies to IC's petition are due on or before October 8, 2008.

Persons seeking further information concerning abandonment procedures may contact the Board's Office of Public Assistance, Governmental Affairs, and Compliance at (202) 245–0238 or refer to the full abandonment or discontinuance regulations at 49 CFR part 1152. Questions concerning environmental issues may be directed to the Board's Section of Environmental Analysis (SEA) at (202) 245–0305. [Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1–800–877–8339.]

An environmental assessment (EA) (or environmental impact statement (EIS), if necessary) prepared by SEA will be served upon all parties of record and upon any agencies or other persons who commented during its preparation. Other interested persons may contact SEA to obtain a copy of the EA (or EIS). EAs in these abandonment proceedings normally will be made available within 60 days of the filing of the petition. The deadline for submission of comments on the EA will generally be within 30 days of its service.

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov.*

Decided: September 9, 2008.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Anne K. Quinlan,

Acting Secretary.

[FR Doc. E8–21675 Filed 9–17–08; 8:45 am]

BILLING CODE 4915–01–P

[1] IC explains that, even though the line is classified as an industrial spur and does not have mileposts at this time, the line was once part of the Chicago and Alton Railroad's main line in Chicago. IC states that it has not located any record of an abandonment for the line or any evidence of the line having been relocated. IC further indicates that it has embargoed the Line since March 2008 due to track conditions.

[2] Effective July 18, 2008, the filing fee for an OFA increased to $1,500. *See Regulations Governing Fees for Services Performed in Connection with Licensing and Related Services—2008 Update*, STB Ex Parte No. 542 (Sub-No. 15) (STB served June 18, 2008).

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Docket No. MC–F–21029]

Stagecoach Group PLC and Coach USA, Inc., et al.—Acquisition of Control—Eastern Travel & Tour, Inc.

AGENCY: Surface Transportation Board, DOT.

ACTION: Notice Tentatively Approving Finance Transaction.

SUMMARY: Stagecoach Group, PLC (Stagecoach), a noncarrier, its noncarrier intermediate subsidiaries (Stagecoach Transport Holdings plc, SCUSI Ltd., Coach USA Administration, Inc.), Coach USA, Inc. (Coach USA), and KILT Trans, Inc. (KILT), a motor passenger carrier (MC–115432) controlled by Coach USA (collectively, applicants), have filed an application under 49 U.S.C. 14303 for acquisition and operation of certain assets of Eastern Travel & Tour, Inc. (Eastern), a motor passenger carrier (MC–429551). Upon acquisition, Eastern will cease operations and KILT will assume such operations. The Board has tentatively approved the transaction, and if no opposing comments are timely filed, this notice will be the final Board action. Persons wishing to oppose the application must follow the rules under 49 CFR 1182.5 and 1182.8.

DATES: Comments must be filed by November 3, 2008. Applicants may file a reply by November 17, 2008. If no comments are received by November 3, 2008, this notice is effective on that date.

ADDRESSES: Send an original and 10 copies of any comments referring to STB Docket No. MC–F–21029 to: Surface Transportation Board, 395 E Street, SW., Washington, DC 20423–0001. In addition, send one copy of comments to applicants' representatives: David H. Coburn and Scott M. Mirelson, Steptoe & Johnson, LLP, 1330 Connecticut Ave., NW., Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Julia Farr (202) 245–0359. [Federal Information Relay Service (FIRS) for the hearing impaired: 1–800–877–8339.]

SUPPLEMENTARY INFORMATION: Stagecoach, headquartered in Scotland, is one of the world's largest providers of passenger transportation services. It operates in several countries, including the United States, through a series of operating divisions. Coach USA is a Delaware corporation that currently controls numerous passenger carriers, including KILT, one of the subjects of this transaction.[1] KILT is currently listed in Federal Motor Carrier Safety Administration (FMCSA) records as Pawtuxet Valley Bus Lines, Inc. Applicants state that KILT will request that FMCSA update its records to reflect the name KILT d/b/a Eastern following approval of the transaction.

Under the proposed transaction, applicants seek permission to acquire certain assets of Eastern, including Eastern's name, buses, customer lists, any property leases, sales records, Web site, and other assets. Eastern currently operates 12 motorcoaches, and provides regular route service between several points in the Mid-Atlantic States, including between New York, NY, and Washington, DC; New York and Baltimore, MD; and New York and Richmond, VA. The proposed transaction contemplates the cessation of operations by Eastern on these and other routes. Utilizing Eastern's assets in combination with KILT's, applicants state that there will be a seamless continuation of services previously provided by Eastern through KILT.

Under 49 U.S.C. 14303, the Board must approve and authorize a transaction it finds consistent with the public interest, taking into consideration at least: (1) The effect of the transaction on the adequacy of transportation to the public; (2) the total fixed charges that result; and (3) the interest of affected carrier employees. Applicants have submitted information, as required by 49 CFR 1182.2, including the information to demonstrate that the proposed transaction is consistent with the public interest under 49 U.S.C. 14303(b), and a statement that the 12-month aggregate gross operating revenues of all motor carrier parties and all motor carriers controlling, controlled by, or under common control with any party exceeded $2 million. Applicants state that the proposed transaction will have no impact on the adequacy of transportation services available to the public inasmuch as the operations of Eastern will remain unchanged, and that fixed charges associated with the proposed transaction will not be adversely impacted. Eastern currently employs approximately 24 persons, and applicants state that KILT is evaluating its employment needs with a view to employing qualified personnel that are currently employed by Eastern to operate the relevant services. Additional information, including a copy of the application, may be obtained from the applicants' representatives.

On the basis of the application, the Board finds that the proposed acquisition of assets is consistent with the public interest and should be authorized. If any opposing comments are timely filed, this finding will be deemed vacated and, unless a final decision can be made on the record as developed, a procedural schedule will be adopted to reconsider the application. *See* 49 CFR 1182.6(c). If no opposing comments are filed by the expiration of the comment period, this notice will take effect automatically and will be the final Board action.

Board decisions and notices are available on the Board's Web site at *http://www.stb.dot.gov.*

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

It is ordered:

1. The proposed acquisition and operation of certain assets of Eastern by applicants is approved and authorized, subject to the filing of opposing comments.

2. If timely opposing comments are filed, the findings made in this decision will be deemed as having been vacated.

3. This decision will be effective on November 3, 2008, unless timely opposing comments are filed.

4. A copy of this decision will be served on: (1) U.S. Department of Transportation, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue, SE., Washington, DC 20590; (2) the U.S. Department of Justice, Antitrust Division, 10th Street & Pennsylvania Avenue, NW., Washington, DC 20530; and (3) the U.S. Department of Transportation, Office of the General Counsel, 1200 New Jersey Avenue, SE., Washington, DC 20590.

Decided: September 11, 2008.

By the Board, Chairman Nottingham, Vice Chairman Mulvey, and Commissioner Buttrey.

Anne K. Quinlan,

Acting Secretary.

[FR Doc. E8–21733 Filed 9–17–08; 8:45 am]

BILLING CODE 4915–01–P

[1] Together, Stagecoach and Coach USA control 65 motor passenger carriers.

DEPARTMENT OF THE TREASURY

Senior Executive Service; Departmental Performance Review Board

AGENCY: Treasury Department.

ACTION: Notice of members of the Departmental Performance Review Board (PRB).

SUMMARY: Pursuant to 5 U.S.C. 4314(c)(4), this notice announces the appointment of members of the Departmental PRB. The purpose of this PRB is to review and make recommendations concerning proposed performance appraisals, ratings, bonuses and other appropriate personnel actions for incumbents of SES positions for which the Secretary or Deputy Secretary is the appointing authority. These positions include SES bureau heads, deputy bureau heads and certain other positions. The Board will perform PRB functions for other key bureau positions if requested.

Composition of Departmental PRB: The Board shall consist of at least three members. In the case of an appraisal of a career appointee, more than half the members shall consist of career appointees. The names and titles of the PRB members are as follows:

Peter B. McCarthy, Assistant Secretary for Management and Chief Financial Officer

Clay Lowery, Assistant Secretary for International Affairs

Eric Solomon, Assistant Secretary for Tax Policy

Kenneth E. Carfine, Fiscal Assistant Secretary

Rochelle F. Granat, Deputy Assistant Secretary for Human Resources and Chief Human Capital Officer

Charles R. Hastings, Deputy Chief Human Capital Officer

Linda E. Stiff, Deputy Commissioner, Services and Enforcement, Internal Revenue Service

John J. Manfreda, Administrator, Alcohol and Tobacco Tax and Trade Bureau

Vicky I. McDowell, Deputy Administrator, Alcohol and Tobacco Tax and Trade Bureau

James H. Freis, Jr., Director, Financial Crimes Enforcement Network

William F. Baity, Deputy Director, Financial Crimes Enforcement Network

Judith R. Tillman, Commissioner, Financial Management Service

David A. Lebryk, Deputy Commissioner, Financial Management Service

Frederick Van Zeck, Commissioner, Bureau of the Public Debt

Nancy C. Fleetwood, Deputy Commissioner, Bureau of the Public Debt
Larry R. Felix, Director, Bureau of Engraving and Printing
Pamela J. Gardiner, Associate Director for Management, Bureau of Engraving and Printing
Andrew D. Brunhart, Deputy Director, United States Mint

DATES: Membership is effective on the date of this notice.

FOR FURTHER INFORMATION CONTACT: Catherine R. Schmader, Executive Resources Program Manager, 1500 Pennsylvania Avenue, NW., ATTN: 1750 Pennsylvania Avenue, NW., Suite 8100, Washington, DC 20220, Telephone: (202) 622–0396.

This notice does not meet the Department's criteria for significant regulations.

Dated: September 8, 2008.

Charles R. Hastings,

Deputy Chief Human Capital Officer.

[FR Doc. E8–21656 Filed 9–17–08; 8:45 am]

BILLING CODE 4811–42–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 1120–REIT

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 1120–REIT, U.S. Income Tax Return for Real Estate Investment Trusts.

DATES: Written comments should be received on or before November 17, 2008 to be assured of consideration.

ADDRESSES: Direct all written comments to Glenn Kirkland Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Allan Hopkins at Internal Revenue Service, room 6129, 1111 Constitution Avenue, NW., Washington, DC 20224, or at (202) 622–6665, or through the Internet at *Allan.M.Hopkins@irs.gov*.

SUPPLEMENTARY INFORMATION:

Title: U.S. Income Tax Return for Real Estate Investment Trusts.

OMB Number: 1545–1004.

Form Number: 1120–REIT.

Abstract: Form 1120–REIT is filed by a corporation, trust, or association electing to be taxed as a REIT in order to report its income, and deductions, and to compute its tax liability. IRS uses Form 1120–REIT to determine whether the income, deductions, credits, and tax liability have been correctly reported.

Current Actions: There are no changes being made to the form at this time. We have updated the number of filers.

Type of Review: Revision of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 1,100.

Estimated Time per Respondent: 129 hours, 17 minutes.

Estimated Total Annual Burden Hours: 142,203.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: September 8, 2008.

Allan Hopkins,

IRS Reports Clearance Officer.

[FR Doc. E8–21784 Filed 9–17–08; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Bureau of the Public Debt

Senior Executive Service; Public Debt Performance Review Board (PRB)

AGENCY: Bureau of the Public Debt, Treasury.

ACTION: Notice of Members of Public Debt Performance Review Board.

SUMMARY: This notice announces the appointment of the members of the Public Debt Performance Review Board (PRB) for the Bureau of the Public Debt (BPD). The PRB reviews the performance appraisals of career senior executives who are below the level of Assistant Commissioner/Executive Director and who are not assigned to the Office of the Commissioner in BPD. The PRB makes recommendations regarding proposed performance appraisals, ratings, bonuses, pay adjustments, and other appropriate personnel actions.

DATES: The membership on the Public Debt PRB as described in the Notice is effective on September 18, 2008.

FOR FURTHER INFORMATION CONTACT: Angela Jones, Director, Human Resources Division, Office of Management Services, BPD, (304) 480–8302.

SUPPLEMENTARY INFORMATION: Pursuant to 5 U.S.C. 4314(c)(4), this Notice announces the appointment of the following primary and alternate members to the Public Debt PRB:

Primary Members: Nancy Fleetwood, Deputy Commissioner, Office of the Commissioner, BPD.Anita Shandor, Assistant Commissioner, Office of Financing, BPD. Cynthia Z. Springer, Executive Director, Administrative Resource Center, BPD. John R. Swales, III, Assistant Commissioner, Office of Retail Securities, BPD.

Alternate Members: Fredrick A. Pyatt, Assistant Commissioner, Office of Management Services, BPD.

Van Zeck,

Commissioner.

[FR Doc. E8–21747 Filed 9–17–08; 8:45 am]

BILLING CODE 4810–39–P

U.S.-CHINA ECONOMIC AND SECURITY REVIEW COMMISSION

Revised Schedule for Open Meetings To Prepare Report to Congress

Advisory Committee: U.S.-China Economic and Security Review Commission.

ACTION: Revised schedule for open meetings to prepare 2008 Annual Report to Congress—September 24–26, 2008, October 6–8, 2008, October 20–22, 2008, and October 23–24, 2008 (if necessary) in Washington, DC.

SUMMARY: Notice is hereby given of meetings of the U.S.-China Economic and Security Review Commission.

NAME: Larry Wortzel, Chairman of the U.S.-China Economic and Security Review Commission.

The Commission is mandated by Congress to investigate, assess, evaluate and report to Congress annually on the U.S.-China economic and security relationship. The mandate specifically charges the Commission to prepare a report to the Congress ''regarding the national security implications and impact of the bilateral trade and economic relationship between the United States and the People's Republic of China [that] shall include a full analysis, along with conclusions and recommendations for legislative and administrative actions * * *''

PURPOSE OF MEETINGS: Pursuant to this mandate, the Commission will meet in Washington, DC on, September 24–26, October 6–8, October 20–22, and October 23–24 (if necessary), 2008, to consider the first and later rounds of drafts of material for its 2008 Annual Report to Congress that have been prepared for its consideration by the Commission staff, and to make modifications to those drafts that Commission members believe are needed. Please check the USCC Web site at *http://www.uscc.gov* for updates on the tentatively scheduled meetings for October 23–24.

TOPICS TO BE DISCUSSED: The Commissioners will be considering draft Report sections addressing the following topics:

- The United States-China trade and economic relationship, including the relationship's current status; significant changes during 2008; the control of China's economy by its government, and the effect of that control on the United States.
- The implications of China's Sovereign Wealth Fund; seafood imports from China into Louisiana and the U.S. Gulf Coast; and R&D activities in China and resulting technology transfers to China for the U.S. economy and security.
- China's Activities Directly Affecting U.S. Security Interests, including China's proliferation policies and practices and China's space and cyber activities.
- China's Energy and Environmental Policies and Activities, including bilateral and multilateral energy and environment agreements; and China's efforts pertaining to climate change.
- China's Foreign and Regional Activities and Relationships in East Asia including those pertaining to Taiwan, Japan, and South Korea, and to its own special administrative region of Hong Kong.
- China's Media and Information Controls.
- China's Compliance with the U.S.-China Memorandum of Understanding on China's Use of Prison Labor.

DATES AND TIMES (EASTERN DAYLIGHT TIME):

—Wednesday, September 24, 2008 (11 a.m. to 5 p.m.).
—Thursday, September 25, 2008 (10 a.m. to 4 p.m.).
—Friday, September 26, 2008 (9 a.m. to 12 p.m.).
—Monday and Tuesday, October 6–7, 2008 (10 a.m. to 4 p.m.).
—Wednesday, October 8, 2008 (9 a.m. to 3 p.m.).
—Monday, October 20, 2008 (11 a.m. to 4 p.m.).
—Tuesday and Wednesday, October 21–22, 2008 (10 a.m. to 4 p.m.).
—Thursday and Friday, October 23–24, 2008 (8:30 a.m. to 5:30 p.m.) (if necessary).

ADDRESSES: All meetings will be held in Conference Room 333 (3rd floor), except the meetings on September 25 and October 23–24 will be held in Conference Room 231 (2nd floor), of The Hall of the States located at 444 North Capitol Street, NW., Washington, DC 20001. Public seating is limited, and will be available on a ''first-come, first-served'' basis. *Advance reservations are not required. All participants must register at the front desk of the lobby.*

REQUIRED ACCESSIBILITY STATEMENT: The entirety of these Commission editorial and drafting meetings will be open to the public. The Commission may recess the public editorial/drafting meetings to address administrative issues in closed session.

FOR FURTHER INFORMATION CONTACT: Kathy Michels, Associate Director, U.S.-China Economic and Security Review Commission, 444 North Capitol Street, NW., Suite 602, Washington DC 20001; phone 202–624–1409; e-mail *kmichels@uscc.gov*.

Authority: Congress created the U.S.-China Economic and Security Review Commission in 2000 in the National Defense Authorization Act (Pub. L. 106–398), as amended by Division P of the Consolidated Appropriations Resolution, 2003 (Pub. L. 108–7), as amended by Public Law 109–108 (November 22, 2005).

Dated: September 12, 2008.

Kathleen J. Michels,

Associate Director, U.S.-China Economic and Security Review Commission.

[FR Doc. E8–21746 Filed 9–17–08; 8:45 am]

BILLING CODE 1137–00–P

DEPARTMENT OF VETERANS AFFAIRS

Advisory Committee on Cemeteries and Memorials; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under Public Law 92–463 (Federal Advisory Committee Act) that a meeting of the Advisory Committee on Cemeteries and Memorials will be held November 18–19, 2008, at the Gaylord National Resort and Convention Center, National Harbor, Maryland. On November 18, the meeting will begin at 8 a.m. and end at 3:45 p.m. On November 19, the meeting will begin at 8:30 a.m. and end at 4 p.m. The meeting is open to the public.

The purpose of the Committee is to advise the Secretary of Veterans Affairs on the administration of national cemeteries, soldiers' lots and plots, the selection of new national cemetery sites, the erection of appropriate memorials, and the adequacy of Federal burial benefits.

On November 18, the Committee will receive updates on National Cemetery Administration issues. On November 19, the Committee will tour the historic Congressional Cemetery, located at 1801 E. Street in Southeast, Washington, DC, and reconvene at the hotel for a business session (beginning at 1 p.m.), which will include discussions of Committee recommendations, future meeting sites, and potential agenda topics for future meetings.

Time will not be allocated for receiving oral presentations from the public. Any member of the public wishing to attend the meeting should contact Mr. Michael Nacincik, Designated Federal Officer, at (202) 461–6240. The Committee will accept written comments. Comments may be transmitted electronically to the Committee at *Michael.n@va.gov* or mailed to the National Cemetery Administration (41C2), 810 Vermont Avenue, NW., Washington, DC 20420. In the public's communications with the

Committee, the writers must identify themselves and state the organizations, associations, or persons they represent.

Dated: September 12, 2008.

By Direction of the Secretary.

E. Philip Riggin,

Committee Management Officer.

[FR Doc. E8–21805 Filed 9–17–08; 8:45 am]

BILLING CODE 8320–01–P

Federal Register

Thursday,
September 18, 2008

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 422 and 423

Medicare Program; Medicare Advantage and Prescription Drug Benefit Programs: Final Marketing Provisions; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 422 and 423

[CMS 4131–F]

RIN 0938–AP24

Medicare Program; Medicare Advantage and Prescription Drug Benefit Programs: Final Marketing Provisions

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule revises the Medicare Advantage (MA) program (Part C) and Medicare Prescription Drug Benefit Program (Part D). The regulation contains new regulatory provisions regarding marketing processes for both programs. The revisions to the Part C and Part D programs are based on lessons we have learned since 2006, the initial year of the prescription drug program and the revised MA program.

DATES: *Effective Date:* The provisions of this regulation are effective September 18, 2008.

FOR FURTHER INFORMATION CONTACT: Chevell Thomas, 410–786–1387.

SUPPLEMENTARY INFORMATION:

I. Background

A. Overview of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) was enacted on December 8, 2003. The MMA established the Medicare Prescription Drug Benefit Program (Part D) and made revisions to the provisions in Medicare Part C, governing what is now called the Medicare Advantage (MA) program (formerly Medicare+Choice). The MMA directed that important aspects of the new Medicare Prescription Drug Benefit Program under Part D be similar to and coordinated with regulations for the MA program.

The MMA also directed implementation of the prescription drug benefit program and revised MA program provisions by January 1, 2006. The final rules for the MA and Part D prescription drug programs appeared in the **Federal Register** on January 28, 2005 (70 FR 4588 through 4741 and 70 FR 4194 through 4585, respectively). Many of the provisions relating to applications, marketing, contracts, and the new bidding process, for the MA program, became effective on March 22, 2005, 60 days after publication of the rule, so that the requirements for both programs could be implemented by January 1, 2006. All of the provisions regarding the new Part D prescription drug program became effective on March 22, 2005.

As we have gained more experience with the MA and the Part D programs, we are revising areas of both programs. Many of these revisions clarify existing policies or codify current guidance for both programs. We believe that these changes will help plans understand and comply with our policies for both programs and aid MA organizations and Part D plan sponsors in implementing their health care and prescription drug benefit plans.

B. Relevant Legislative History and Overview

The Balanced Budget Act of 1997 (BBA), Public Law 105–33, established a new ''Part C'' in the Medicare statute (sections 1851 through 1859 of the Social Security Act (the Act)) which provided for a Medicare+Choice (M+C) program. Under section 1851(a)(1) of the Act, every individual entitled to Medicare Part A and enrolled under Medicare Part B, except for most 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 he or she lived.

The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA), Public Law 106–111, 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.

As noted above, the MMA was enacted on December 8, 2003. Title I of the MMA added a new ''Part D'' to the Medicare statute (sections 1860D–1 through 1860D–42) creating the Medicare Prescription Drug Benefit Program, the most significant 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 which was established by the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33). Title II of the MMA renamed the M+C program the MA program and included new payment and bidding provisions, added authority for new regional MA plans and special needs plans, reestablished authority for medical savings account (MSA) plans that had been provided in the BBA on a temporary basis, and made other changes to the provisions of Part C. Title I of the MMA created prescription drug benefits under Medicare Part D, and a new retiree drug subsidy program.

Both the MA and prescription drug benefit regulations were published separately, as proposed and final rules, though their development and publication were closely coordinated. On August 3, 2004, we published in the **Federal Register** proposed rules for the MA program (69 FR 46866 through 46977) and the Medicare Prescription Drug Benefit Program (69 FR 46632 through 46863). In response to public comments on the proposed rules, we made several revisions to the proposed policies for both programs. For further discussion of these revisions, see the respective final rules (70 FR 4588–4741) and (70 FR 4194–4585).

Based on what we learned in program experience subsequent to the promulgation of the initial regulations implementing the MMA, on May 16, 2008, we proposed additional revisions to the Part C and D regulations that proposed to incorporate certain existing policies into the regulations, and make some revisions to policies based on program experience (73 FR 28556). The proposals in this May 16, 2008, notice of proposed rulemaking (proposed rule) included proposals addressing the marketing of Part C and Part D plans to Medicare beneficiaries. While the proposed rule also included a wide range of other proposals, in this final rule, we are only finalizing certain proposals in the May 16, 2008, proposed rule relating to marketing.

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), Public Law 110–275 was enacted on July 15, 2008, and amended titles XVIII and XIX of the Social Security Act to make various revisions to the Medicare statute intended to improve the Medicare program. Section 103 established new statutory prohibitions and limitations for MA plans and Medicare Prescription Drug plans (PDPs) on certain sales and marketing activities. Many of these new statutory marketing provisions were similar (or identical) to provisions that we proposed in our May 16, 2008, proposed rule. For example, MIPPA specifically prohibits, while performing marketing activities to promote or sell MA plans or PDPs, any unsolicited means of direct contact with beneficiaries, cross-selling of non-health related products, and providing meals. It also prohibits sales and marketing

activities in health care settings (excluding common areas) and at educational events.

MIPPA also places limits on other marketing activities. Specifically, it limits the following: the scope of the discussion during an appointment set with a beneficiary to discuss an MA plan or PDP to what was agreed upon with the beneficiary in advance; the ability to use names and logos of co-branded network providers on plan membership and marketing materials; the value of gifts and promotional items provided to beneficiaries; and the compensation paid by plans to agents for selling MA and Part D products. In addition, it requires the training and testing of agents and brokers selling MA and Part D products. MIPPA also requires plans and CMS to collaborate and share information with the States.

The above MIPPA provisions enact into statute provisions we proposed through our authority to establish marketing rules through rulemaking, and thus effectively would supersede our regulatory proposals. Pursuant to MIPPA, the marketing prohibitions provisions mentioned above apply to the plan year beginning on January 1, 2009. In keeping with statutory intent and based on policy concerns related to inappropriate marketing activity, we believe that regulations setting forth important protections for beneficiaries should be in effect before the 2009 plan year marketing campaign begins this fall on October 1, 2008. We are finalizing our May 16, 2008 proposals in these areas in this final rule so that the marketing rules in question can be effective for the 2009 benefit year marketing campaign, beginning October 1, 2008. These provisions are set forth in this final rule at § 422.2268, § 423.2268, 422.111(b) and 423.128(b).

Specifically, this final rule finalizes six new marketing provisions and modifies the disclosure and dissemination of Part D information provisions and the file and use provision set forth in the May 16, 2008, proposed rule. The remaining proposals in the proposed rule either were superseded by statutory provisions that we will reflect in the regulations as part of an interim final rule, or will be finalized in a future final regulation in which we will respond to any public comments on those proposals in the May 16th proposed rule that were not superseded by MIPPA provisions.

II. Provisions of the Proposed Regulations

Because this final rule finalizes only the recodification and modification of existing sections of the marketing regulations at § 422.80, § 423.50, § 422.111, and § 423.128 and finalizes only six of the new provisions from the proposed rule, we shall only discuss these aspects of the May 16, 2008 proposed rule here. The following table displays how the proposed rule proposed to recodify existing marketing provisions, and the bullets that follow the table set forth those proposals in the May 16, 2008 proposed rule that we are addressing in this final rule.

TABLE 1—PROVISIONS AFFECTING BOTH THE PART C AND PART D PROGRAMS

Provision	Part 422—subpart	Part 422 CFR section	Part 423 subpart	Part 423 CFR section
Marketing: Definitions	Subpart V (all marketing sections)	422.2260	Subpart V (all marketing sections)	423.2260
Review and Distribution of Marketing Materials.		422.2262		423.2262
Guidelines for CMS Review		422.2264		423.2264
Deemed Approval		422.2266		423.2266
Marketing: Standards for MA/Part D marketing.		422.2268		423.2268
Marketing: Licensing of marketing representatives and confirmation of marketing resources.		422.2272		423.2272
Marketing: Employer group retiree marketing.		422.2276		423.2276
Disclosure requirements and Dissemination of Part D information.	Subpart C	422.111	Subpart C	423.128

- § 422.2262(b) and § 423.2262(b)—we proposed to eliminate the file and use eligibility process.
- § 422.2268(b) and § 423.2268(b)—we proposed to prohibit the offering of gifts to potential enrollees unless the gifts are of nominal value, and prohibit providing meals to beneficiaries while conducting marketing activities. We are only finalizing the prohibition on meals in this final rule, and thus are separating these two prohibitions. The nominal gifts provision will be addressed in a separate rule that implements the requirement that new MIPPA rules be in place no later than November 15, 2008.
- § 422.2268(d) and § 423.2268(d)—we proposed to extend the prohibition against door-to-door solicitation to include other instances of unsolicited direct contact including outbound telemarketing without the beneficiary initiating contact.
- § 422.2268(f) and § 423.2268(f)—we proposed to prohibit the cross-selling of non-health care related products during any sales, marketing, or presentation for an MA plan or PDP.
- § 422.2268(k) and § 423.2268(k)—we proposed to prohibit conducting sales presentations or distributing and accepting plan applications in provider offices or other places where health care is delivered.
- § 422.2268(l) and § 423.2268(l)—we proposed to prohibit conducting sales activities, distributing, or collecting applications at education events.
- § 422.2272(c) and § 423.2272(c)—we proposed that plans must appoint and use only State licensed representatives to conduct direct marketing activities in accordance with applicable State appointment laws.
- § 422.111 and § 423.128—we proposed that plans must disclose the information specified in §§ 422.111(b) and 423.128(b) to its members both at the time of enrollment and at least annually thereafter, 15 days before the annual coordinated election period.

III. Analysis of and Response to Public Comments

We received a total of 405 timely comments on the May 16, 2008 proposed rule, and will only address here those comments that pertain to the proposals we are finalizing in this final rule. We received comments from managed care organizations and other insurance industry representatives, pharmacy benefit management firms,

pharmacies and pharmacy education and practice-related organizations, beneficiary advocacy groups, representatives of health care providers, States, employers and benefits consulting firms, members of Congress, beneficiaries, and others. The comments ranged from general support or opposition to the proposed provisions to very specific questions or comments regarding the proposed changes.

Brief summaries of each proposed provision, a summary of the public comments we received, and our responses to the comments are set forth below.

Medicare Advantage and Prescription Drug Program Marketing Requirements (Proposed New Subparts V)

A. General

In order to implement standards consistent with ''fair marketing'' practices in accordance with sections 1851(h) and 1860D–1(b)(1)(B)(vi) of the Act, and to ensure beneficiaries receive the necessary information to make informed choices during the annual election period, we proposed to amend and expand our marketing regulations for both the MA and the Part D programs. Moreover, due to the proposed addition of new marketing provisions and the need to clarify current marketing regulations, we proposed to remove §§ 422.80 and 423.50 of subpart B, which currently specify the requirements related to the approval of marketing materials and instead include this core of our marketing requirements in a new subpart V at 42 CFR parts 422 and 423 specific to the marketing regulations for each program.

Comment: We received several comments recommending changes to the content of the existing requirements contained in § 422.80 and § 423.50.

Response: In the proposed rule we made no changes to the requirements in §§ 422.80 and 423.50 other than to include them in a new subpart V (§§ 422.2260 and 423.2260). Because we did not propose modifications to the content of this section in the proposed rule other than relocating the text to a new subpart, the comments are beyond the scope of this regulation. However, there is one exception. A commenter requested that we remove the second sentence at §§ 422.2268(a) and 423.2268(a) because it creates ambiguity with respect to the prohibition outlined in the first sentence. We agree and are removing the sentence.

Comment: One commenter expressed concern about the time frame for implementing certain provisions prior to the annual election period (AEP) and open enrollment period (OEP) and recommended that the effective date of any provisions of the final regulations be effective after the 2009 AEP and OEP (April 1 or later). Other commenters expressed their desire for the provisions to be effective no sooner than 2010.

Response: This final rule contains the six provisions from the May 2008 proposed rule that we believe should be implemented prior to October 1, 2008, the beginning of the marketing period for contract year 2009, in order to protect beneficiaries during the annual election period. These six provisions are in accordance with requirements contained in section 103 of MIPPA that will take effect by operation of statute on January 1, 2009. In light of our program experience, we believe that the beneficiary protections in these six provisions should be put into effect before the 2009 benefit year marketing campaign and annual election period. Other provisions from the May 2008 proposed rule will be addressed in separate regulations, one will reflect other statutory provisions in MIPAA, and one will respond to comments on the other provisions in the May 2008 proposed rule that were not addressed in MIPAA. We will consider this comment in relation to the latter remaining provisions.

Comment: A few commenters requested clarification of the extent to which the proposed marketing requirements apply to cost plans or employer group plans; recommending that, if the proposed marketing requirements do not apply to cost plans or employer group plans, CMS modify the regulations to apply the proposed marketing requirements to such plans.

Response: Cost plans are subject to provisions found in § 417.28 and the guidance contained in the *Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plan, 1876 Cost Plans.* Employer group plans are MA and Part D plans. Additional guidance on employer group plans will be forthcoming in chapter 9 of the *Medicare Managed Care Manual.* The statutory provisions that the provisions of this final rule mirror only apply to MA plans under Part C and PDPs under Part D.

B. Review and Distribution of Marketing Materials: File and Use (§ 422.2262(b), § 423.2263(b))

In addition to moving our requirements concerning the approval of marketing materials and election forms to §§ 422.2262 and 423.2262 of the Part C and Part D program regulations, respectively, we are proposing to modify the ''file and use'' review process.

While the statute requires the submission of marketing materials to CMS for a 45 day period of CMS review, based on years of program experience CMS recognized that some MA organizations consistently met all marketing standards, and that their marketing materials warranted less scrutiny. CMS accordingly established a file and use policy that was designed to streamline the marketing materials approval process for these MA plans. Under this file and use policy, Medicare health plans that demonstrated to the satisfaction of CMS that they continually met a particular high standard of performance were able to publish and distribute certain marketing materials within 5 days of submission to CMS under section 1851(h)(1), without waiting for a response from CMS.

In effect, these materials were deemed approved by CMS after 5 days based on CMS's prior review of earlier materials. The criteria in order to be eligible for the original file and use policy were that a contracting entity had to have submitted at least eighteen months of marketing materials for CMS review, and at least ninety percent of the materials submitted within the past six months had to meet applicable marketing standards.

In the regulations implementing the MMA, CMS adopted a separate file and use policy that was based on the nature of the marketing materials in question, rather than the track record of the MA organization or PDP sponsor. Under this policy, an MA organization or PDP sponsor certifies that it is using either model language already reviewed and approved by CMS, or types of marketing materials that CMS has identified as not containing substantive content. As with the original policy that focused on the organization, the materials covered by this new file and use certification policy could be used 5 days after submission, without any explicit approval from CMS. In the case of MA organizations, this certification is made at the time of submission, while PDP sponsors are permitted to so certify in their contracts.

In order to level the playing field among contractors, eliminate redundancies, and focus resources on materials that have content that warrants CMS scrutiny, we are proposing to eliminate file and use status based on an organization's track record, and apply a uniform policy of applying the file and use policy to marketing materials that either use model language without substantive modification, or materials that are

identified by CMS as not containing substantive content warranting CMS review. The same approach to certifying that these types of materials are being used would apply for both MA organizations and Part D sponsors. We would include the proposed file and use provision in § 422.2262(b) and § 423.2262(b) of the MA and Part D programs, respectively.

Comment: There were several general comments on the CMS review process for marketing materials, including a request for further definition of ''substantive content.''

Response: Over the past 2 years CMS has implemented several mechanisms to enhance the consistency of our review process, and we will continue to refine our processes. We consider the suggestion to make more materials eligible for file and use a good one, and we have done so recently and may continue to do so in the future. A list of materials CMS has identified as ''not containing substantive content'' and eligible for file and use is available in the Health Plan Management System (HPMS) marketing module. With respect to shortening the review period to 30 days, the statute requires the submission of marketing materials to CMS for a 45-day period of review. Materials that are not deemed eligible for the 5-day file and use policy must be submitted for a 45-day review period. Finally, CMS will take under consideration suggestions to clarify the review process for plans that operate in more than one geographic area, and to allow such plans to submit materials to the lead office only for review.

Comment: One commenter agrees with the 45-day rule for marketing materials, but suggests that CMS attach the civil monetary penalty (per enrollee affected) as penalty for violating the certification without exceptions.

Response: CMS may impose a civil monetary penalty (CMP) on an organization when the organization's conduct adversely affects or has the substantial likelihood of adversely affecting one or more enrollees. One of the violations for which a CMP can be assessed is that the organization substantially fails to comply with marketing requirements (§§ 422.510(a)(12) and 423.509(a)(9)). If CMS determines an organization's substantial failure to adhere to marketing requirements has adversely affected or has the substantial likelihood of adversely affecting one or more enrollees, CMS may impose a CMP. It is important to note that CMS has other enforcement options, such as marketing and enrollment sanctions, for organizations that fail to adhere to marketing requirements. Under these sanctions, CMS may restrict a plan from marketing during marketing season or from accepting new enrollments for a period of time. For example, since marketing season begins on October 1st of every year, CMS may decide to impose a sanction against a plan for a marketing violation that prevents the plan from marketing until a later date, such as October 15th or November 1st. Similarly, CMS may prohibit a plan from accepting new enrollments for several months.

Comment: We received several comments in support of this rule change, and one comment opposing our elimination of the file and use policy for marketing materials.

Response: Section 423.2262 does not eliminate the file and use process, it only eliminates the file and use status based on an organization's track record. Instead a uniform policy will be applied, so that all contractors are eligible to submit any material deemed file and use qualified.

Comment: CMS received one comment that this change will over burden CMS and could lead to a negative impact on members. CMS must release models in time for document preparation and review time to be allowed.

Response: The elimination of file and use based on status will not increase the number of documents that CMS must review through the 45-day review process—model documents previously eligible for file and use will remain eligible for file and use. In addition, CMS is moving towards more standardization of certain model documents, which will then increase the number of documents eligible for file and use, thereby significantly shortening the amount of time required for CMS review. CMS has successfully released several model documents for plan review and modification earlier in the year, and will continue towards that goal.

Comment: Several comments suggested that CMS should add a requirement that plan sponsors file marketing materials with State regulators, so that States will be able to differentiate between CMS-approved and unapproved material and take action accordingly.

Response: It is not necessary for plans to file marketing materials with State regulators. All CMS approved marketing materials contain a unique material identification number. If anyone has a question about the legitimacy of plan marketing material, they can report it to CMS and it will be verified. If CMS determines that the material was not reviewed and approved prior to use, we will initiate a compliance action. If CMS determines that the material was appropriately submitted and approved, but determines as a result of a complaint that there is a problem with the material, it will contact the plan to have the material taken out of use.

C. Standards for MA and PDP Marketing (§§ 422.2268, 423.2268)

We proposed making an organizational change for this section, consistent with our proposal to create a new subpart V at 42 CFR part 422 and part 423 specific to marketing regulations. We are redesignating §§ 422.80 and 423.50 as §§ 422.2268 and 423.2268, respectively.

Comment: We received several comments requesting that we clarify that pharmacies are not obligated to distribute plan information to beneficiaries for Part D plans with which they do not have contracts. One commenter stated they do not believe that pharmacies should be prevented from providing comparative Part D plan information to patients if they do not accept and display marketing materials from all Part D sponsors. A commenter stated that some pharmacies may not contract with some Part D plans, and as a result may not be familiar with their terms and conditions nor have ready access to those plans' marketing materials. Some commenters also stated that the regulatory language in proposed § 422.2268(j) was not consistent with § 423.2268(j). Commenters stated that the final Part D technical rule that published April 15, 2008, (73 FR 20486) modified 42 CFR 423.50(f) requiring providers such as a pharmacy provider to display and distribute comparative plan marketing materials only from plans with which the provider contracts. One commenter recommended that CMS retain the recently amended § 423.50(f) and remove the language proposed in § 422.2268(j) and § 423.2268(j). There were also some commenters that opposed the existing provision.

Response: We are revising proposed § 423.2268(j) to be consistent with § 423.50(f)(v) as published in the Policy and Technical Changes to the Medicare Prescription Drug Benefit final rule (73 FR 20486) to include '' accept and display materials from MA organizations or Part D plan sponsors with which the provider, provider group or pharmacy is contracted.'' We are also modifying the regulatory language in § 422.2268(j) to be consistent with the language provided in § 423.2268(j). With respect to commenters that opposed the provision, as opposed to seeking

clarification, these comments are outside the scope of this rulemaking.

Comment: One commenter contended that this provision does not reflect guidance CMS issued October 30, 2006, that allows comparisons to be limited to SNPs as long as the remaining MA plans are identified. The Commenter recommended having this guidance explicitly recognized in the new regulation.

Response: The guidance released on October 30, 2006, references provider affiliation announcements in which SNPs may announce an ongoing affiliation or arrangement. This guidance will be included in the updated *Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plan, 1876 Cost Plans and other guidance.* This guidance requires that all affiliated plans be listed on affiliation announcements. In some cases, a disclaimer indicating that other plans are available is required. Highlighting the affiliated SNP plans within the list of all affiliated plans or listing the affiliated SNP plans along with the disclaimer is consistent with our guidance.

Comment: One commenter requested that CMS continue to allow providers to use an objective third party to create MA health plan benefit comparisons (all or a subset) that are distributed to beneficiaries/patients consistent with the Medicare marketing guidelines.

Response: This is still allowed. The *Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plan, 1876 Cost Plans* provides specific guidance for materials created by third parties.

D. Employer Group Retiree Marketing (§§ 422.2276, 423.2276)

We proposed an organizational change for this section, consistent with our proposal to create a new subpart V at 42 CFR part 422 and part 423 specific to marketing regulations. We are redesignating § 422.80(f) as § 422.2276 and, to be consistent, are adding § 423.2276.

Comment: We received no comments about the reorganization or the addition of § 423.2276. The only comments received expressed a concern about employer group marketing materials not being subject to prior review and approval.

Response: We have considered this comment and believe that employer group marketing is very different from marketing individual plans. Therefore, we are finalizing the provision without modification.

E. Licensing of Marketing Representatives and Confirmation of Marketing Resources (§§ 422.2272, 423.2272)

In response to questions from the Part D industry regarding State licensure of marketing representatives, we adopted in our *Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plan, 1876 Cost Plans* the requirement that MA organizations and Part D sponsors that conduct marketing through employees or independent agents use State-licensed, certified, or registered individuals to do so, if a State licenses such agents. The use of only State-licensed marketing representatives helps ensure that the marketing representatives meet minimum standards of integrity and professionalism in order to market to Medicare-eligible beneficiaries. This Medicare requirement permits Medicare to benefit from State efforts to deny licensure to under-educated, unscrupulous or otherwise substandard individuals, and helps ensure that Medicare beneficiaries are not the victims of substandard or inappropriate marketing activities.

Based on the experience we have gained since the start of the Part D program, and continued experience with the Medicare Advantage program, we proposed to codify in the regulation our existing requirement that MA organizations and Part D sponsors utilize only State-licensed marketing representatives to do marketing in the States that license such agents.

We further proposed to add a regulatory requirement to §§ 422.2272 and 423.2272 that MA organizations and PDP sponsors that market through agents, not only be required to use licensed agents, but would be required to report to States that they are using such agents, in a manner consistent with State appointment laws. State appointment laws require MA and PDP sponsors to appoint marketing representatives before the agent can market a plan's product. Appointment laws may require an insurance plan to maintain a registry of marketers who sell their plans, including maintaining a list of license numbers, dates the individual began selling policies for the insurance company, and stopped selling plans for the insurance company. While we previously required only that licensed agents be used, and did not require that the appointment of such agents be reported to the State agency that regulates agents, we believe this latter requirement would enable States to monitor the agents' activities in connection with their Medicare marketing for the purpose of monitoring the agent's fitness to engage in marketing in the State. We believe Medicare beneficiaries would benefit from this State monitoring.

We recognize that, under the preemption provisions in section 1856(b)(3) of the Act (incorporated for PDPs under section 1860D–12(g)), States do not have the authority to regulate the marketing of Medicare Part C and D plans. However, as noted, any abuses by an agent in marketing such plans would have direct relevance to the State's oversight of the agent generally, and implications for the agent's marketing of products over which the State has jurisdiction, and Medicare beneficiaries would benefit from having the agents who engage in Medicare marketing subject to this State oversight.

In the context of the requirement that MA organizations and Part D sponsors utilize only State-licensed marketing representatives, and report the appointment of such agents to States consistent with the procedures under State appointment laws, it is important to discuss the activities that would not trigger the need for using State-licensed marketing representatives. As standard practice, MA organizations and Part D sponsors employ customer service representatives who answer questions and accept enrollments on behalf of enrollees who have decided to enroll in a particular plan offered by the organization. We recognize that plan customer service representatives play an important role in disseminating information by answering factual questions posed by beneficiaries, and that such an activity is distinguishable from the act of steering to a plan (''marketing,'' as defined in the *Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plan, 1876 Cost Plans*).

Additionally, taking demographic information from someone who has decided to enroll in the plan, in order to complete an application, is not steering in that the beneficiary has already made a choice to enroll in a plan. Accordingly, we believe providing factual information, fulfilling a request for materials, and taking demographic information in order to complete an enrollment application at the initiative of the enrollee by a customer service representative (CSR), are legitimate customer service activities that would

not trigger the need for using State-licensed marketing representatives.

Comment: Many commenters agreed with the requirement that MA organizations and Part D sponsors that conduct marketing through agents must use State-licensed, certified, or registered individuals.

One commenter urged that the proposed rule on licensed agents include clarifying language similar to the language in the preamble, and in the *Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plan, 1876 Cost Plans.*

Response: We have considered this comment and have determined that the proposed provision should be finalized without modification. The *Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plan, 1876 Cost Plans* provide the clarification requested and we believe that the guidelines are the appropriate vehicle to do this.

Comment: A few commenters asked if the appointment of agents/brokers was warranted for stand-alone prescription drug plans (PDPs), because the marketing of these plans differs significantly from MA and MA–PD marketing.

Response: We believe that while the marketing of MA plans may differ from PDPs, in accordance with provisions in section 103 of MIPPA that will take effect on January 1, 2009, we are, in this final rule, requiring effective October 1, 2008, that MA organizations and PDP sponsors appoint their marketing representatives before the agents can begin to market a plan's product.

Comment: A few commenters would like the requirement for the licensing and appointment of independent agents/brokers to be effective on January 1, 2010 or later.

Response: As we have learned from our experience over the past several years and in order to better protect Medicare beneficiaries from practices that could mislead or confuse them, we believe that this requirement must be implemented before the fall 2008 marketing period during which plans for 2009 are marketed. These provisions would take effect by operation of MIPAA effective January 1, 2009, even if we had not acted to finalize these provisions of the proposed rule in this regulation. Therefore, we will proceed with implementing these rules as final and effective October 1, 2008.

Comment: Many commenters suggested that all MA and PDP enrollment applications should include the National Insurance Producer Registry (NIPR) license number. A few commenters urged more expansive CMS oversight and greater investment of resources in enforcement.

Response: We believe that States currently provide appropriate oversight, and have the necessary reporting mechanisms in place to track and monitor agent activity. The intent of this requirement is to strengthen our ability to collaborate with States in addressing fraudulent and inappropriate marketing practices.

Comment: A number of commenters requested that CMS develop guidance specifying the information that Plans must provide to States and establish a streamlined process for data submission.

Response: We believe States currently provide appropriate oversight and have the necessary reporting mechanisms in place to track and monitor agent activity. The intent of this requirement is to provide support to States as they exercise their oversight authority and we note that the requirement we are finalizing is generally in accordance with the Medicare Improvements for Patients and Providers Act (MIPPA). We will consider this comment when updating marketing guidance in the future.

Comment: Many commenters noted that our proposed regulatory language did not clearly state that CMS is requiring action that parallels information requirements under State appointment laws, because the regulation did not require compliance with all aspects of the State appointment process. By preventing the application of any State fees pursuant to the State appointment process, and requiring plans only to report to States that they are acting ''consistent with the appointment process'' may undermine States' ability to enforce their own appointment laws.

A few commenters believed CMS should revise this section to clarify that State agent appointment laws are enforceable against MA and Part D plan sponsors.

Response: We have considered these comments. Section 103 of MIPPA requires that plans pay fees to States under appointment laws, effective January 1, 2009.

Comment: A commenter questioned if CSRs who respond to beneficiaries' requests for a meeting with an agent need to be licensed.

Response: As discussed in the preamble, we recognize that CSRs play an important role disseminating information by performing activities like answering factual questions posed by beneficiaries. These activities are activities that we distinguish from activities that could result in steering a beneficiary to a particular plan. In keeping with that context, Customer Service Representatives (CSRs) scheduling agent appointments in response to a beneficiary request is not an activity that would require a licensed agent to fulfill.

Comment: A commenter asked if a CSR could answer questions about plans offered by a sponsor.

Response: Section 422.2272 permits CSRs to answer factual questions posed by beneficiaries.

Comment: A few commenters asked whether employees of external agents and brokers who perform ''customer service'' functions, but are not involved in the actual selling of plan products, could also do so without being State-licensed or appointed.

Response: Individuals performing customer service functions such as providing factual information, fulfilling a request for material, and taking demographic information are considered CSRs. When performing these functions, they do not need to be State-licensed or appointed.

E. Standards for MA/Part D Marketing (§§ 422.2268 and 423.2268)

In addition, we also proposed to clarify in §§ 422.2268 and 423.2268 several standards for MA and PDP marketing. In §§ 422.2268(d) and 423.2268(d) we clarify that the prohibition on door-to-door solicitation includes other instances of unsolicited direct contact, such as outbound calling without the beneficiary initiating contact, calling to confirm that the beneficiary is in receipt of mailed information, and accepting appointments made by third parties or independent agents without the beneficiary initiating contact; but does not include calling existing members. Although, plans may not contact former members who have disenrolled or are in the process of disenrolling. We believe this clarification would help prevent inappropriate conduct on the part of agents in aggressively pursuing the marketing of MA plans and PDPs to beneficiaries outside of approved common areas that may be used for marketing displays and presentations (for example, approaching beneficiaries directly in parking lots).

We also proposed to clarify in §§ 422.2268(l) and 423.2268(l) that plans may not engage in sales or marketing activities, including the distribution or collection of plan applications, at educational events. These events may be sponsored by plans or by outside entities, and are events

that are promoted to be educational in nature and have multiple vendors, such as health information fairs, conference expositions, State-or community-sponsored events, etc. In §§ 422.2268(k) and 423.2268(k) we clarified that sales and marketing activities, including the distribution or collection of plan applications, are only permitted in common areas of health care settings (for example, hospital cafeterias or conference rooms), and would be prohibited in areas where patients primarily intend to receive health care services (for example, waiting rooms and pharmacy counter areas). The term ''health care setting'' refers to all settings where providers operate, including but not limited to pharmacies, physicians' offices, hospitals, and long-term care facilities. In the proposed rule, we added § 423.2268(i) to be consistent with § 422.2268(i). We received no comments on this change.

We further proposed a regulatory requirement in §§ 422.2268 and 423.2268, providing additional protections to ensure beneficiaries are not the victims of inappropriate marketing techniques. In §§ 422.2268(f) and (b) and § 423.2268(f) and (b), we proposed to prohibit in any MA or Part D sales activity or presentation, the provision of meals or the cross-selling of non-health care related products to a prospective enrollee.

Comment: Commenters that supported the unsolicited contact prohibition requested that CMS further define cold calls by clarifying if calls are permissible to the following: (1) Existing membership and beneficiaries that have an existing relationship with a producer, (2) business reply cards, and (3) follow-up calls on plan mailings.

Response: These clarifications will be updated in the *Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plan, and 1876 Cost Plans and other guidance.*

Comment: Many of the comments were not wholly opposed to the prohibition on meals, and instead were requesting clarification on the definition of meals.

Response: Comments received will be taken under consideration when updating the *Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plan, and 1876 Cost Plans and other guidance.*

Comment: Several commenters opposed the provision prohibiting outbound calls. Some stated that it is too restrictive, minimizes growth in the program, and is inconsistent with common marketing practices. Commenters stated that restricting calls will prevent beneficiaries from learning about their full range of healthcare options and is considered discriminatory since it creates an imbalance with Medigap plans. Some commenters stated this provision impacts low-income and non-English speaking populations where communication through mailings has been less effective, specifically beneficiaries with Medicare and Medicaid. Commenters also stated that the current CMS rules in the *Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plan, 1876 Cost Plans* provides adequate protection. Commenters that supported the provision on unsolicited contacts recommended that CMS implement reporting requirements to identify and prevent unsolicited door-to-door sales and require documentation on how an invitation was secured for an in-home presentation.

Response: We believe that this change is necessary to ensure the protection of beneficiaries from inappropriate or fraudulent marketing activities such as high-pressure sales tactics or inappropriate use of beneficiary information. Section 103 of MIPPA prohibits unsolicited means of direct contact including door-to-door solicitation or any outbound telemarketing, and therefore we will proceed without modification in the final regulation. The *Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plan, 1876 Cost Plans* and other guidance are also in the process of being updated and will set forth in detail requirements for outbound calls to existing membership and plan mailings.

In response to the comment regarding reporting requirements for door-to-door solicitation and in-home appointments, we will consider including detailed guidance in the *Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plan, 1876 Cost Plans and other guidance.* However, organizations should have internal reporting requirements established to maintain appropriate oversight of these and all marketing activities.

Comment: Some commenters opposed the provision that prohibits sales activities at educational events. One commenter suggested that CMS require agents and brokers to register with their carrier and CMS at seminars and group sales events. Enrollments should be allowed to take place as a result of the seminar at the end or at a later date. Many commenters stated that enrollment materials should be available for distribution only. Commenters supporting the provision also suggested that there should be a disclaimer provided at education events that states, ''This is an education event only and no sales activity will be conducted, including distribution or collection of plan applications.'' Many commenters requested additional clarification on the difference between sales events and education events. Commenters also stated they are concerned with CMS' ability to enforce this provision.

Response: We believe the sole purpose of an education event is to provide objective information about the Medicare program, not steering an enrollee towards a specific plan or limited number of plans. When a beneficiary receives informational materials used to promote an organization or materials that include enrollment information for an organization, this is considered a marketing activity. Additionally, section 103 of MIPPA prohibits sales or marketing activities for enrollment in MA plans in the healthcare setting or at educational events except in common areas of healthcare settings. Therefore, we are finalizing the provision as proposed. We will also further clarify here that sales activities or sales events are marketing activities that steer or attempt to steer, an undecided potential enrollee towards a plan, or limited number of plans, including an effort that involves compensation directly or indirectly to the party conducting the effort if it may lead to enrollment in a plan. In response to the disclaimer requirement for education events, we will consider this requirement when updating the *Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plan, 1876 Cost Plans and other guidance.*

Comment: One commenter suggested that CMS develop easy to understand educational materials and require plans to distribute those materials to beneficiaries, regarding the disenrollment options available to beneficiaries who may have erroneously or inappropriately enrolled in an MA–PD or a Private-Fee-for-Service Plan.

Response: We will consider additional methods for ensuring beneficiaries are aware of their options to disenroll if the beneficiary has been erroneously or inappropriately enrolled in an MA–PD or a Private-Fee-for-Service Plan. However, CMS currently provides several resources that

organizations can access to provide educational information on the Medicare Program. For example, plans may refer to the CMS partnership Web site for general outreach and education information at *http://www.cms.hhs.gov/partnerships.* Also beneficiaries may be referred to 1–800–MEDICARE if they have been inappropriately enrolled in a health plan.

Comment: We received several comments stating that the provision for plan sales activities in a healthcare setting is inconsistent with the *Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plan, 1876 Cost Plans* and is overly restrictive. Commenters requested clarification on the phrase ''other places where healthcare is delivered'', and suggested instead to prohibit such activities in ''provider offices, other places where a healthcare provider delivers healthcare services to a Medicare beneficiary''. One commenter suggested that CMS model the language included in the recently passed Medicare bill (MIPPA). Some commenters stated that sales activities and applications should be prohibited at pharmacies and any part of a retail store in which a pharmacy is located.

Response: We have reviewed this comment and will revise §§ 422.2268(k) and 423.2268(k) to include the following language from section 103 of MIPPA ''areas where health care is delivered to individuals, except in the case where such activities are conducted in common areas in health care settings.''

Comment: Commenters recommended that CMS amend the rule to clarify that marketing may not take place in areas within healthcare settings where individuals receive care, rather than in the entire building.

Response: We have considered the comment; however, we will retain the provision as proposed. Clarification is provided in the *Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plan, 1876 Cost Plans* where we state ''Common areas, where marketing activities are allowed, include areas such as hospital or nursing home cafeterias, community or recreational rooms and conference rooms. If a pharmacy counter is located within a retail store, common areas would include the space outside of where patients wait for services or interact with pharmacy providers and obtain medications.''

Comment: Commenters stated that CMS did not address in the preamble or proposed regulation sales activities in hospitals or skilled nursing facilities. Some commenters stated that the provisions will impact seniors who are hospitalized or living in long-term care facilities, and that a waiver should be signed to allow marketing in any section that is available. Commenters also stated that this provision would impact beneficiaries that receive care from dialysis facilities where they lack common areas such as lobbies or patient-accessible areas.

Response: In response to the first comment, the *Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plan, 1876 Cost Plans* clarifies that upon request by the beneficiary, plans are permitted to schedule appointments with beneficiaries residing in long-term care facilities just as with other individuals living in a private residence. In response to the comments regarding marketing to patients that are hospitalized or receiving care in a dialysis center, these are areas where patients receive care primarily and therefore are prohibited areas. The preamble provides clarification on activities that can be permitted in common areas and activities that would be prohibited. Furthermore, the *Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plan, 1876 Cost Plans* also provide detail on the requirements for plan activities in a healthcare setting.

Comment: One commenter recommended that CMS provide clarification as to whether providers could provide printed materials in waiting rooms regarding MA or Part D plans, which do not compare or contrast different health plans but focus instead on a single health plan.

Response: The clarification is provided in the *Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plan, 1876 Cost Plans* where it is stated that ''providers are permitted to make available and/or distribute plan marketing materials for all plans with which the provider participates.'' Therefore, if a provider is only contracted with one health plan they are only obligated to display materials for that plan. Otherwise, the provider must display information from all plans with which the provider contracts.

Comment: CMS received many comments on the prohibition on providing meals at marketing events, both in favor and opposed. Commenters in favor of the prohibition expressed that the inclusion of meals as a prohibited item would help protect beneficiaries by preventing mass enrollments without personal attention to the appropriateness of the plan. Comments opposed to the provision on meals were varied. Some stated it is overly restrictive, while others stated that there is no relationship between offering meals at an enrollment event and inappropriate sales tactics, and that meal settings can allow beneficiaries to feel more comfortable and less pressured than an in-home visit. Commenters stated that hosting meal events is a key marketing strategy, and the provision will have a significant impact on beneficiary attendance in marketing seminars. Several commenters stated that the current marketing guidance is sufficient. Some comments requested clarification on the term meals and the limitation—for example, is it acceptable if the beneficiary purchases their own meal or if a volunteer association arranges the meals, or if the meals are provided at an event where no enrollment forms are distributed or collected. One commenter stated that limiting food to snacks would be difficult to enforce. Several organizations made recommendations on different strategies of implementation, including the suggestions that organizations should be prohibited from advertising that a meal will be provided at a plan sponsored event, that meals be allowed at events where applications are not accepted, that a disclaimer be required that the meal is not a contingency for signing up for a plan, or that organizations should be prohibited from spending a dollar limit per person on all food and beverage items at a given event. Comments were received that this provision would deny restaurants an important source of revenue, and that beneficiaries also benefit from the opportunity to get free meals.

Response: Based on oversight activities, we believe it is important to protect the integrity of the sales and marketing process by moving forward with this prohibition. Furthermore, MIPPA prohibits meals at marketing events. Therefore, we adopt the prohibition on meals as proposed. The *Medicare Marketing Guidelines for: Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plan, 1876 Cost Plans* and other guidance will provide more detail on this requirement. As, noted, the issue of gifts will be addressed separately.

Comment: One commenter argued that cross-selling of all non-Medicare

products should be prohibited, not just non-healthcare related products. In this commenter's view, a prohibition on all non-Medicare products would ensure that beneficiaries focus on Medicare related products. Several commenters were in agreement with prohibiting the marketing of non-health care related products during a sale of Medicare Products, but similarly recommended that regulations governing cross-selling be expanded to bar the cross-selling of all non-Medicare related products. One commenter recommended that plans be permitted to cross sell health related items on inbound calls when a beneficiary has initiated the call. Some commenters requested clarification on what is considered health related products for the purposes of Medicare cross-selling requirements. A commenter believed that the agent oversight would be a huge administrative burden, and that the prohibition of cross selling would be inconvenient for potential members who are seeking to purchase other products.

Response: We welcome the support for banning the marketing of non-health care related products. We are not changing this language to refer to non-Medicare related products however, for two reasons. First, non-Medicare health care coverage is subject to Medigap restrictions, and we would not expect MA organizations or PDP sponsors to attempt to sell non-Medicare health care products. Also, Congress has addressed the issue of cross-selling in a new section 1851(j)(2) that, effective January 1, 2009, prohibits the sale of ''non-health care related products (such as annuities and life insurance).'' We believe that our final rule should track the statute in this area.

F. Disclosure of Plan Information (§§ 422.111 and 423.128)

We are finalizing our proposal in our May 16, 2008 proposed rule to specify in §§ 422.111(a)(3) and 423.128(a)(3) that plans must disclose the information specified in §§ 422.111(b) and 423.128(b) of the MA and Part D program regulations, respectively, both at the time of enrollment and at least annually thereafter, 15 days before the annual coordinated election period. This is essential to ensuring that current enrollees receive comprehensive information necessary for making an informed decision regarding their health care options prior to the annual coordinated election period. Note that MIPPA made a related change affecting special needs plans disclosure requirements which we will discuss in a regulation to be published at or about the same time as this final rule.

Comment: A commenter suggested that new enrollees receive comprehensive information about their benefit package prior to their purchase rather than after the sale. The commenter stated that more comprehensive information is essential for the consumer and the agent to know ahead of time in order to determine if a product is suitable for a particular individual.

Response: We agree that disclosure of plan information continues to be an important feature that allows beneficiaries to make an informed decision about their healthcare options. MA plans and PDPs are obligated to provide details on benefits and rules prior to enrollment through pre-enrollment materials including the Summary of Benefits. The Summary of Benefits provides comparative information of Original Medicare and the benefits of the MA plan or PDP. We also believe that the Medicare & You Handbook along with other information channels such as the State Health Insurance Assistance Programs (SHIPs) and 1–800–MEDICARE provides an opportunity for Medicare beneficiaries to receive comprehensive information prior to enrollment on the choices available to them. Therefore, we will continue to allow plans the option of providing the Annual Notice of Change/Evidence of Coverage (ANOC/EOC) prior to enrollment and upon beneficiary request.

Comment: Several commenters suggested that CMS articulate penalties for plans that do not adhere to the disclosure requirement for the ANOC/EOC, since there have been plans that have made these disclosures far too late in each of the past 3 years.

Response: Pursuant to §§ 422.752(c) and 423.752(c), CMS may impose CMPs on an organization for any of the determinations at § 422.510(a) (except §§ 422.510(a)(4)) or 423.509(a) (except § 423.509(a)(4)) if CMS determines that the organization's conduct has adversely affected or has the substantial likelihood of adversely affecting one or more enrollees. Determinations that would justify the imposition of CMPs include the MA organization or Part D sponsor failing substantially to carry out the terms of its contract with CMS, the MA organization or Part D sponsor carrying out its contract with CMS in a manner that is inconsistent with the effective and efficient implementation of this part, and the MA organization substantially failing to comply with the marketing requirements at § 422.80 or the Part D sponsor substantially failing to comply with the dissemination of information requirements at § 423.128. Therefore, if CMS determines an organization's failure to comply with marketing disclosure requirements supports a determination pursuant to § 422.510(a) or § 423.509(a) and adversely affects or has the substantial likelihood of adversely affecting one or more enrollees, CMS may consider imposing a CMP.

Comment: One commenter that supported the disclosure of plan information requested that CMS extend the proposal to require that plans disclose information 30 days before the annual coordinated election period.

Response: We have reviewed this comment and we believe this provision will allow beneficiaries adequate time to make an informed decision about their health care options. Therefore, we will proceed with this provision in the final regulation without modification.

Comment: One commenter stated thirty days prior to the benefit becoming effective is a more appropriate requirement with respect to employer groups, when the annual coordinated period is not specified.

Response: Employer sponsored ''800 series'' plans, Direct Contract plans or individual MA plans that are subject to Medicare marketing and disclosure requirements are subject to any applicable timing requirements for issuance of annual disclosure materials prior to the Annual Election Period (AEP). CMS has waived or modified applicable timing requirements in certain circumstances where a particular employer/union sponsor has an open enrollment period that differs from Medicare's AEP. Under these circumstances, the timing for issuance of these materials would be based on the employer/union sponsor's open enrollment period. In circumstances where there is no specified open enrollment period, CMS will clarify in the Medicare Managed Care Manual for Employer Groups and the Prescription Drug Benefits Manual for Employer Groups that disclosure materials based on the AEP must be received by beneficiaries no later than 15 days before the beginning of the plan year.

IV. Provisions of the Final Regulations

This final rule relocates to the new subpart V, sections from subparts B and C related to marketing definitions, marketing materials, and other marketing requirements:

A. Definitions Concerning Marketing Materials (§§ 422.2260, 423.2260)

We are making an organizational change for this section, consistent with

our proposal to create a new subpart V of 42 CFR parts 422 and 423 specific to marketing. We are moving the definition of marketing materials to §§ 422.2260 and 423.2260 of the Part C and D program regulations, respectively.

B. Reviews and Distribution of Marketing Materials: File and Use (§§ 422.2262, 423.2262)

• We are making an organizational change for this section, consistent with our proposal to create a new subpart V of 42 CFR parts 422 and 423 specific to marketing. We are moving §§ 422.80(a) and 423.50(a), which describe the review and distribution of marketing materials, to §§ 422.2264 and 423.2264, respectively, and making the language consistent between the two sections as 423.50 was missing the provision now located at § 423.2264(a)(2)(i); allowing Part D sponsors to distribute their marketing materials 5 days following their submission to CMS provided the Part D sponsor is deemed to meet certain performance requirements established by CMS. In addition to moving these requirements to §§ 422.2262 and 423.2262 of the Part C and D program regulations, respectively, we proposed to modify the ''file and use'' review process. We are moving forward with our proposal to eliminate the file and use eligibility process.

C. Guidelines for CMS (§§ 422.2264, 423.2264)

We are making an organizational change for this section, consistent with our proposal to create a new subpart V of 42 CFR parts 422 and 423 specific to marketing regulations. We are moving §§ 422.80(c) and 423.50(d), which describe specific guidelines for CMS review of marketing materials and election forms, to §§ 422.2264 and 423.2264, respectively.

D. Deemed Approval (§§ 422.2266, 423.2266)

Consistent with our proposal to create a new subpart V of 42 CFR parts 422 and 423 specific to marketing regulations, we are making an organizational change for this section. We are removing §§ 422.80(d) and 423.50(e) and adding §§ 422.2266 and 423.2266, respectively. The provision concerns CMS' deemed approval of the distribution of marketing materials.

E. Standards for MA and PDP Marketing (§§ 422.2268, 423.2268)

This final rule also incorporates six of the new provisions from the proposed rule and relocates several of the provisions that already existed in §§ 422.80 and 423.50. The remaining provisions from the May 2008 proposed rule will be incorporated into regulations that will be released later this year. There are four provisions of this final rule that differ from the May 16, 2008, proposed rule:

• Sections 422.2268(a) and 423.2268(a) in the proposed rule have been modified by removing the sentence, ''This does not prohibit explanation of any legitimate benefits the beneficiary might obtain as an enrollee of the MA plan, such as eligibility to enroll in a supplemental benefit plan that covers deductibles and coinsurance, or preventive services'' and ''This does not prohibit explanation of any legitimate benefits the beneficiary might obtain as an enrollee of the Part D plan,'' respectively. This was done because each sentence creates ambiguity with respect to the prohibition against cash inducements in the respective first sentence of the provision.

• Sections 422.2268(b) and 423.2268(b) have been redesignated as § 422.2268(p) and 423.2268(p), respectively. This modification separates the prohibition against providing meals to prospective enrollees at promotional and sales activities from the proposed nominal gifts provision. The nominal gifts provision will be addressed in a separate rule that implements the requirement that new MIPPA rules be in place no later than November 15, 2008.

• Sections 422.2268(j) and 423.2268(j) in the proposed rule have been revised in this final rule to be consistent with each other and with § 423.50(f)(v) published in the April 15, 2008, Policy and Technical Changes to the Medicare Prescription Drug Benefit final rule.

• Sections 422.2268(k) and 423.2268(k) in the proposed rule have been revised in this final rule to be consistent with the language in section 103 of MIPPA.

F. Licensing of Marketing Representatives and Confirmation of Marketing (§§ 422.2272, 423.2272)

We are making an organizational change for this section, consistent with our proposal to create a new subpart V of 42 CFR 422 and 423 specific to marketing regulations. We are moving §§ 422.80(e)(2) and 423.50(f)(2), which describe standards of marketing, to §§ 422.2272 and 423.2272, respectively. We are adding §§ 422.2272(c) and 423.2272(c) which require plans to appoint and use only State-licensed representatives to conduct direct marketing activities in accordance with State appointment laws.

G. Employer Group Retiree Marketing (§§ 422.2276, 423.2276)

We are making an organizational change for this section, consistent with our proposal to create a new subpart V of 42 CFR 422 and 423 specific to marketing regulations. We are moving §§ 422.80(f) to § 422.2276 and adding § 423.2276, which describe requirements for employer group retiree marketing.

H. Disclosure of Plan Information (§§ 422.111 and 423.128)

We are finalizing our proposal in our May 16, 2008, proposed rule to specify in §§ 422.111(a)(3) and 423.128(a)(3) that plans must disclose the information specified in §§ 422.111(b) and 423.128(b) of the MA and Part D program regulations, respectively, both at the time of enrollment and at least annually thereafter, 15 days before the annual coordinated election period.

V. Waiver of 30-Day Delay in Effective Date

Section 553(d) of the APA (5 U.S.C. section 553(d)) ordinarily requires a 30-day delay in the effective date of final rules after the date of their publication in the **Federal Register**. This 30-day delay in effective date can be waived, however, if an agency finds for good cause that the delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the finding and its reasons in the rule issued.

In this case, we believe it is in the public interest to implement these provisions upon publication in order to be effective by October 1, 2008, when MA and PDP marketing season begins. Failure to implement these provisions prior to the beginning of the marketing season would hinder CMS's ability to protect its beneficiaries by ensuring that they receive the necessary information to make informed choices during the annual election period. These provisions prevent agents and brokers from engaging in sales and marketing activities that may pressure beneficiaries to make plan choices for reasons other than those that best meet their health care needs. Without this waiver, these provisions would not be effective until January 1, 2009 as specified in MIPPA.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-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 Paperwork Reduction Act of 1995 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.

We solicited public comment on each of these issues for the following sections of this document that contain information collection requirements:

Section 422.2260 Definitions concerning marketing materials.

Section 422.2260 defines the marketing materials that an MA organization must provide to Medicare beneficiaries. While there is burden associated with this requirement, we believe the burden associated with these requirements is exempt from the requirements of the Paperwork Reduction Act of 1995 (PRA) as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

Section 422.2262 Review and distribution of marketing materials.

Section 422.2262(a)(i) states that at least 45 days before the date of distribution the MA organization submits the material or form to CMS for review under guidelines in Section 422.2264 of this Part.

The burden associated with this is the time and effort put forth by the MA organization to submit the material to CMS for review. We estimate it would take one MA organization 720 minutes/12 hours to comply with this requirement. We estimate 670 MA organizations would be affected annually by this requirement; therefore, the total annual burden associated with this requirement is 8,040 hours. The burden for this requirement is approved under OMB#: 0938–0753.

This section also requires the MA organization to certify that in the case of these certain marketing materials designated by CMS, it followed all applicable marketing guidelines or used model language specified by CMS without modification.

The burden associated with this requirement is the time and effort put forth by the MA organization to provide such certification. While there is burden associated with this requirement, we believe the burden associated with these requirements is exempt from the requirements of the Paperwork Reduction Act of 1995 (PRA).

Section 422.2264 Guidelines for CMS review.

Section 422.2264 states that in reviewing marketing material or election forms under § 422.2262 of this Part, CMS determines that the marketing materials (a) provide, in a format (and, where appropriate, print size), and using standard terminology that may be specified by CMS, the following information to Medicare beneficiaries interested in enrolling:

(1) Adequate written description of rules (including any limitations on the providers from whom services can be obtained), procedures, basic benefits and services, and fees and other charges.

(2) Adequate written description of any supplemental benefits and services.

(3) Adequate written explanation of the grievance and appeals process, including differences between the two, and when it is appropriate to use each.

(4) Any other information necessary to enable beneficiaries to make an informed decision about enrollment.

(b) Notify the general Public of its enrollment period in an appropriate manner, through appropriate media, throughout its service and if applicable, continuation areas.

(c) Includes in the written materials notice that the MA organization is authorized by law to refuse to renew its contract with CMS, that CMS also may refuse to renew the contract, and that termination or non-renewal may result in termination of the beneficiary's enrollment in the plan.

(d) Ensure that materials are not materially inaccurate or misleading or otherwise make material misrepresentations.

(e) For markets with a significant non-English speaking population, provide materials in the language of these individuals.

The burden with these guidelines is the time and effort put forth by the MA organization to provide adequate written descriptions of rules, of any supplemental benefits and services, explanation of the grievance and appeals process, and any other information necessary to enable beneficiaries to make an informed decision about enrollment. It also requires the MA organization to notify the general public of its enrollment period in an appropriate manner and include in the written materials notice that the MA organization is authorized by law to refuse to renew its contract with CMS. While there is burden associated with this requirement, we believe the burden associated with these requirements is exempt from the requirements of the Paperwork Reduction Act of 1995 (PRA) as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

Section 422.2272 Licensing of marketing representatives and confirmation of marketing resources.

Section 422.2272(b) states that an MA organization must establish and maintain a system for confirming that enrolled beneficiaries have, in fact, enrolled in the MA plan and understand the rules applicable under the plan.

The burden associated with this requirement is the time and effort put forth by the MA organization to establish and maintain such a system. While there is burden associated with this requirement, we feel the burden associated with these requirements is exempt from the requirements of the Paperwork Reduction Act of 1995 (PRA) as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

Section 422.2276 Employer group retiree marketing.

Section 422.2276 describes the development of marketing materials for employer group retiree marketing. While there is burden associated with this requirement, we believe the burden associated with these requirements is exempt from the requirements of the Paperwork Reduction Act of 1995 (PRA) as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

Section 423.2260 Definitions concerning marketing materials.

Section 423.2260 defines the marketing materials that a Part D Sponsor must provide to Medicare beneficiaries. While there is burden associated with this requirement, we believe the burden associated with these requirements is exempt from the requirements of the Paperwork Reduction Act of 1995 (PRA) as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

Section 423.2262 Review and distribution of marketing materials.

Section 423.2262(a)(1)(i) requires the Part D sponsor to submit the marketing material or form to CMS for review under the guidelines in § 423.2264.

The burden associated with these requirements is the time and effort put forth by the Part D sponsor to submit the marketing materials to CMS and to provide certification. We estimate it would take one Part D sponsor (720 minutes/12 hours) to comply with this requirement. We estimate 87 Part D sponsors would be affected annually by this requirement; therefore, the total annual burden associated with this requirement is 1044 hours. The burden for this requirement is approved under OMB#: 0938–0964.

Section 423.2264 Guidelines for CMS review.

Section 423.2264 reads that in reviewing marketing material or enrollment forms under § 423.2262, CMS determines (unless otherwise specified in additional guidance) that the marketing materials (a) provide, in a format (and, where appropriate, print size), and using standard terminology that may be specified by CMS, the following information to Medicare beneficiaries interested in enrolling:

(1) Adequate written description of rules (including any limitations on the providers from whom services can be obtained), procedures, basic benefits and services, and fees and other charges.

(2) Adequate written explanation of the grievance and appeals process, including differences between the two, and when it is appropriate to use each.

(3) Any other information necessary to enable beneficiaries to make an informed decision about enrollment.

(b) Notify the general public of its enrollment period in an appropriate manner, through appropriate media, throughout its service area.

(c) Include in the written materials notice that the Part D plan is authorized by law to refuse to renew its contract with CMS, that CMS also may refuse to renew the contract, and that termination or non-renewal may result in termination of the beneficiary's enrollment in the Part D plan. In addition, the Part D plan may reduce its service area and no longer be offered in the area where a beneficiary resides.

(d) Ensure that materials are not materially inaccurate or misleading or otherwise make material misrepresentations.

(e) For markets with a significant non-English speaking population, provide materials in the language of these individuals.

The burden with these guidelines is the time and effort put forth by the Part D plan to provide adequate written descriptions of rules, of the grievance and appeals process, and any other information necessary to enable beneficiaries to make an informed decision about enrollment. It also requires the Part D plan to notify the general public of its enrollment period in an appropriate manner and include in the written materials notice that the Part D plan is authorized by law to refuse to renew its contract with CMS. While there is burden associated with this requirement, we believe the burden associated with these requirements is exempt from the requirements of the Paperwork Reduction Act of 1995 (PRA) as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

Section 423.2272 Licensing of marketing representatives and confirmation of marketing resources.

Section 423.2272(b) requires the Part D organization to establish and maintain a system for confirming that enrolled beneficiaries have in fact enrolled in the PDP and understand the rules applicable under the plan.

The burden associated with this requirement is the time and effort put forth by the Part D sponsor to establish and maintain such a system. While there is burden associated with this requirement, we believe the burden associated with these requirements is exempt from the requirements of the Paperwork Reduction Act of 1995 (PRA) as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

Section 423.2276 Employer group retiree marketing.

Section 423.2276 describes the development of marketing materials for employer group retiree marketing. While there is burden associated with this requirement, we believe the burden associated with these requirements is exempt from the requirements of the Paperwork Reduction Act of 1995 (PRA) as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

As reflected in the table that follows, the aggregate burden associated with the collection of information section of this final rule totals 9,084 hours.

OMB No.	Requirements	Number of respondents	Burden hours	Total annual burden (hours)
Exempt/None	422.2260	N/A	N/A	N/A
0938–0753	422.2262(a)(i)	670	12	8,040
0938–0753	422.2264	N/A	N/A	N/A
0938–0753	422.2272(b)	N/A	N/A	N/A
Exempt/None	423.2260	N/A	N/A	N/A
0938–0964	423.2262(a)(1)(i)	87	12	1,044
0938–0964	423.2264	N/A	N/A	N/A
0938–0964	423.2272(b)	N/A	N/A	N/A
Total Aggregate Burden				9,084

We have submitted a copy of this final rule to OMB for its review of the information collection requirements described above.

VII. 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), Executive Order 13132 on Federalism, and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 (as amended) 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). The provisions of this final rule require plans to submit marketing materials to CMS for review. We estimate the total cost (MA and Part D programs) of these provisions as $197,295. As a result, this final rule does not reach this economic threshold and thus is not considered a major rule.

We use the figure of $14.68 (based on the United States Department of Labor (DOL) (*http://www.bls.gov/oes2006.htm*) 2006 BLS occupational employment statistics for the hourly wages of word processors and typists) plus the added OMB figures of 12 percent for overhead and 36 percent for benefits to represent average costs to plans, sponsors and downstream entities. (Note that the wages cited below include the hourly wage + an additional 48 percent to reflect overhead, benefit costs for total wages of $21.73). The costs for these provisions, in the context of each program, are as follows:

- Submission of marketing materials, MA program ($21.73 × 8,040 hours = $174,709).
- Submission of marketing materials, Part D program ($21.73 × 1,044 hours = $22,686).

The RFA requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. 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 $6.5 million to $31.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. MA organizations and Part D sponsors, the only entities that will be affected by the final provisions, are not generally considered small business entities. Since they must follow minimum enrollment requirements (5,000 enrollees in urban areas and 1,500 enrollees in non-urban areas), the revenue generated from enrollment generally exceeds the revenue threshold required for analysis. While a very small rural plan could fall below the threshold, we do not believe that there are more than a handful of such plans.

A fraction of MA organizations and sponsors are considered small businesses because of their non-profit status. For an RFA analysis to be required, 3–5 percent of the identified small entities' revenue would have to be impacted by the final provisions. We do not believe that any of these provisions meet this threshold. Many of the provisions, discussed in section II, Analysis of and Response to Public Comments, are clarifications of existing policy or require minimal costs. Therefore, because the rule will not have a significant economic impact on a substantial number of small entities, we are not preparing an analysis for the RFA.

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 by State, local or tribal governments, in the aggregate, or by the private sector of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $130 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. This rule will not have a substantial direct effect on State or local governments, preempt States, or otherwise have a Federalism implication.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, 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 B—Eligibility, Election, and Enrollment

§ 422.80 [Removed]

■ 2. Remove § 422.80.

Subpart C—Benefits and Beneficiary Protections

■ 3. Amend § 422.111 by revising paragraph (a)(3) to read as follows:

§ 422.111 Disclosure requirements

* * * * *

(a) * * *

(3) At the time of enrollment and at least annually thereafter, 15 days before the annual coordinated election period.

* * * * *

■ 4. New subpart V is added to read as follows:

Subpart V—Medicare Advantage Marketing Requirements

Sec.

422.2260 Definitions concerning marketing materials.
422.2262 Review and distribution of marketing materials.
422.2264 Guidelines for CMS review.
422.2266 Deemed approval.
422.2268 Standards for MA organization marketing.
422.2272 Licensing of marketing representatives and confirmation of marketing resources.
422.2274 [Reserved]
422.2276 Employer group retiree marketing.

Subpart V—Medicare Advantage Marketing Requirements

§ 422.2260 Definitions concerning marketing materials.

As used in this subpart—

Marketing materials. Marketing materials include any informational materials targeted to Medicare beneficiaries which:

(1) Promote the MA organization, or any MA plan offered by the MA organization.

(2) Inform Medicare beneficiaries that they may enroll, or remain enrolled in, an MA plan offered by the MA organization.

(3) Explain the benefits of enrollment in an MA plan, or rules that apply to enrollees.

(4) Explain how Medicare services are covered under an MA plan, including conditions that apply to such coverage.

(5) May include, but are not limited to, the following:

(i) General audience materials such as general circulation brochures, newspapers, magazines, television, radio, billboards, yellow pages, or the Internet.

(ii) Marketing representative materials such as scripts or outlines for telemarketing or other presentations.

(iii) Presentation materials such as slides and charts.

(iv) Promotional materials such as brochures or leaflets, including materials for circulation by third parties (for example, physicians or other providers).

(v) Membership communication materials such as membership rules, subscriber agreements, member handbooks and wallet card instructions to enrollees.

(vi) Letters to members about contractual changes; changes in providers, premiums, benefits, plan procedures etc.

(vii) Membership or claims processing activities (for example, materials on rules involving non-payment of premiums, confirmation of enrollment or disenrollment, or annual notification information).

§ 422.2262 Review and distribution of marketing materials.

(a) *CMS review of marketing materials.* (1) Except as provided in paragraph (b) of this section, an MA organization may not distribute any marketing materials (as defined in § 422.2260 of this part), or election forms, or make such materials or forms available to individuals eligible to elect an MA organization unless—

(i) At least 45 days (or 10 days if using marketing materials that use, without modification, proposed model language as specified by CMS) before the date of distribution the MA organization has submitted the material or form to CMS for review under the guidelines in § 422.2264 of this Part; and

(ii) CMS does not disapprove the distribution of new material or form.

(2) [Reserved]

(b) *File and use.* The MA organization may distribute certain types of marketing materials, designated by CMS, 5 days following their submission to CMS if the MA organization certifies that in the case of these designated marketing materials, it followed all applicable marketing guidelines and, when applicable, used model language specified by CMS without modification.

§ 422.2264 Guidelines for CMS review.

In reviewing marketing material or election forms under § 422.2262 of this part, CMS determines that the marketing materials—

(a) Provide, in a format (and, where appropriate, print size), and using standard terminology that may be specified by CMS, the following information to Medicare beneficiaries interested in enrolling:

(1) Adequate written description of rules (including any limitations on the providers from whom services can be obtained), procedures, basic benefits and services, and fees and other charges;

(2) Adequate written description of any supplemental benefits and services;

(3) Adequate written explanation of the grievance and appeals process, including differences between the two, and when it is appropriate to use each; and

(4) Any other information necessary to enable beneficiaries to make an informed decision about enrollment.

(b) Notify the general public of its enrollment period in an appropriate manner, through appropriate media, throughout its service area and if applicable, continuation areas.

(c) Include in written materials notice that the MA organization is authorized by law to refuse to renew its contract with CMS, that CMS also may refuse to renew the contract, and that termination or non-renewal may result in termination of the beneficiary's enrollment in the plan.

(d) Ensure that materials are not materially inaccurate or misleading or otherwise make material misrepresentations.

(e) For markets with a significant non-English speaking population, provide materials in the language of these individuals.

§ 422.2266 Deemed approval.

If CMS has not disapproved the distribution of marketing materials or forms submitted by an MA organization with respect to an MA plan in an area, CMS is deemed not to have disapproved the distribution in all other areas covered by the MA plan and organization except with regard to any portion of the material or form that is specific to the particular area.

§ 422.2268 Standards for MA organization marketing.

In conducting marketing activities, MA organizations may not—

(a) Provide cash or other monetary rebates as an inducement for enrollment or otherwise.

(b) [Reserved]

(c) Engage in any discriminatory activity such as, for example, attempts to recruit Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas.

(d) Solicit door-to-door for Medicare beneficiaries or through other unsolicited means of direct contact, including calling a beneficiary without the beneficiary initiating the contact.

(e) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the MA organization. The MA organization may not claim it is recommended or endorsed by CMS or Medicare or that CMS or Medicare recommends that the beneficiary enroll in the MA plan. It may, however, explain that the organization is approved for participation in Medicare.

(f) Market non-health care related products to prospective enrollees during any MA or Part D sales activity or presentation. This is considered cross-selling and is prohibited.

(g) [Reserved]

(h) [Reserved]

(i) Distribute marketing materials for which, before expiration of the 45-day period, the MA organization receives from CMS written notice of disapproval because it is inaccurate or misleading, or misrepresents the MA organization, its marketing representatives, or CMS.

(j) Use providers or provider groups to distribute printed information comparing the benefits of different health plans unless the providers, provider groups, or pharmacies accept and display materials from all health plans with which the providers, provider groups, or pharmacies contract. The use of publicly available comparison information is permitted if approved by CMS in accordance with the Medicare marketing guidance.

(k) Conduct sales presentations or distribute and accept MA plan

enrollment forms in provider offices or other areas where health care is delivered to individuals, except in the case where such activities are conducted in common areas in health care settings.

(l) Conduct sales presentations or distribute and accept plan applications at educational events.

(m) Employ MA plan names that suggest that a plan is not available to all Medicare beneficiaries. This prohibition shall not apply to MA plan names in effect on July 31, 2000.

(n) [Reserved]

(o) Engage in any other marketing activity prohibited by CMS in its marketing guidance.

(p) Provide meals for potential enrollees, which is prohibited, regardless of value.

(q) [Reserved]

§ 422.2272 Licensing of marketing representatives and confirmation of marketing resources.

In its marketing, the MA organization must:

(a) Demonstrate to CMS' satisfaction that marketing resources are allocated to marketing to the disabled Medicare population as well as beneficiaries age 65 and over.

(b) Establish and maintain a system for confirming that enrolled beneficiaries have, in fact, enrolled in the MA plan, and understand the rules applicable under the plan.

(c) Employ as marketing representatives only individuals who are licensed by the State to conduct marketing activities (as defined in the Medicare Marketing Guidelines) in that State, and whom the organization has informed that State it has appointed, consistent with the appointment process provided for under State law.

§ 422.2274 [Reserved]

§ 422.2276 Employer group retiree marketing.

MA organizations may develop marketing materials designed for members of an employer group who are eligible for employer-sponsored benefits through the MA organization, and furnish these materials only to the group members. These materials are not subject to CMS prior review and approval.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 5. 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 B—Eligibility, Election, and Enrollment

§ 423.50 [Removed]

■ 6. Remove § 423.50.

Subpart C—Benefits and Beneficiary Protections

■ 7. Amend § 423.128 by revising paragraph (a)(3) to read as follows:

§ 423.128 Dissemination of Part D Plan Information.

(a) * * *

(3) At the time of enrollment and at least annually thereafter, 15 days before the annual coordinated election period.

■ 8. Add new subpart V to read as follows:

Subpart V—Part D Marketing Requirements

Sec.
423.2260 Definitions concerning marketing materials.
423.2262 Review and distribution of marketing materials.
423.2264 Guidelines for CMS review.
423.2266 Deemed approval.
423.2268 Standards for Part D marketing.
423.2272 Licensing of marketing representatives and confirmation of marketing resources.
423.2274 [Reserved]
423.2276 Employer group retiree marketing.

Subpart V—Part D Marketing Requirements

§ 423.2260 Definitions concerning marketing materials.

As used in this subpart—

Marketing Materials. Marketing Materials include any informational materials targeted to Medicare beneficiaries which—

(1) Promote the Part D plan.

(2) Inform Medicare beneficiaries that they may enroll, or remain enrolled in a Part D plan.

(3) Explain the benefits of enrollment in a Part D plan, or rules that apply to enrollees.

(4) Explain how Medicare services are covered under a Part D plan, including conditions that apply to such coverage.

(5) May include, but are not limited to—

(i) General audience materials such as general circulation brochures, newspapers, magazines, television, radio, billboards, yellow pages, or the Internet.

(ii) Marketing representative materials such as scripts or outlines for telemarketing or other presentations.

(iii) Presentation materials such as slides and charts.

(iv) Promotional materials such as brochures or leaflets, including materials for circulation by third parties (for example, physicians or other providers).

(v) Membership communication materials such as membership rules, subscriber agreements, member handbooks and wallet card instructions to enrollees.

(vi) Letters to members about contractual changes; changes in providers, premiums, benefits, plan procedures etc.

(vii) Membership or claims processing activities.

§ 423.2262 Review and distribution of marketing materials.

(a) *CMS review of marketing materials.* (1) Except as provided in paragraph (a)(2) of this section, a Part D plan may not distribute any marketing materials (as defined in § 423.2260 of this Part), or enrollment forms, or make such materials or forms available to Part D eligible individuals unless—

(i) At least 45 days (or 10 days if using certain types of marketing materials that use, without modification, proposed model language as specified by CMS) before the date of distribution, the Part D sponsor submits the material or form to CMS for review under the guidelines in § 423.2264; and

(ii) CMS does not disapprove the distribution of new material or form.

(2) [Reserved]

(b) *File and use.* The Part D sponsor may distribute certain types of marketing material, designated by CMS, 5 days following their submission to CMS if the Part D sponsor certifies that in the case of these marketing materials, it followed all applicable marketing guidelines and, when applicable, used model language specified by CMS without modification.

§ 423.2264 Guidelines for CMS review.

In reviewing marketing material or enrollment forms under § 423.2262, CMS determines (unless otherwise specified in additional guidance) that the marketing materials—

(a) Provide, in a format (and, where appropriate, print size), and using standard terminology that may be specified by CMS, the following information to Medicare beneficiaries interested in enrolling:

(1) Adequate written description of rules (including any limitations on the providers from whom services can be obtained), procedures, basic benefits and services, and fees and other charges;

(2) Adequate written explanation of the grievance and appeals process, including differences between the two, and when it is appropriate to use each; and

(3) Any other information necessary to enable beneficiaries to make an informed decision about enrollment.

(b) Notify the general public of its enrollment period in an appropriate manner, through appropriate media, throughout its service area.

(c) Include in the written materials notice that the Part D plan is authorized by law to refuse to renew its contract with CMS, that CMS also may refuse to renew the contract, and that termination or non-renewal may result in termination of the beneficiary's enrollment in the Part D plan. In addition, the Part D plan may reduce its service area and no longer be offered in the area where a beneficiary resides.

(d) Ensure that materials are not materially inaccurate or misleading or otherwise make material misrepresentations.

(e) For markets with a significant non-English speaking population, provide materials in the language of these individuals.

§ 423.2266 Deemed approval.

If CMS has not disapproved the distribution of marketing materials or forms submitted by a Part D sponsor for a Part D plan in a Part D region, CMS is deemed to not have disapproved the distribution of the marketing material or form in all other Part D regions covered by the Part D plan, with the exception of any portion of the material or form that is specific to the Part D region.

§ 423.2268 Standards for Part D marketing.

In conducting marketing activities, a Part D plan may not—

(a) Provide cash or other remuneration as an inducement for enrollment or otherwise.

(b) [Reserved]

(c) Engage in any discriminatory activity such as, for example, attempts to recruit Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas.

(d) Solicit door-to-door for Medicare beneficiaries or through other unsolicited means of direct contact, including calling a beneficiary without the beneficiary initiating the contact.

(e) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the Part D sponsor or its Part D plan. The Part D organization may not claim that it is recommended or endorsed by CMS or Medicare or that CMS or Medicare recommends that the beneficiary enroll in the Part D plan. The Part D organization may explain that the organization is approved for participation in Medicare.

(f) Market non-health care related products to prospective enrollees during any MA or Part D sales activity or presentation. This is considered cross-selling and is prohibited.

(g) [Reserved]

(h) [Reserved]

(i) Distribute marketing materials for which, before expiration of the 45-day period, the PDP Sponsor receives from CMS written notice of disapproval because it is inaccurate or misleading, or misrepresents the PDP Sponsor, its marketing representatives, or CMS.

(j) Use providers, provider groups, or pharmacies to distribute printed information for beneficiaries to use when comparing the benefits of different Part D plans unless providers, provider groups or pharmacies accept and display materials from all Part D plan sponsors with which the providers, provider groups or pharmacies contract. The use of publicly available comparison information is permitted if approved by CMS in accordance with the Medicare marketing guidelines.

(k) Conduct sales presentations or distribute and accept Part D plan enrollment forms in provider offices, pharmacies or other areas where health care is delivered to individuals, except in the case where such activities are conducted in common areas in health care settings.

(l) Conduct sales presentations or distribute and accept plan applications at educational events.

(m) Employ Part D plan names that suggest that a plan is not available to all Medicare beneficiaries.

(n) [Reserved]

(o) Engage in any other marketing activity prohibited by CMS in its marketing guidance.

(p) Provide meals for potential enrollees, which are prohibited, regardless of value.

(q) [Reserved]

§ 423.2272 Licensing of marketing representatives and confirmation of marketing resources.

In its marketing, the Part D organization must—

(a) Demonstrate to CMS's satisfaction that marketing resources are allocated to marketing to the disabled Medicare population as well as beneficiaries age 65 and over.

(b) Establish and maintain a system for confirming that enrolled beneficiaries have in fact enrolled in the PDP and understand the rules applicable under the plan.

(c) Employ as marketing representatives only individuals who are licensed by the State to conduct direct marketing activities (as defined in the Medicare Marketing Guidelines) in that State, and whom the sponsor has informed that State it has appointed, consistent with the appointment process provided for under State law.

§ 423.2274 [Reserved]

§ 423.2276 Employer group retiree marketing.

Part D sponsors may develop marketing materials designed for members of an employer group who are eligible for employer-sponsored benefits through the Part D sponsor, and furnish these materials only to the group members. These materials are not subject to CMS prior review and approval.

Authority: (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: August 19, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: August 27, 2008.

Michael O. Leavitt,

Secretary.

[FR Doc. E8–21674 Filed 9–15–08; 9:00 am]

BILLING CODE 4120–01–P

Federal Register

Thursday,
September 18, 2008

Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 417, 422 and 423

Medicare Program; Revisions to the Medicare Advantage and Prescription Drug Benefit Programs; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 417, 422 and 423

[CMS 4138–IFC]

RIN 0938–AP52

Medicare Program; Revisions to the Medicare Advantage and Prescription Drug Benefit Programs

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period (IFC) revises the regulations governing the Medicare Advantage (MA) program (Part C), prescription drug benefit program (Part D) and section 1876 cost plans. This IFC makes conforming changes to the MA regulations to reflect new statutory requirements regarding special needs plans (SNP), private-fee-for-service plans (PFFS), regional preferred provider organizations (RPPO) plans, Medicare medical savings accounts (MSA) plans, and new statutory provisions governing cost-sharing for dual-eligible enrollees in the MA program prescription drug pricing, coverage, and payment processes in the Part D program. In addition, this IFC sets forth new requirements governing the marketing of Part C and Part D plans which by statute must be in place at a date specified by the Secretary, but no later than November 15, 2008. Both the conforming changes to the regulations to reflect new statutory provisions and the new marketing requirements are based on provisions in the Medicare Improvements for Patients and Providers Act (MIPPA), which became law on July 15, 2008.

DATES: *Effective Date:* September 18, 2008.

Comment Date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on November 17, 2008.

ADDRESSES: In commenting, please refer to file code CMS–4138–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' and enter the filecode to find the document accepting comments.

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–4138–IFC, P.O. Box 8016, Baltimore, MD 21244–8016.

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–4138–IFC, 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 either of the following addresses:

a. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201;

(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.)

b. 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the ''Collection of Information Requirements'' section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Private-Fee-For-Service Plans—Sabrina Ahmed, 410–786–7499.

Special Needs Plans—LaVern Baty, 410–786–5480.

Cost Plans—Chris McClintick, 410–786–4682.

Medicare Medical Savings Account Plans—Anne Manley, 410–786–1096.

Enrollment—Lynn Orlosky, 410–786–9064.

Payment—Frank Szeflinski, 303–844–7119.

Marketing—Camille Brown, 410–786–0274, or Chevell Thomas, 410–786–1387.

Contract provision relating to Part D drug benefit—Vanessa Duran, 410–786–8697, or Deborah Larwood, 410–786–9500.

Low-income subsidy and late enrollment penalties—Deondra Moseley, (410) 786–4577 or Meghan Elrington, (410) 786–8675.

SUPPLEMENTARY INFORMATION:

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://regulations.gov. Follow the search instructions* on that Web site to view public comments.

Comments received timely will be also 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.

I. Background

A. Overview of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) was enacted on December 8, 2003. The MMA established the Medicare prescription drug benefit program (Part D) and made revisions to the provisions in Medicare Part C, governing what is now called the Medicare Advantage (MA) program (formerly Medicare+Choice). The MMA directed that important aspects of the new Medicare prescription drug benefit program under Part D be similar to and coordinated with regulations for the MA program.

The MMA also directed implementation of the prescription drug benefit and revised MA program provisions by January 1, 2006. The final rules for the MA and Part D prescription drug programs appeared in the **Federal Register** on January 28, 2005 (70 FR 4588 and 70 FR 4194, respectively). Many of the provisions relating to applications, marketing, contracts, and the new bidding process, for the MA program, became effective on March 22, 2005, 60 days after publication of the rule, so that the requirements for both programs could be implemented by January 1, 2006. All of the provisions regarding the new Part D prescription drug program became effective on March 22, 2005.

As we gained more experience with the MA program and the prescription drug benefit program, we proposed to revise areas of both programs and issued a proposed rule on May 16, 2008 (73 FR 28556) that would have clarified existing policies or codified current guidance for both programs. Several of these proposed regulatory revisions have been overtaken by statutory provisions enacted in the Medicare Improvements for Patients and Providers Act (MIPPA) (Pub. L. 110–275), enacted on July 15, 2008. These MIPPA provisions directly address in statute several issues we proposed to address through rulemaking, and thus supersedes our rulemaking in these areas. Comments on our proposals in these areas thus are no longer relevant, as we have no authority to depart from the statutory requirements Congress has enacted (these requirements largely track the regulatory proposals in the May 16 proposed rule). Because the law has changed in these areas, however, conforming changes must be made to the relevant sections of the Code of Federal Regulations in order for the regulations to accurately reflect the new state of the law under MIPPA. This interim final rule with comment period (IFC) makes these changes.

MIPPA also called upon the Secretary to revise the marketing requirements for Part C and Part D plans in several areas specified in MIPPA. With the exceptions noted in this interim final rule, these new rules are to take effect at a date specified by the Secretary, but no later than November 15, 2008. This IFC contains provisions that implement these latter MIPPA requirements. Some provisions in our May 16 proposed rule addressed issues in areas in which MIPAA required that we establish marketing limits no later than November 15th. As a result, to the extent our policies were informed by these comments, we will address them in our discussion of the marketing provisions we have developed in implementing these provisions of MIPPA. In addition we will publish in the near future, a separate final rule responding to public comments on those provisions of the May 16, 2008 proposed rule that were not addressed in MIPPA. Because MIPPA and the May 16, 2008 proposed rule often specified requirements in the same general areas, we are publishing separate regulations in order to clearly distinguish between provisions which are statutory and those provisions which we proposed to promulgate through rulemaking and will be finalizing based on public notice and comment.

B. Relevant Legislative History and Overview

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) established a new ''Part C'' in the Medicare statute (sections 1851 through 1859 of the Social Security Act (the Act)) which provided for a Medicare+Choice (M+C) program. Under section 1851(a)(1) of the Act, every individual entitled to Medicare Part A and enrolled under Medicare Part B, except for most 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 he or she lived.

The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA), Public Law 106–111, 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.

As noted above, the MMA was enacted on December 8, 2003. Title I of the MMA added a new ''Part D'' to the Medicare statute (sections 1860D–1 through 1860D–42) creating the Medicare Prescription Drug Benefit Program, the most significant 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 Part C program. Title II of the MMA renamed the M+C program the MA program and included new payment and bidding provisions, new regional MA plans and special needs plans, reestablished authority for medical savings account (MSA) plans that had been provided in the BBA on a temporary basis, and made other changes. Title I of the MMA created prescription drug benefits under Medicare Part D, and a new retiree drug subsidy program.

Both the MA and prescription drug benefit regulations were published separately, as proposed and final rules, though their development and publication were closely coordinated. On August 3, 2004, we published in the **Federal Register** proposed rules for the MA program (69 FR 46866) and the prescription drug benefit program (69 FR 46632). In response to public comments on the proposed rules, we made several revisions to the proposed policies for both programs. For further discussion of these revisions, see the respective final rules (70 FR 4588) and (70 FR 4194).

On July 15, 2008, the Medicare Improvements for Patients and Providers Act became law, leading to the revisions to the MA and Part D prescription drug benefit programs discussed in Section II, Provisions of the Interim Final Rule.

II. Provisions of the Interim Final Rule

In the sections that follow, we discuss the revisions made in this IFC to final provisions to the regulations in 42 CFR 417, 422 and 423 governing, respectively, section 1876 cost plans, and the MA and prescription drug benefit programs. Several of the final provisions affect both the MA and Part D programs. In our discussion, we note when a provision affects both the MA and prescription drug benefit and include in section II C, a table comparing the proposed Part C and Part D program changes by specifying each issue and the sections of the Code of Federal Regulations that we are revising for both programs.

A. Changes to the Regulations in Part 422—Medicare Advantage Program

1. Special Needs Plans

The Congress first authorized special needs plans (SNP) to exclusively or disproportionately serve individuals with special needs. The three types of special needs individuals eligible for enrollment identified by the Congress include (1) institutionalized individuals (defined in § 422.2 as an individual residing or expecting to reside for 90 days or longer in a long term care facility), (2) individuals entitled to medical assistance under a State plan under title XIX, and (3) other individuals with severe or disabling chronic conditions that would benefit from enrollment in a SNP.

The number of SNPs approved as of January 2008, is 787. This figure includes 442 dual-eligible SNPs, 256

chronic care SNPs, and 89 institutional SNPs.

a. Model of Care (§ 422.101(f))

Section 164 of MIPPA adds care management requirements for all SNPs effective January 1, 2010, as set forth in section 1859(f)(5) of the Act (42 U.S.C. 1395w–28(f)). The new mandate requires dual-eligible, institutional, and chronic condition SNPs to implement care management requirements having two explicit components. While our revisions specifically reflect the MIPPA provisions, it should be noted that in our May 16, 2008 proposed rule, we proposed other, related provisions which we will finalize, based on public notice and comments, in a final rule to be published soon after this IFC.

The first component is an evidence-based model of care with an appropriate network of providers and specialists to meet the specialized needs of the SNP target population. We do not endorse any particular set of evidence-based guidelines or protocols but expect that SNPs will develop such guidelines and protocols through sources such as the Agency for Healthcare Research and Quality (*http://www.ahrq.gov/*). The AHRQ does not endorse any particular set of evidence-based guidelines or protocols but its Web site includes access to nationally-recognized evidence-based practices. The second component is a battery of care management services that includes (1) a comprehensive initial assessment and annual reassessments of the individual's physical, psychosocial, and functional needs, (2) an individualized plan of care having goals and measurable outcomes, including specific services and benefits to be provided, and (3) an interdisciplinary team to manage care. In addition, MIPPA mandates the periodic audit of SNPs to ensure that plans meet the model of care requirements.

In this IFC, we are revising § 422.101(f), effective January 1, 2010, to reflect the new MIPPA provisions requiring a SNP model of care. Specifically, we are revising the regulation to reflect the statutory components described in the preceding paragraph. We also issued guidance on the SNP model of care in our 2008 and 2009 Call Letters. Care coordination and a provider network comprised of clinical experts pertinent to the target population have been the cornerstones of the SNP model of care.

We expect that MA organizations having the commitment and resources to serve vulnerable special needs beneficiaries through SNPs will perpetually evaluate their own model of care by collecting and analyzing performance data to continually improve their model of care. Through the analysis of SNP performance data and monitoring visits, the review of scientific research on the efficacy of other care models, and feedback from beneficiaries, advocacy groups, and healthcare professionals, we will continue to evaluate models of care. As we look longitudinally at evidence-based advancements in care coordination, we will also issue guidance through our Call Letters and informational memoranda to share innovations and facilitate improvement in the SNP model of care framework.

b. Dual-Eligible SNPs and Contracts With States (§ 422.107)

In the May 16, 2008 proposed rule, we proposed in new section § 422.107 to require, effective January 1, 2010, that MA organizations offering a dual-eligible SNP have a documented relationship with the State Medicaid agency, and that the arrangements, at a minimum, include a means to (1) verify enrollees' eligibility for both Medicare and Medicaid, (2) identify and share information on Medicaid provider participation, and (3) identify Medicaid benefits which are not covered by Medicare.

CMS' proposed § 422.107, which sought to require a documented relationship between MA organizations and State Medicaid agencies for dual-eligible SNPs, has been superseded by Section 164 of MIPPA. Section 164 of MIPPA adds new requirements to section 1859(f) of the Act for dual-eligible SNPs. Beginning on January 1, 2010, MA organizations offering new dual-eligible SNPs must have a contract with the State Medicaid agency to provide benefits, or arrange for benefits to be provided, for individuals entitled to receive medical assistance under title XIX. In order to implement the MIPPA requirement for a contract, we are specifying in this IFC that the contract with the state Medicaid agency include the category(ies) of eligibility covered under the SNP, the service area covered under the SNP, and the contract period for the SNP. We also specify that MA organizations with existing dual-eligible SNPs may continue to operate through 2010 without a State contract provided they meet all other statutory requirements, that is, care management and quality improvement program requirements. It should also be noted that under MIPPA, States are not required to enter into written contracts with plans, and plans that do not establish contracts with States in 2010 cannot expand their service areas.

We are incorporating the above MIPPA requirements in a revised version of our proposed § 422.107, with an effective date of January 1, 2010.

c. SNPs and Quality Improvement Program (§ 422.152)

Section 164 of MIPPA adds a new clause (ii) to section 1852(e)(3)(A) of the Act and a new paragraph (6) to section 1857(d) of the Act. Section 1852(e)(3)(A)(ii) of the Act now mandates that, beginning on a date specified by the Secretary (but in no case later than January 1, 2010), data collected, analyzed, and reported as part of the plan's quality improvement program must measure health outcomes and other indices of quality at the plan level with respect to the model of care as required in section 1859(f)(2–5). As a Medicare Advantage plan, each SNP must implement a documented quality improvement program for which all information is available for submission to CMS or for review during monitoring visits. The focus of the SNP quality improvement program should be the monitoring and evaluation of the performance of its model of care (see § 422.101(f)). The program should be executed as a three-tier system of performance improvement. The first tier consists of data on quality and outcomes that is collected and analyzed to enable beneficiaries to compare and select from among health coverage options. In calendar year (CY) 2008, CMS required the submission of thirteen HEDIS measures and three structure and process measures to pilot the development of comparative measures to facilitate beneficiary choice. We continue to work on this initiative and will issue guidance to SNPs on collecting comparative measures for submission using CMS required tools in CY 2009.

The second tier of the quality improvement program for SNPs, effective January 1, 2010 replaces the requirements in § 422.152(b) with requirements in a new § 422.152(g) that reflects the new statutory requirement that SNPs collect, analyze, and report data that measures the performance of their plan-specific model of care (section 1852(e)(3)(A)(ii) of the Act). This new rule establishes CMS requirements for measuring essential components of the model of care using a variety of plan-determined methodologies such as claims data, record reviews, administrative data, clinical outcomes, and other existing valid and reliable measures (ACOVE, MDS, HEDIS, CAHPS, HOS, OASIS, etc.) at the plan level to evaluate the effectiveness of the process of care and

clinical outcomes. Specifically, each SNP should collect, analyze, and be prepared to report data for its performance on: Access to care; improvement in beneficiary health status; care management through its staffing structure and processes; assessment and stratification of health risk; care management through an individualized plan of care; provision of specialized clinical expertise targeting its special needs population; the coordination and delivery of services and benefits through transitions across settings and providers; the coordination and delivery of extra services and benefits that meet the needs of the most vulnerable beneficiaries; the use of evidence-based practices and/or nationally recognized clinical protocols; and the application of integrated systems of communication. Each SNP must coordinate the systematic collection of data using indicators that are objective, clearly defined, and based on measures having established validity and reliability. Indicators should be selected from a variety of quality and outcome measurement domains such as functional status, care transitioning, disease management, behavioral health, medication management, personal and environmental safety, beneficiary involvement and satisfaction, and family and caregiver support. SNPs must document all aspects of the quality improvement program including data collection and analysis, actions taken to improve the performance of the model of care, and the participation of the interdisciplinary team members and network providers in quality improvement activities.

We are developing the third tier of the quality improvement program which is the required reporting of monitoring data. The monitoring data will consist of a prescribed sample of data that SNPs will already be collecting in tier two to measure the performance of their model of care. We will draw from a pool of measures across several service delivery domains, and, whenever possible, use valid measures that SNPs have reported they currently collect. We are also soliciting comments from the public regarding the types of monitoring data that we should require SNPs to submit. We will issue guidance on the requirement to report monitoring data and the collection methodology after reviewing the public comments and completing development of the initiative for implementation in calendar year 2010.

Section 1857(d)(6) stipulates that CMS will conduct reviews of the SNP model of care in conjunction with the periodic audits of the MA organizations. As of January 1, 2010, these reviews will focus on how the SNPs have operationalized their models of care and how their quality improvement programs have affected their care management as structured by the model of care.

d. Special Needs Plans and Other MA Plans With Dual-Eligibles: Responsibility for Cost-Sharing (§ 422.504(g)(1))

Section 165 of MIPPA, which revised section 1852(a) of the Act, provides that for those persons who are full benefit dual-eligible individuals or a qualified Medicare beneficiary enrolled in a dual-eligible special needs plan, as described in section 1859(b)(6)(B)(ii) of the Act, the plan may not impose cost-sharing that exceeds the amount of cost-sharing that would be permitted if the individual were under title XIX and were not enrolled in a special needs plan. The effective date of this provision is January 1, 2010. In order to reflect this provision, we are updating our regulations by updating part 42 by adding new paragraph (g)(1)(iii) to § 422.504(g).

Additionally, section 164 of MIPPA requires that the plan provide each prospective enrollee, prior to enrollment, a comprehensive written statement, describing the benefits and cost-sharing protections for which the individual would be entitled under title XIX as well as the MA plan.

We are reflecting these statutory requirements in the regulations at § 422.504(g)(1), effective January 1, 2010.

While our revisions specifically reflect the MIPPA provisions, it should be noted that in our May 16, 2008 proposed rule, we proposed other, related provisions which we will finalize, based on public notice and comments, in a final rule to be published soon after this IFC.

2. Revisions to Requirements for MA PFFS Plans (§ 422.114)

Section 162 of MIPPA revised the requirements for PFFS plans in a number of significant ways that will affect how employer and non-employer PFFS plans can meet access requirements. Below we describe each of the changes to PFFS plans as a result of MIPPA.

Note: See also section A.3., Revision to Quality Improvement Programs, for discussion of new requirements related to PFFS plans and quality improvement features.

a. Changes in Access Requirements for PFFS Plans

Section 162(a)(3) of MIPPA amended section 1852(d)(4)(B) of the Act to require, effective January 1, 2010, that PFFS plans meeting access standards based on signed contracts meet access standards with respect to a particular category of provider by establishing contracts or agreements with a sufficient number and range of providers to meet the access and availability standards described in section 1852(d)(1) of the Act. Section 1852(d)(1) of the Act describes the requirements that MA organizations offering a ''network'' MA plan must satisfy when selecting providers to furnish benefits covered under the plan.

We are revising § 422.114(a)(2)(ii) to reflect this new statutory requirement.

b. Requirement for Certain Non-Employer PFFS Plans To Use Contract Providers

Prior to MIPPA, section 1852(d)(4) of the Act and § 422.114(a) described how an MA organization that offers an MA PFFS plan must demonstrate to CMS that it can provide sufficient access to services covered under the plan. An MA organization was permitted to meet access requirements if, with respect to a particular category of providers, the plan has met one of the conditions in § 422.114(a)(2). That is, the plan has—

- Payment rates that are not less than the rates that apply under Original Medicare for the provider in question;
- Contracts or agreements with a sufficient number and range of providers to furnish the services covered under the MA private fee-for-service plan; or
- A combination of the above.

Section 1852(j)(6) of the Act and § 422.216(f) provide that if a provider who does not have a contract or agreement with a PFFS plan furnishes services to an enrollee of that plan that are not considered emergency services, the provider is deemed to have a contract with the PFFS plan if the following conditions are met:

(1) The provider is aware, in advance of furnishing health care services, that the patient is enrolled in a PFFS plan.

(2) The provider has reasonable access to the plan's terms and conditions of payment.

(3) The provider furnishes services that are covered by the plan.

Section 162(a)(1) of MIPPA added a new paragraph (5) to section 1852(d) of the Act. The new paragraph creates a requirement for certain non-employer MA PFFS plans to establish contracts

with providers. Specifically, for plan year 2011 and subsequent plan years, MIPPA requires that non-employer/union MA PFFS plans (employer/union sponsored PFFS plans are addressed in a separate provision of MIPPA) that are operating in a network area (as defined in section 1852(d)(5)(B) of the Act) must meet the access standards described in section 1852(d)(4). As noted above, in order to meet the access standards in section 1852(d)(4), PFFS plans must have contracts with a sufficient number and range of providers to meet the access and availability standards described in section 1852(d)(1) of the Act. These PFFS plans may no longer meet the access standards by paying not less than the original Medicare payment rate and having providers deemed to be contracted, as provided under § 422.216(f). Section 162(a)(1) of MIPPA is reflected in regulations at 42 CFR 422.114(a)(3).

''Network area'' is defined in section 1852(d)(5)(B) of the Act, for a given plan year, as the area that the Secretary identifies (in the announcement of the risk and other factors to be used in adjusting MA capitation rates for each MA payment area for the previous plan year) as having at least two network-based plans (as defined in section 1852(d)(5)(C) of the Act) with enrollment as of the first day of the year in which the announcement is made. For plan year 2011, we will inform PFFS plans of their network areas in the announcement of CY 2010 MA capitation rates, which will be published on the first Monday of April, 2009. We will use enrollment data for January 1, 2009 to identify the location of network areas.

''Network-based plan'' is defined in section 1852(d)(5)(C) of the Act as (1) an MA plan that is a coordinated care plan as described in section 1851(a)(2)(A)(i) of the Act, excluding non-network regional PPOs; (2) a network-based MSA plan; or (3) a section 1876 cost plan. Types of coordinated care plans that meet the definition of a ''network-based plan'' are HMOs, PSOs, local PPOs, as well as regional PPOs with respect to portions of their service area in which access standards are met through establishing written contracts or agreements with providers. MIPPA specifies that the term ''network-based plan'' excludes a regional PPO that meets access requirements in its service area substantially through the authority of § 422.112(a)(1)(ii), rather than through written contracts. Section 422.112(a)(1)(ii) permits regional PPOs to meet access requirements using methods other than written agreements with providers (that is, allowing members to see non-contract providers at in-network cost sharing in areas where the plan does not have established a network of contracted providers).

For purposes of determining the network area of a PFFS plan, we will determine whether any network-based plans with enrollment exist in each of the counties located within the PFFS plan's service area. Beginning in plan year 2011, in counties where there is availability of two or more network-based plans (such as an HMO plan, a PSO plan, a local PPO plan, a network regional PPO plan, a network-based MSA plan, or a section 1876 cost plan), a PFFS plan operating in these counties must establish a network of contracted providers to furnish services in these counties in accordance with the amended section 1852(d)(4)(B) of the Act. In such counties, a PFFS plan would no longer be able to meet access requirements through providers deemed to have a contract with the plan at the point of service in these counties. In counties where there are no network-based plan options, or only one other network-based plan, the statute allows PFFS plans to continue to meet access requirements in accordance with section 1852(d)(4) of the Act and § 422.114(a)(2). Regardless of whether a PFFS plan meets access requirements through deeming or is subject to the requirement that it establish a network of providers with signed contracts, providers who do not have a contract with the PFFS plan may continue to be deemed to have a contract with the plan if the deeming conditions described in § 422.216(f) are met.

An existing PFFS plan may have some counties in its current service area that meet the definition of a network area and other counties that do not. In order to operationalize section 162(a)(1) of MIPPA, CMS will not permit a PFFS plan to operate a mixed model where some counties in the plan's service area are considered network areas and other counties that are non-network areas. Beginning in plan year 2011, an MA organization offering a PFFS plan will be required to create separate plans within its existing service areas where it is offering PFFS plans based on whether the counties located in those service areas are considered network areas or not. For example, if an existing PFFS plan has some counties in its current service area that are network areas and other counties that are non-network areas, then in order to operate in this service area in plan year 2011 and subsequent plan years, the MA organization must establish a unique plan with service area consisting of the counties that are network areas and another plan with service area consisting of the counties that are non-network areas. Consequently, the PFFS plan operating in the counties that are network areas must establish a network of contracted providers in these counties in accordance with section 1852(d)(4)(B) of the Act in order to meet access requirements. The PFFS plan operating in the counties that are not network areas can continue to meet access requirements under § 422.114(a)(2) by paying rates at least as high as rates under Medicare Part A or Part B to providers deemed to have a contract with the plan if the conditions described in § 422.216(f) are met. The MA organization must file separate plan benefit packages for the PFFS plan that will operate in network areas and the plan that will operate in non-network areas. We recognize that the creation of unique plans based on network and non-network areas will potentially create an artificial increase in the total number of PFFS plans offered in plan year 2011 and subsequent plan years; this would not reflect an actual increase in PFFS plan offerings, but rather a change in how these PFFS offerings are structured and identified.

For purposes of making the judgment of provider network adequacy for PFFS plans that will be required to operate using a network of contracted providers in plan year 2011 and afterwards, we will apply the same standards for PFFS plans that we apply to coordinated care plans. To determine where a PFFS plan's proposed network meets access and availability standards, we will follow the procedure described in the section above on ''changes in access requirements for PFFS plans.''

We are revising § 422.114(a)(3) to reflect the requirements in section 162(a)(1) of MIPPA.

c. Requirement for All Employer/Union Sponsored PFFS Plans To Use Contracts With Providers

Section 162(a)(2) of MIPPA amended section 1852(d) of the Act by adding a new requirement for employer/union sponsored PFFS plans. For plan year 2011 and subsequent plan years, MIPPA requires that all employer/union sponsored PFFS plans under section 1857(i) of the Act meet the access standards described in section 1852(d)(4) of the Act only through entering into written contracts or agreements in accordance with section 1852(d)(4)(B) of the Act, and not, in whole or in part, through establishing payment rates meeting the requirements under section 1852(d)(4)(A) of the Act.

We are revising § 422.114(a) to reflect this statutory change. Specifically, § 422.114(a) now sets forth how an MA organization that offers a PFFS plan must demonstrate to CMS that it can provide sufficient access to services covered under the plan. In order to meet the access requirements beginning plan year 2011, an employer/union sponsored PFFS plan must establish written contracts or agreements with a sufficient number and range of health care providers in its service area for all categories of services in accordance with the access and availability requirements described in section 1852(d)(1) of the Act. An employer/union sponsored PFFS plan will not be allowed to meet access requirements by establishing payment rates for a particular category of provider that are at least as high as rates under Medicare Part A or Part B. While an employer/union-sponsored PFFS plan must meet access standards through signed contracts with providers, providers that have not signed contracts can still be deemed to be contractors under the deeming procedures in section 1852(j)(6) that currently apply.

We are adding paragraph (a)(4) to § 422.114 in order to reflect this new statutory requirement for employer/union sponsored PFFS plans.

d. Variation in Payment Rates to Providers

Section 162(b) of MIPPA added a clarification to the definition of an MA PFFS plan found at section 1859(b)(2) of the Act. Prior to MIPPA, the statute defined an MA PFFS plan as an MA plan that pays providers at a rate determined by the plan on a fee-for-service basis without placing the provider at financial risk; does not vary the rates for a provider based on the utilization of that provider's services; and does not restrict enrollees' choice among providers who are lawfully authorized to provide covered services and agree to accept the plan's terms and conditions of payment. Section 162(b) of MIPPA added that although payment rates cannot vary based solely on utilization of services by a provider, an MA PFFS plan is permitted to vary the payment rates for a provider based on the specialty of the provider, the location of the provider, or other factors related to the provider that are not related to utilization.

Furthermore, this section of MIPPA also allows MA PFFS plans to increase payment rates for a provider based on increased utilization of specified preventive or screening services. Section 162(b) of MIPPA is effective at the time of publication of this rule.

We are revising paragraph (a)(3)(ii) of § 422.4 and paragraph (a) of § 422.216 to add the clarifications in Section 162(b) of MIPPA.

3. Revisions to Quality Improvement Programs § 422.152

a. Requirement for MA PFFS and MSA Plans To Have a Quality Improvement Program

Section 163(a) of MIPPA repeals, effective January 1, 2010, the current statutory exemption found at section 1852(e)(1) of the Act for MA PFFS plans and MSA plans from the requirement that MA plans have quality improvement programs meeting specified statutory requirements. Beginning plan year 2010, each MA PFFS and MSA plan must have an ongoing quality improvement program that meets the requirements under § 422.152(a).

We are revising § 422.152(a) to delete language exempting PFFS and MSA plans from having quality improvement programs.

b. Data Collection Requirements for MA PFFS and MSA Plans

Section 1852(e)(3)(A)(i) of the Act amended by Section 163(b)(1) of MIPPA by adding that MA PFFS and MSA plans must provide for the collection, analysis, and reporting of data that permits the measurement of health outcomes and other indices of quality, but these requirements for PFFS and MSA plans can not exceed the requirements established for MA local plans that are PPO plans beginning in plan year 2011 and are subject to an exception for plan year 2010 (as discussed below). We interpret this to mean that for plan year 2011 and subsequent plan years, similar to MA local plans that are PPO plans, PFFS, and MSA plans are required to collect, analyze, and report health outcomes and quality data only to the extent that data are furnished by providers who have a contract with the PFFS or MSA plan. For plan year 2011 and subsequent plan years, we are requiring that the data collection requirements for MA PFFS and MSA plans are not subject to requirements that exceed the requirements specified in § 422.152(e) for MA local plans that are PPO plans.

The statute provides for a special rule that applies for plan year 2010, when MA PFFS and MSA plan quality requirements are not restricted to the data collection requirements established for MA local plans that are PPO plans under § 422.152(e). Instead, they must, for 2010 only, meet the data collection requirements with respect to administrative claims data, as specified in CMS guidance. We interpret this exception to mean that for plan year 2010, MA PFFS and MSA plans are required to report quality data based on administrative claims data from all providers that include contract, deemed (applicable to PFFS plans only), and non-contract providers.

c. Data Collection Requirements for MA Regional Plans

Section 163(b)(2) deleted clause (ii) of Section 1852(e)(3)(A) of the Act. Section 1852(e)(3)(A)(ii) had provided for CMS to establish separate regulatory requirements for MA regional plans relating to the collection, analysis, and reporting of data that permit the measurement of health outcomes and other indices of quality and also provided that these requirements for MA regional plans could not exceed the requirements established for MA local plans that are PPO plans. Furthermore, section 163(b)(3) amended Section 1852(e)(3)(iii) of the Act by adding that MA regional plans are subject to the data collection requirements under Section 1852(e)(3)(A)(i) of the Act only to the extent that data are furnished by providers who have a contract with the MA regional plan. This provision is effective for plan years beginning on or after 2010 and allows for consistent data collection requirements between MA local plans that are PPO plans and MA regional plans.

No change to regulatory text is needed since existing language in § 422.152(e) describes the requirements for MA local plans that are PPO plans as well as MA regional plans.

4. Phase-Out of Indirect Medical Education Component of MA Capitation Rate (422.306)

Section 161 of MIPPA adds a new paragraph (4) to § 1853(k) of the Act. The new paragraph directs the Secretary to phase-out indirect medical education (IME) amounts from MA capitation rates. The maximum adjustment percentage per year is .60. Implementation of the IME payment phase-out begins in plan year 2010. Each year after 2010 the maximum adjustment percentage will increase up to an additional .60 percent until the entire IME portion of the MA capitation rate in an area is reduced to zero. PACE programs are excluded from the IME payment phase-out. Payment to teaching facilities for indirect medical education expenses for MA plan enrollees will continue to be made under § 1886(d)(11) of the Act by original Medicare.

We are adding a new paragraph (c) to § 422.306 to reflect this statutory IME phase-out.

B. Changes to the Part D Prescription Drug Benefit Program

1. Use of Prescription Drug Event Data for Purposes of Section 1848(m) (423.322(b))

Section 132 of MIPPA revises section 1848(m) of the Act, as added and amended by section 131 of MIPPA, to provide incentive payments to eligible professionals for successful electronic prescribing. A successful electronic prescriber for a reporting period is one who meets the requirements for submitting data on electronic prescribing quality measures or, if the Secretary determines appropriate, submitted a sufficient number (as determined by the Secretary) of prescriptions under Part D during the reporting period. Congress added paragraph (3)(iv) to section 1848(m) to permit the Secretary to use the data regarding drug claims (prescription drug event data) submitted for payment purposes under the authority of section 1860D–15 of the Act as necessary for purposes of carrying out section 1848(m), notwithstanding the limitations set forth under section 1860D–15(d)(2)(B) and (f)(2) of the Act.

Consistent with the authority granted to the Secretary regarding the use of the prescription drug event data for purposes of section 1848(m), we have revised § 423.322(b) to remove the restriction placed on officers, employees and contractors of the Department of Health Human Services when using these data in accordance with section 1848(m).

2. Elimination of Medicare Part D Late Enrollment Penalties Paid by Subsidy Eligible Individuals (§§ 423.46 and 423.780)

Each year since the beginning of the Medicare prescription drug program, CMS has conducted a Medicare payment demonstration entitled ''Elimination of the 2006 Late Enrollment Penalty,'' such that Medicare beneficiaries who qualify for the low-income subsidy for Medicare prescription drug coverage were able to enroll in a Medicare prescription drug with no penalty. The demonstration has tested the number and characteristics of the beneficiaries that benefited from the waiver of the LEP, and the cost of the waiver to Medicare. Originally, this payment demonstration, as announced on June 14, 2006, allowed certain Medicare beneficiaries to enroll in a Medicare prescription drug plan through December 31, 2006 with no late enrollment penalty. Specifically, CMS did not collect the late enrollment penalty from beneficiaries who enrolled in Medicare Part D in 2006 and were either eligible for the low-income subsidy or lived in an area affected by Hurricane Katrina. This payment demonstration was amended to include beneficiaries who were eligible for the low-income subsidy and enrolled in Medicare Part D in 2007 and 2008.

Section 114 of MIPPA revises the statute to incorporate the terms of the demonstration into the Part D program. We accordingly are revising section 423.780(e) in order to reflect this MIPPA change. Under the revised regulation, CMS will not charge subsidy eligible individuals (defined in 423.773) a late enrollment penalty. This provision will become effective January 1, 2009 when the current demonstration that is supplanted by section 114 of MIPPA ends. We also are making a conforming change to § 423.46(a) to reflect the fact that subsidy eligible individuals may enroll in Medicare prescription drug plan with no penalty.

3. Prompt Payment of Clean Claims (§ 423.505 and § 423.520)

Section 171 of MIPPA amended sections 1860–12(b) and 1857(f) of the Act by adding provisions with regard to prompt payment by prescription drug plans (PDPs) and Medicare Advantage prescription drug (MA–PD) plans, both of which are Part D sponsors as defined in § 423.4. We have codified these new requirements in § 423.505 and § 423.520 of this IFC.

In accordance with the new sections 1860D–12(b)(4) and 1857(f)(3)(A) of the Act, and as codified in § 423.520 of this IFC, effective January 1, 2010, CMS' contract with Part D sponsors must include a provision requiring sponsors to issue, mail, or otherwise transmit payment for all clean claims submitted by network pharmacies—except for mail-order and long-term care pharmacies—within specified timeframes for electronic and all other (non-electronically submitted) claims.

Consistent with section 1860D–12(b)(4)(A)(ii) of the Act, a clean claim is defined in § 423.520(b) of this IFC as a claim that has no defect or impropriety—including any lack of any required substantiating documentation—or particular circumstance requiring special treatment that prevents timely payment of the claim from being made under the requirements of § 423.520 of this IFC. We note that this definition is consistent with the clean claim definitions under Parts A, B, and C of Medicare, as required under sections 1816(c)(2)(B), 1842(c)(2)(B), and 1857(f)(1) of the Act, respectively.

As provided in section 1860D–12(b)(4)(B) of the Act and codified in §§ 423.520(a)(1)(i) and (ii) of this IFC, Part D sponsors must make payment for clean claims within 14 days of the date on which an electronic claim is received and within 30 days of the date on which non-electronically submitted claims are received. Consistent with MIPPA, sections 423.520(a)(2)(i) and (ii) of this IFC define receipt of an electronic claim as the date on which the claim is transferred, and receipt of a non-electronically submitted claim as the 5th day after the postmark day of the claim or the date specified in the time stamp of the transmission, whichever is sooner.

Additionally, as provided in section 1860D–12(b)(4)(D)(i) of the Act and as codified in § 423.520(c)(1) of this IFC, a claim will be deemed to be a clean claim to the extent that the Part D sponsor that receives the claim does not issue notice to the submitting network pharmacy of any deficiency in the claim within 10 days after an electronic claim is received and within 15 days after a non-electronically submitted claim is received. A claim deemed to be a clean claim must be paid by the sponsor within 14 days (for an electronic claim) or 30 days (for a non-electronic claim) of the date on which the claim is received, as provided in §§ 423.520(a)(1)(i) and (ii) of this IFC.

Under section 1860D–12(b)(4)(D)(ii) of the Act and in § 423.520(c)(2) of this IFC, if the Part D sponsor determines that a submitted claim is not a clean claim, it is required to notify the submitting pharmacy that the claim has been determined not to be clean, specify all the defects or improprieties rendering the claim not a clean claim, and list all additional information necessary for the sponsor to properly process and pay the claim. This notification must be provided within 10 days after an electronic claim is received for an electronic claim, and within 15 days after a non-electronically submitted claim is received.

Once the submitting pharmacy resubmits the original claim with the additional information specified by the Part D sponsor as necessary for properly processing and paying the claim, the sponsor has 10 days, consistent with section 1860D–12(b)(4)(D)(iii) of the Act, and, as specified in § 423.520(c)(3) of this IFC to provide notice to the submitting pharmacy of any defect or impropriety in the resubmitted claim. If the sponsor does not provide notice to the submitting pharmacy of any defect

or impropriety in the resubmitted claim within 10 days of the sponsor's receipt of such claim, the resubmitted claim is deemed to be a clean claim and must be paid consistent with the timeframes specified in § 423.520(a)(1) of this IFC (within 14 days of the date on which a resubmitted electronic claim is received and within 30 days of the date on which a non-electronically resubmitted claim is received).

To clarify these requirements, we provide the following example. Assume a Part D sponsor receives an electronic claim on January 1, 2010. If the sponsor were to find a defect or impropriety in that claim, it would be required to communicate that defect or impropriety to the submitting pharmacy no later than January 11, 2010 (within the 10-day window established in § 423.520(c)(1)(i) of this IFC). If the sponsor received a resubmitted claim on January 12, 2010, it would then be required to either deem the claim to be clean or else provide notice to the submitting pharmacy of any defect or impropriety with the resubmitted claim no later than January 22, 2010 (within the 10-day window established in § 423.520(c)(2)(ii) of this IFC). Assuming the resubmitted claim contains all additional information necessary for the sponsor to properly process and pay the claim, the sponsor would be required to pay the resubmitted claim within 14 days of receiving it—in this case, not later than February 5, 2010.

In accordance with section 1860D–12(b)(4)(D)(iv) of the Act, § 423.520(d) this IFC specifies that payment for a clean claim is considered to have been made on the date payment for an electronic claim is transferred and on the date a non-electronic claim is submitted to the United States Postal Service or common carrier, respectively. To the extent that a Part D sponsor does not issue, mail, or otherwise transmit payment for a clean claim within 14 days of the date on which an electronic claim is received and within 30 days of the date on which a non-electronically submitted claim is received, as specified in § 423.520(a)(1) of this IFC, section 1860D–12(b)(4)(C) of the Act requires that the sponsor pay interest to the submitting pharmacy. As required under section 1860D–12(b)(4)(C)(i) of the Act, and as codified in § 423.520(e)(1) of this IFC, the Part D sponsor must pay such interest at a rate equal to the weighted average of interest on 3-month marketable Treasury securities determined for such period, increased by 0.1 percentage point for the period beginning on the day after the required payment date and ending on the date on which the payment is made under § 423.520(d) of this IFC. For purposes of CMS payments to Part D sponsors for qualified prescription drug coverage, any interest amounts paid under § 423.520(e)(1) of this IFC do not count against the Part D sponsor's administrative costs, nor are they treated as allowable risk corridor costs, under § 423.308. In other words, the Part D sponsor is fully liable for any interest payments for claims not paid timely, consistent with § 423.520(d) of this IFC. In accordance with section 1860D–12(b)(4)(C)(ii) of the Act and as codified in § 423.520(e)(2) of this IFC, CMS may determine that a Part D sponsor will not be charged interest under § 423.520(e)(1) as appropriate, including in exigent circumstances such as natural disasters and other similar unique and unexpected events that prevent timely claims processing. CMS will make such determinations on a case-by-case basis at the sponsor's request.

Section 1860D–12(b)(4)(E) of the Act and § 423.520(f) of this IFC require that a Part D sponsor pay all electronically submitted clean claims by electronic funds transfer (EFT) if the submitting network pharmacy requests payment via EFT or has previously requested payment via EFT. For ease of sponsor execution, the requirement that payment be provided via EFT if a sponsor has previously requested EFT payment means that any such previous request must have occurred during the current contract year. This requirement also means that all Part D sponsors must have the capacity to pay via EFT so that they may pay via EFT any of their network pharmacies requesting payment for submitted claims in this manner. In addition, under § 423.520(f), for any payment made via EFT, the Part D sponsor may also make remittance electronically.

In accordance with section 1860D–12(b)(4)(F)(i) of the Act and as codified in § 423.520(g)(1) of this IFC, the requirements in § 423.520 do not in any way prohibit or limit a claim or action that any individual or organization may have against a pharmacy, provider, or Part D sponsor that is unrelated to the new requirements in § 423.520. Further, as provided under section 1860D–12(b)(4)(F)(ii) of the Act and § 423.520(g)(2) of this IFC, consistent with any applicable Federal or State law, a Part D sponsor may not retaliate against an individual, provider, or pharmacy for any such claim or action. Finally, as provided under section 1860d–12(b)(4)(G) of the Act and codified in § 423.520(h), any determination that a claim submitted by a network pharmacy is a clean claim as defined in § 423.520(b) of this IFC shall not be construed as a positive determination regarding the claim's eligibility for payment under Title XVIII of the Act. In addition, any determination that a claim is a clean claim as defined in § 423.520(b) of the Act is not an indication that the government approves, or acquiesces regarding the submitted claim and does not relieve any party of civil or criminal liability, nor offer defense to any administrative, civil, or criminal action, with respect to the submitted claim.

In addition to adding a new § 423.520 to reflect the prompt payment requirements of section 1860D–12(b)(4) of the Act, we are amending § 423.505(b) to include the prompt payment provisions as one of the required elements of the contract between CMS and the Part D sponsor. Therefore, § 423.505(b)(19) of this IFC requires that, effective contract year 2010, the contract between CMS and the Part D sponsor must include the prompt payment provisions at § 423.520 of this IFC.

We are also amending § 423.505(i)(3) with respect to contracts or written arrangements between Part D sponsors and pharmacies or other providers, first tier, downstream and related entities to ensure that Part D sponsors' contracts with these entities include prompt payment provisions consistent with § 423.520. Section 423.505(i)(3)(vi) thus requires that sponsors' pharmacy contracts include the prompt payment provisions of § 423.520. We intend to review pharmacy contract templates (except for mail-order and LTC pharmacy templates) for new applicants to ensure the addition of these prompt payment provisions.

We are aware that some pharmacies, particularly independent pharmacies, work with agents for purposes of negotiating and/or signing contracts with Part D sponsor, and that these agents may receive claim payments from Part D sponsors on their participating pharmacies' behalf. To the extent that such agents are authorized to receive payment on behalf of a participating pharmacy for claims submitted to a Part D sponsor, there is no distinction between a pharmacy and its agent for purposes of the prompt payment provisions at § 423.520. Thus, the prompt payment provisions at § 423.520 extend to an agent authorized to receive payment for claims submitted to a Part D sponsor, as long as it is in compliance with all Federal and State laws.

The revisions to the regulations reflecting the above-described MIPPA prompt payment provisions are all effective on January 1, 2010.

4. Submission of Claims by LTC Pharmacies (§ 423.505)

Section 172 of MIPPA amended sections 1860D–12(b) and 1857(f)(3) of the Act to add a provision on the submission of claims by pharmacies located in or having a contract with a long-term care facility. Effective January 1, 2010, new sections 1860D–12(b)(5) and 1867(f)(3)(B) of the Act direct us to incorporate into each contract CMS enters into with a Part D sponsor a provision addressing the submission of claims by long-term care pharmacies. Specifically, CMS contracts with Part D sponsors must provide that long-term care pharmacies must have not less than 30 days, nor more than 90 days, to submit claims to the sponsor for reimbursement under the plan. We are codifying this new statutory contract requirement at § 423.505(b)(20). Effective January 1, 2010, this provision will apply to any claim submitted by a long-term care pharmacy, as defined in § 423.100.

It is important to note that this new requirement does not eliminate the requirement, specified in a CMS policy memorandum dated May 25, 2007 (available at *insert URL*) for Part D sponsors to provide a new timely claims filing period for claims incurred by dual-eligible beneficiaries during a period of retroactive Part D enrollment. The CMS memorandum, entitled ''Special Transition Period for Retroactive Enrollment,'' requires that in retroactive enrollment situations Part D sponsors must use the date of Medicaid notification to establish a new timely claims filing period to ensure that dual-eligible beneficiaries and other parties, including pharmacies, have the opportunity to request reimbursement for claims incurred during the retroactive period. Therefore, consistent with this policy, sponsors must provide a new period, as specified in § 423.505(b)(20), for long-term care pharmacies to submit claims for reimbursement.

Effective contract year 2010, new sections 1860D–12(b)(5) and 1867(f)(3)(B) of the Act require that CMS contracts with Part D sponsors include a provision requiring sponsors to provide long-term care pharmacies (as defined in § 423.100) not less than 30 days, nor more than 90 days, to submit claims for reimbursement under the plan. In addition to adding this requirement to the contract provisions specified in § 423.505(b), we are amending § 423.505(i) to specify that timeframes for submission of claims by long-term care pharmacies must be contained in Part D sponsor contracts with the long-term care pharmacies. As provided in § 423.505(i)(3)(vii), all sponsor contracts with long-term care pharmacies must contain a provision that establishes timeframes, consistent with § 423.505(b)(20), for the submission to the sponsor of claims for reimbursement.

5. Regular Update of Prescription Drug Pricing Standard (§ 423.505)

Section 173 of MIPPA amended sections 1860D–12(b) and 1857(f)(3) of the Act, effective January 1, 2009, to add a provision on the regular updating of prescription drug pricing standards. In accordance with new sections 1860D–12(b)(6) and 1857(f)(3)(C) of the Act, which we are codifying in § 423.505(b)(21) of this IFC effective January 1, 2009, CMS' contracts with Part D sponsors must include a provision requiring sponsors to regularly update any prescription drug pricing standard they use to reimburse network pharmacies based on the cost of the drug (for example, average wholesale price, wholesale average cost, average manufacturer price, average sales price). As codified in §§ 423.505(b)(21)(i) and (ii), these updates, if applicable, must occur on January 1 of each contract year and not less frequently than every 7 days thereafter.

We are also amending § 423.505(i)(3) with respect to contracts or written arrangements between Part D sponsors and pharmacies or other providers, first tier, downstream and related entities to ensure that Part D sponsors' contracts with these entities include provisions for regularly updating any prescription drug pricing standard used by sponsors to reimburse their network pharmacies, as provided in § 423.505(b)(21) of this IFC. Specifically, section 423.505(i)(3)(vi)(A) of this IFC requires that sponsors' pharmacy contracts include the pricing standard update requirements at § 423.505(b)(21) of this IFC, if applicable.

Implicit in the statutory requirement that pricing standards be updated is the fact that such standards are being used. This information is also necessary in order to monitor for compliance with MIPPA updating requirement. Accordingly, § 423.505(i)(3)(viii)(B) of this IFC specifies that a Part D sponsor's pharmacy contract must indicate the source used by the Part D sponsor for making such pricing updates.

Given the applicability of the pricing standard update provisions beginning in contract year 2009, Part D sponsors must ensure that they amend their current pharmacy contracts consistent with § 423.505(i)(3)(viii) of this IFC. CMS will review pharmacy contract templates (except for mail-order and LTC pharmacy templates) for new applicants beginning for contract year 2010 to ensure the addition of this provision, if applicable.

We are aware that some pharmacies, particularly independent pharmacies, work with agents for purposes of negotiating and/or signing contracts with Part D sponsors, and that these agents may receive claim payments from Part D sponsors on their participating pharmacies' behalf. To the extent that such agents are authorized to receive payment on behalf of a participating pharmacy for claims submitted to a Part D sponsor, there is no distinction between a pharmacy and its agent for purposes of the drug pricing standard update requirements at § 423.505(b)(21) of this IFC. Thus, the drug pricing standard update requirements at § 423.505(b)(21) of this IFC extend to an agent authorized to receive payment for claims submitted to a Part D sponsor, as long as it is in compliance with all Federal and State laws.

6. Use of Part D Data (§ 423.505(m))

On May 28, 2008, prior to the passage of MIPPA, CMS published a final regulation (73 FR 30664) regarding the collection and use of Part D claims data. This regulation resolved the statutory ambiguity between section 1860D–12(b)(3)(D) and section 1860D–15 of the Act. One of the incorporated provisions at section 1860D–12(b)(3)(D) of the Act, is section 1857(e)(1) of the Act, which provides broad authority for the Secretary to add terms to the contracts with Part D sponsors, including terms that require the sponsor to provide the Secretary, ''with such information as the Secretary may find necessary and appropriate.'' As we stated in our final rule on Part D claims data, we believe that the broad authority of section 1860D–12(b)(3)(D) of the Act authorizes CMS to collect the same prescription drug event data we currently collect to properly pay sponsors under the statute for other purposes unrelated to payment. However, we acknowledged that section 1860D–15 of the Act contains provisions that might be viewed as limiting such collection, thus compelling CMS to clarify the Secretary's broad authority under section 1860D–12(b)(3)(D) in our final regulation. Accordingly, in the final Part D data rule, we implemented the broad authority of section 1860D–12(b)(3)(D) of the Act to permit the Secretary to collect claims data that are collected for Part D payment purposes for other research, analysis, reporting, and public health functions. For a complete

discussion of this regulation, please see the final Part D data rule at 73 FR 30664.

Section 181 of MIPPA amends section 1860D–12(b)(3)(D) to make clear that, notwithstanding any other provision of law, information provided to the Secretary under the application of section 1857(e)(1) may be used for purposes of carrying out Part D, and may be used to improve public health through research on the utilization, safety, effectiveness, quality, and efficiency of healthcare services. Thus, MIPPA further strengthens CMS' final rule on Part D claims data and confirms our authority to use claims data collected under 1860D–12 of the Act for purposes of reporting to the Congress and the public, conducting evaluations of the overall Medicare program, making legislative proposals to Congress, and conducting demonstration projects.

While MIPPA does not alter our ability to collect and use data for purposes outlined in our final rule on Part D claims data, section 181 of MIPPA adds a provision with respect to the disclosure of claims data to Congressional support agencies. Specifically, section 181 of MIPPA adds clause (ii) to section 1860D–12(b)(3)(D), which requires the Secretary to make data collected under section 1860D–12(b)(3)(D) available to Congressional support agencies, in accordance with their obligations to support Congress as set out in their authorizing statutes, for the purposes of conducting Congressional oversight, monitoring, making recommendations, and analysis of the Part D program. In our previously issued final rule on Part D claims, we specified that we would only release the minimum data necessary to Congressional oversight agencies in accordance with our data sharing policies. Section 1860D–12(b)(3)(D), as amended, removes the minimum necessary data restriction when data are requested by a Congressional support agency that is requesting the data in accordance with its obligation to support Congress as set out in its authorizing statute.

Section 423.505(f)(3) of the regulation establishes that Part D plan sponsors must submit the 37 original data elements included as part of their drug claims ''for all purposes deemed necessary and appropriate by the Secretary, including, but not limited to,'' reporting to Congress and the public on the operation of the Part D program, conducting evaluations of the overall Medicare program, making legislative proposals, conducting demonstrations and pilot projects, supporting care coordination and disease management programs, supporting quality improvement and performance measurement activities, and populating personal health care records. Section 423.505(m)(1) of the regulations currently provides that with respect to data collected under section 423.505(f)(3), ''CMS may release the minimum data necessary for a given purpose to Federal executive branch agencies, congressional oversight agencies, States, and external entities in accordance with the applicable Federal laws, CMS data sharing procedures, and subject, in certain cases to encryption and or aggregation of certain sensitive information. MIPPA revised 1860D–12(b)(3)(D) of the Act to provide specifically that information collected pursuant to this section be made available to Congressional support agencies, in accordance with their obligations to support Congress as set out in their authorizing statutes, for the purposes of conducting Congressional oversight, monitoring, making recommendations, and analysis of the Medicare Part D program. Consistent with this new statutory provision, we have revised § 423.505(m)(1) of our regulations, to omit any reference to ''Congressional oversight agencies.'' We are also adding a new paragraph § 423.505(m)(3) specifying that the Secretary will make the information collected under § 423.505(f)(3) available to Congressional support agencies in accordance with their obligations to support Congress as set out in their authorizing statutes.

We are using the same definition for Congressional support agencies in § 423.505(m)(3) that we previously used for Congressional oversight agencies in the regulation at § 423.505(m)(1)(iv). As with the definition of Congressional oversight agencies at 423.505(m)(1)(iv), we are not including Congressional Research Service (CRS) as a Congressional support agency unless it is requesting the data on behalf of a Congressional committee consistent with 2 U.S.C. 166(d)(1). As previously explained in the preamble to CMS–4119–F, when CRS is not acting as the agent of a Congressional committee, it does not have the same authority to request data from departments or agencies of the United States, and would be restricted in the same manner as external entities when requesting prescription drug event data.

7. Exemptions From Income and Resources for Determination of Eligibility for Low-Income Subsidy (§ 423.772)

Section 1860 D–14 of the Social Security Act describes the rules for determining financial eligibility for the Medicare Part D Low-Income Subsidy (LIS). These rules closely conform to the Supplemental Security Income (SSI) methodology for determining financial eligibility. Section 116 of MIPPA amended the types of income and resources to be taken into consideration for determining financial eligibility for LIS to deviate from the SSI methodology in two areas. Specifically, section 116 of MIPPA amended 1860D–14(a)(3) by exempting from the determination of LIS the following:

- Support and maintenance furnished in kind from income; and
- Value of any life insurance policy from resources.

Support and maintenance furnished in kind is any food or shelter that is given to the applicant/spouse or received because someone else pays for it. This includes room, rent, mortgage payments, real property taxes, heating fuel, gas, electricity, water, sewage, and garbage collection services.

Life insurance policy includes whole life, term, and products that combine features of whole life and term policies.

In general, it is the responsibility of the Social Security Administration to determine eligibility for LIS. However, the Centers for Medicare & Medicaid Services (CMS) maintain in regulation broad parameters for income and resources for the Medicare Part D Low-Income Subsidy. These regulations also govern how State Medicaid Agencies process LIS applications when individuals apply there. In order for CMS regulations to conform to the new law, CMS is updating its regulations to reflect the new exclusions from income and resources.

In order to reflect these changes, we are revising the definitions of ''income'' and ''resources'' in § 423.772.

The amendments made by this provision are effective with respect to LIS applications filed on or after January 1, 2010.

C. Changes to the MA and Prescription Drug Benefit Programs

In order to assist readers in understanding how the final provisions we discuss in this section apply to both programs, we are including Table 1, which highlights the provisions affecting both programs and the pertinent Part 422 and Part 423 CFR sections.

TABLE 1—PROVISIONS AFFECTING BOTH THE PART C AND PART D PROGRAMS

Provision	Part 422–subpart	Part 422 CFR section	Part 423—subpart	Part 423 CFR section
Disclosure of plan information	Subpart C	422.111	Subpart C	423.128
Marketing: Standards for MA/Part D marketing:	Subpart V	422.2268		423.2268
• Nominal gifts				
• Scope of marketing				
• Co-branding				
• Including plan type in plan name				
Marketing: Reporting terminations	Subpart V	422.2272		423.2272
Marketing:	Subpart V	422.2274		423.2274
• Broker and agent compensation				
• Training and testing				

1. Disclosure of Plan Information (§§ 422.111)

Section 164 of the Medicare Patients and Providers Improvement Act revised section 1859(f) of the Act to require, effective January 1, 2010, disclosure of SNP plan information to beneficiaries. In order to reflect the MIPPA changes, we are adding new paragraph (b)(iii) to § 422.111. The addition requires to require dual-eligible SNPs to provide the information specified in §§ 422.111(b) and 423.128(b) of the MA and Part D program regulations, both prior to enrollment to each prospective enrollee and at least annually thereafter, 15 days before the annual coordinated election period. CMS plans to develop a model comprehensive statement for beneficiaries that could be included with any description of benefits offered by the SNP plan. Note that in a related final rule to be published on or about the date of publication of this IFC, we will be finalizing provisions from the May 16, 2008 proposed rule related to disclosure of plan information for MA organizations.

2. Medicare Advantage and Prescription Drug Program Marketing Requirements (New Subparts V)

a. General

In a separate final rule (that appears in this issue of the **Federal Register**) finalizing several of the marketing provisions proposed in our May 16, 2008 proposed rule we established a new marketing subpart V for Parts 422 and 423. In this IFC, we refer to the codification of marketing requirements that reflects those changes (revised Code of Federal Regulations sections established in the final rule). With the exception of the provisions relating to including plan type in the name of the plan, and the reporting by plans of agent and broker terminations to States, all of the Part C and Part D marketing requirements discussed below are effective upon publication of this interim final rule.

b. Standards for MA and PDP Marketing (§§ 422.2268, 423.2268)

In the May 16, 2008 proposed rule, we proposed several regulatory requirements in §§ 422.2268 and 423.2268, providing additional protections to ensure that beneficiaries are not the victims of inappropriate marketing techniques. Several areas we addressed in these proposed regulatory marketing requirements were addressed by Congress in MIPPA, which required in section 103(b)(1)(B) that the Secretary ''establish limitations with respect to'' five areas specified in statute. With the exceptions noted above, these MIPPA-mandated marketing limitations are required to be in effect ''on a date specified by the Secretary, but in no case later than November 15, 2008.'' Because this deadline is less than 150 days after the enactment of MIPPA, under section 1871(b)(2)(B) of the Act, we may publish rules implementing these MIPPA provisions without prior notice and comment. Some provisions in the May 16, 2008 proposed rule were similar to those in MIPPA. As a result, to the extent that our policies were informed by comments we received on the proposed rule, we will discuss the public comments in connection with the marketing provisions we have developed in implementing the MIPPA provisions.

(i) Nominal Gifts

In our May 16, 2008 NPRM, we proposed a new regulatory requirement in §§ 422.2268(b) and 423.2268(b) under which organizations would be required to limit the offering of gifts and other promotional items offered to potential enrollees at promotional events to gifts of ''nominal value'' that are offered to all potential enrollees. This proposed paragraph also contained a prohibition against offering meals that we are addressing in a separate rule.

In section 103(b)(1)(B) of MIPPA, the Secretary was charged with ''establish[ing] limitations with respect to * * * the offering of gifts and other promotional items other than those of nominal value (as determined by the Secretary) to prospective enrollees at promotional activities.'' Section 103(b)(2) of the MIPPA revises the Act to apply these same guidelines to PDP sponsors.

We are implementing this MIPAA requirement in a revised version of the nominal value gift portion of our proposed §§ 422.2268(b) and 423.2268(b). Commenters on our May 16, 2008 proposed version asked if the requirement that promotional items be available to all eligible individuals meant that the promotional items had to be offered to current members. Other commenters recommended that a dollar limit approach be adopted to ensure that the permitted promotional items were truly of nominal value.

Our revised version of the nominal gift portion of our proposed §§ 422.2268(b) and 423.2268(b) clarifies that the promotional items must be available to all potential enrollees at promotional events without regard for whether or not the beneficiary enrolls. With respect to the dollar amount issue, the Marketing Guidelines and guidance currently specify a dollar limit of $15 to ensure that promotional items are of nominal value. CMS will update this number as necessary to account for inflation and other relevant factors. Examples of nominal gifts include pens, pencils, and calendars.

(ii) Limiting the Scope of Health Care Products To Be Discussed

In §§ 422.2268(g) and 423.2268(g) of the May 16, 2008, rule, we proposed to limit any appointment with a beneficiary involving marketing of health care related products (for example, whether Medicare supplement, Medicare Advantage, stand-alone PDP will be discussed) to the scope agreed upon by the beneficiary. We further proposed to require, that, in advance of any marketing appointment, the beneficiary

must have the opportunity to agree to the range of choices that will be discussed, and that agreement would have to be documented by the plan. Under proposed §§ 422.2268(h) and 423.2268(h), additional lines of plan business (for example, MA, MA–PD, PDP or Medigap) not identified prior to the in-home appointment would require a separate appointment that could not be re-scheduled until 48 hours after the initial appointment.

In section 103(b)(1)(B) of MIPPA, the Secretary was charged with ''establish[ing] limitations with respect to * * * the scope of any appointment with respect to the marketing of a Medicare Advantage plan.'' Section 103(b)(2) of MIPPA revises the Act to apply these same guidelines to PDP sponsors. The statute further provides that ''[s]uch limitation shall require advance agreement with a prospective enrollee on the scope of the marketing appointment and documentation of such agreement by the Medicare Advantage organization. In the case where the marketing appointment is in person, such documentation shall be in writing.''

We are here adopting our proposed version of §§ 422.2268(g) and (h) and 423.2268(g) and (h) to implement these MIPPA provisions, and in light of a comment on the proposed rule expressing confusion about what a line of business is, we clarify here that ''lines of business'' are considered Prescription Drug Plans, Medicare Advantage Prescription Drugs Plans or Medicare Advantage only and Medigap.

(iii) Use of Names and Logos, Co-Branding

As an additional beneficiary protection, in §§ 422.2268(n) and 423.2268(n) of the May 16 proposed rule, we proposed to limit the use of names and/or logos of co-branded network providers on member information and marketing materials including plan membership identification cards. We also proposed to codify existing policies that MA organizations may include on plan membership cards, provider names/logos that are specific to the members selection of providers or provider organizations. In addition, all member information and marketing materials except for plan identification cards should indicate that other providers are available in the network. We believed that this requirement would reduce the tendency of members to mistakenly believe they must use the co-branded network provider in order to obtain plan benefits.

In section 103(b)(1)(B) of MIPPA, the Secretary was charged with ''establish[ing] limitations with respect to * * * ''[t]he use of the name or logo of a co-branded provider on Medicare Advantage plan membership and marketing materials.'' Section 103(b)(2) of MIPPA revises the Act to apply these same guidelines to PDP sponsors.

We are implementing this requirement through a modified version of our proposed §§ 422.2268(n) and 423.2268(n). Specifically, as a result of comments on the May 16, 2008 proposed rule, we are revising the proposed version of these rules to clarify that MA organizations may include provider names/logos on the member identification card related to the member selection of specific providers or provider organizations. We further clarify here that ''other marketing materials'' requiring the statement that other providers are available in the network, are marketing materials as defined in §§ 422.2260 and 423.2260.

(iv) Inclusion of Plan Type in Plan Name

Section 103(c)(1) of MIPPA requires that MA organizations and PDP sponsors include the plan type within the name of each plan being offered for plan years beginning on or after January 1, 2010. We are adding new paragraph (q) in §§ 422.2268 and 423.2268 to reflect this requirement. For consistency across plans, it will be required that the plan type is included at the end of the plan name. For example, a plan previously submitted as ''Medicare ABCXYZ Gold'' could be submitted as ''Medicare ABCXYZ Gold HMO'' or ''Medicare ABCWYZ Gold HMO Plan.''

c. Reporting Agent and Broker Terminations (§§ 422.2272 and 423.2272)

Section 103 of the Medicare Improvements for Patients and Providers Act (MIPPA), requires us to expand our proposed requirements on plans that use licensed agents and brokers. In accordance with MIPPA, §§ 422.2272(d) and 423.2272(d) implement the requirement, effective January 1, 2009, that MA organizations and Part D sponsors are required to report to the State in which the MAO or Part D sponsor appoints an agent or broker, the termination of any such agent or broker, including the reasons for the termination if State law requires that the reasons for the termination be reported.

d. Broker and Agent Compensation (§§ 422.2274, 423.2274)

Section 103(b)(1)(B) of MIPPA revises the Act to charge the Secretary with establishing guidelines to ''ensure that the use of compensation creates incentives for agents and brokers to enroll individuals in the Medicare Advantage plan that is intended to best meet their health care needs.'' Section 103(b)(2) of MIPPA revises the Act to apply these same guidelines to PDP sponsors.

This is another area that we addressed in proposals set forth in the May 16 proposed rule. Our proposed rules were based on our program experience showing that the current compensation structure permitted under the Marketing Guidelines had the potential to create a financial incentive for agents to only market and enroll beneficiaries in some plan products and not others. This compensation structure has led some agents to encourage beneficiaries to enroll in products that may not meet the beneficiaries' health needs but pays the agents the highest commission. In addition, there is a potential financial incentive for agents to encourage beneficiaries to change plans each year. Therefore, in order to prevent agents from unnecessarily moving beneficiaries from plan to plan and to ensure that beneficiaries are receiving the information and counseling necessary to select the best plan based on their health care needs, CMS proposed in the May 16 proposed rule to add new rules regarding compensation at §§ 422.2274(a)(1) and (a)(2) and 423.2274(a)(1) and (a)(2).

In developing our policy for implementing the MIPPA changes to the Act regarding agent and broker compensation, we benefited from public comments we received on our proposal in our May 16 proposed rule.

For example, several commenters on that proposal wanted clarification on the definition of ''independent broker or agent,'' and whether the changes apply to both independent agents selling Medicare products and plan employees or to the employer retiree group market. There was a strong feeling among the commenters on the May 16 proposed rule that the nature of compensation for employees was very different than that of independent agents, and that it would be difficult to develop a level compensation structure for both groups.

Several commenters wanted clarification on the distinction between compensation and commission. Also, commenters had questions specifically about bonuses. Some recommended that prizes, awards, trips, and similar

bonuses and incentives be excluded from the proposed provisions. Some commenters felt that these incentives should be prohibited. Others felt there should be exceptions made for convention credits, exceptions for incentives that reward high member retention, or one-time bonuses for administrative efficiency (for example, encourage electronic submission of applications).

Several commenters recommended a new provision that level commissions be advanced to agents, but have to be earned at a level rate (for example, one-twelfth of the annual amount per month as long as the member is active with the plan sponsor). Along with the new provision, the commenters requested that CMS continue to require plans to charge back all commissions for applications that result in rapid disenrollments within 60 days. One of the commenters asked that the period for charge back be expanded to 6 months. There was one commenter who wanted to know how the proposed structure would work with mid-year plan changes or renewals (for example, with full duals).

The comments we received through the public notice and comment process helped us implement the MIPPA changes to the Act regarding agent and broker compensation. As a result, the structure we are implementing in this IFC, while directed to Medicare Advantage organizations and Part D sponsors that market ''through independent brokers or agents,'' includes compensation paid to employees that is based on volume of sales. By ''independent brokers or agents'' we mean contracted brokers or agents, whether they sell for one plan, multiple plans, or work through a Field Marketing Organization (FMO), general agent (GA), or other similar subcontracted marketing organizations.

The proposal in the May 16 proposed rule defined commission to include other compensation. Based on the comments received on that proposed rule, our definition of compensation under our rule implementing MIPPA includes pecuniary or non-pecuniary remuneration of any kind relating to the sale or renewal of the policy (for example, commissions, bonuses, gifts, prizes, awards, and finders' fees). Salary or other benefits related to employment are excluded from this definition (except if related to volume of sales). The payment of fees to comply with State appointment laws, training, certification, and testing costs; and reimbursement for mileage to and from appointments with beneficiaries and reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials are also not considered compensation. We have clarified our proposal by revising paragraph (a)(1) of §§ 422.2274 and 423.2274 to clarify what is considered compensation.

We also include in this IFC a provision that compensation for a sale is earned in months 4 through 12 of the enrollment year as long as the member is active with the plan. If an enrollee leaves the plan prior to month 4, no compensation is earned. If an enrollee leaves the plan after month 3, compensation is paid on a prorated basis only for the months in which the enrollee was actually a member of the plan.

We also received comments on our proposal in the proposed rule that the commission an agent received in the first year after an enrollment could not exceed the commission the agent receives in all subsequent years. Many commenters recommended that CMS follow the industry standard practice for Medicare supplements or modify the provision to allow for a higher commission in the first year because there is a significantly greater amount of work done in the initial year than in subsequent ones. They requested that the subsequent years be limited to five years. They also wanted clarification on what was meant by ''all subsequent years.''

Based in part on these comments, in developing our policy implementing MIPPA's changes to the Act regarding agent and broker compensation, this IFC provides that an agent's aggregate first year compensation can not exceed 200 percent of the aggregate compensation in each individual subsequent renewal year, of which there must be a total of 5 renewal years. This creates a 6-year compensation cycle. This means that in the first year, the compensation paid can be no more than 200 percent of the compensation paid in the second year or any individual subsequent renewal year, up to a total of 5 renewal years (6-year total compensation cycle). The agent will receive renewal compensation for the 5-year renewal period (years 2 through 6) based on this compensation structure as long as the member remains active in a like-plan type (for example, PDP, MA plan, or cost plan). We believe that this provision places limits on compensation paid to agents. It also encourages agents to establish longer term relationships with their clients, rather than short term relationships. This provision eliminates the incentive for agents to move their clients from plan to plan since the compensation that agents receive for a replacement plan will be nearly the same as if the client had stayed in the original plan. Additionally, since most plan changes occur in the first three months of the plan year and agents typically are paid for the entire year in the first three months, we are requiring that agents and brokers earn compensation for months four through twelve and that they be paid by a given plan only for months in which the beneficiary is enrolled in that plan. This means that plans may pay agents and brokers up-front or prorate compensation payments over 12 months or over months 4 through 12, but when a beneficiary disenrolls from the plan, the plan must recover all compensation paid-for months in which the beneficiary is not enrolled, and during months 1 through 3 if the beneficiary disenrolls during the first 3 months and compensation was paid in advance.

Several commenters on the proposal in the May 16 proposed rule expressed concern about our proposal in 422.2274(a)(2) and 423.2274(a)(2) that commissions must be the same for all plan and plan product types offered by plan's parent organization. These commenters wanted ''parent organization'' defined. They were also concerned about how this would apply to field marketing organizations (FMOs) and general agents (GA), organizations composed of various levels of agents and that provide additional services beyond selling insurance products (for example, training, document management and storage, office space, supplies, and equipment). The questions about FMOs centered around whether the commission was paid at the ''street level'', meaning directly to the agent, or at the FMO level, where the FMO would then be responsible for paying the agent. One commenter suggested that plans could include a term in their contracts with FMOs stating that the FMO would receive a fee from the plan and out of that fee, the agent would be paid the specified amount in accordance with CMS' rules. The statement could be detailed enough to address the prohibition against prizes, awards, trips and other types of incentives. One commenter suggested that CMS should consider evaluating fees paid to FMOs for future regulation.

There were many comments about variable commissions. Several addressed the problems that a national plan would face in developing a commission that would apply across the country because the average may be too high for some areas and too low for others. They recommended that commissions should be based on local

geographic areas. One commenter stated that basic drug plans should have reduced commissions or not have commissions at all because leveling them with commissions for enhanced plans would create additional costs that would make it difficult for them to meet the regional low-income benchmarks. Several commenters felt that there should be a different commission for MA plans and PDPs. Some suggested that there should be different commissions for all MA types. One commenter asked whether the level commission applied to other products (for example, Medicare supplements, dental, vision, auto, etc).

Several commenters suggested ways to design a variable commission including—commissions based on percent of premium amount; tiered commission structure based on volume of sales; commissions based on amount of work required to sell product; commissions based on education, experience, tenure, or services provided; commissions based on performance; establishing a cap on commissions, separate commissions for agents that only provide leads; or special commissions for SNPs.

Based in part on the issues raised by the above comments received on the May 16 proposed rule, CMS is adopting a different approach to compensation structure that focuses on creating incentives for agents and brokers to enroll beneficiaries in MA and Part D plans that best meet beneficiaries' health care needs. This shifts the focus from specific dollar values, as proposed in the May 16 proposed rule, to guidelines specifying how compensation is disbursed, whether an agent receives a new or renewal compensation, and what qualifies as compensation. However, CMS still expects that plans will set compensation at levels that are reasonable and reflect fair market value for the services. Accordingly, under this IFC, compensation can vary (for example, by geographic area, plan type, agent experience), but is subject to the requirements that renewal compensation be paid for five renewal years (6-year total compensation cycle), that compensation for a change in plans during that five-year period be the same as the renewal compensation, and the initial compensation may not exceed 200 percent of the renewal compensation. CMS encourages plans to keep compensation as level as possible across plan types and among agents providing similar services. As discussed above, we define ''compensation'' as including pecuniary or non-pecuniary remuneration of any kind relating to the sale or renewal of the policy (for example, commissions, bonuses, gifts, prizes, awards, and finders' fees). Salary or other benefits related to employment are excluded from this definition (except if related to volume of sales). The payment of fees to comply with State appointment laws, training and testing, certification, and reimbursement for mileage to and from appointments with beneficiaries and reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials are also not considered compensation. Specifically, under the rule set forth in this IFC implementing our charge under MIPPA, MA organizations and PDP sponsors must adopt a compensation structure according to the following:

- The aggregate first year compensation is no more than 200 percent of the aggregate compensation paid for selling or servicing the enrollee in each individual subsequent year, of which there must be five total renewal years creating a 6-year compensation cycle.
- If compensation is paid in the first year, renewal compensation must be paid for no fewer than 5 renewal years (6-year compensation cycle), provided that the enrollee remains enrolled in the plan.
- No entity may provide and no agent or broker may receive aggregate compensation greater than the renewal compensation payable by the replacing plan on renewal policies if an existing policy is replaced with a like plan type during the first year and 5 renewal years (6-year compensation cycle). ''Like plan type'' refers to PDP, MA or MA–PD, or cost plan. Examples of replacements with like plan type are—PDP replace with another PDP, MA or MA–PD replaced with another MA or MA–PD, and cost plan replaced with another cost plan. If a PDP is added to an MA-only plan, then a new compensation is paid for enrollment in the PDP.
- Compensation (for both first-year and renewals) is to be earned for months 4 through 12 of the enrollment year. Plans may pay agents and brokers up-front or prorate compensation payments over 12 months or over months 4 through 12, but when a beneficiary disenrolls voluntarily or involuntarily from the plan, the plan must recover all compensation paid-for months in which the beneficiary is not enrolled, and for months 1 through 3 if the beneficiary disenrolls during the first 3 months and compensation was paid in advance.
- Organizations and sponsors must establish a compensation structure for new and replacement enrollments and renewals effective in a given plan year. Compensation structures must be in place by the beginning of the plan marketing period, October 1.
- Compensation structures must be available upon CMS request including for audits, investigations, and to resolve complaints.

The compensation structure is designed to help prevent inappropriate moves of beneficiaries from plan-to-plan. Parties remain responsible, however, for compliance with fraud and abuse laws, including the anti-kickback statute. Depending on the circumstances, agent and broker relationships can be problematic under the anti-kickback statute if they involve, by way of example only, compensation in excess of fair market value, compensation structures tied to the health status of the beneficiary (for example, cherry-picking), or compensation that varies based on the attainment of certain enrollment targets. We note that the Office of the Inspector General (OIG) advisory opinion process is available to parties seeking OIG's opinion as to the legality of a particular arrangement. Information about this process is available on the OIG's Web site at *http://oig.hhs.gov/fraud/advisoryopinions.html.*

e. Agent and Broker Training (§§ 422.2274 and 423.2274)

Section 103(b)(1)(B) of MIPPA revised the Act to charge the Secretary with establishing ''limitations with respect to the use by a Medicare Advantage organization of any individual as an agent, broker, or other third party representing the organization that has not completed an initial training and testing program and does not complete an annual retraining and testing program.'' Section 103(b)(2) of MIPPA revises the Act to apply these same limitations to PDP sponsors.

In our May 16 proposed rule, we proposed rules establishing a requirement for training of agents that we hereby adopt under this IFC to implement the above MIPPA language. These rules are set forth in this IFC at §§ 422.2274 and 423.2274.

In 422.2274(b) and 423.2274(b), MA organizations and PDP sponsors are required to train all agents selling Medicare products on Medicare rules, regulations and compliance-related information annually.

In 422.2274(c) and 423.2274(c), agents selling Medicare products are required annually to pass written or electronic tests on Medicare rules, regulations and information on the plan products they intend to sell.

In 422.2274(d) and 423.2274(d), MA organizations and PDP sponsors are

required to provide to CMS the information designated by CMS as necessary to conduct oversight of marketing activities.

In 422.2274(e) and 423.2274(e), MA organizations and PDP sponsors are required to comply with State requests for information about the performance of licensed agents or brokers as part of a State investigation into the individual's conduct. CMS will establish and maintain a memorandum of understanding (MOU) to share compliance and oversight information with States that agree to the MOU.

D. Changes to Section 1876 Cost Plans

Clarifying the Conditions Under Which 1876 Cost Plans or Portions of Their Service Areas May Be Prohibited

Section 1876(h)(5)(C) of the Social Security Act (the Act) prohibits the renewal of a cost plan, or a portion of a cost plan's service area in an area where, during the previous year, two or more organizations offering a local MA plan meet a minimum enrollment test, or two or more organizations offering a regional MA plan meet the same test. The test is that the local or regional plan must have at least 5000 enrollees in any portion of its service area that includes a Metropolitan Statistical Area (MSA) with a population over 250,000 (enrollment in counties contiguous to the MSA count toward the 5000) and enrollment of at least 1,500 in the other portion of its service area. Section 167 of MIPPA clarified the application of minimum enrollment requirements by revising paragraphs 1876(h)(5)(C) of the Act.

The MIPPA-based revisions include clarifying in 1876(h)(5)(C)(iii) that the two plans triggering the prohibition may not be offered by the same MA organization.

In addition, by revising 1876(h)(5)(C)(iii)(I) of the Act, MIPPA clarified that if a cost plan's service area falls within more than one MSA with a population over 250,000 and the local or regional plans have a minimum of 5000 enrollees, the determination to prohibit a plan will be made with respect to each MSA and counties contiguous to each MSA.

If a cost plan's service area or portion of a service area falls in one MSA only, the determination to prohibit a plan will be based on the competing local or regional plans' enrollments in that MSA only.

In order to reflect these changes we are revising paragraphs (c)(1)–(3) of § 417.402 of Title 42 of the Code of Federal Regulations.

III. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

IV. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued. Below, we discuss the provisions of the rule and our reasons for the waiver of notice-and-comment procedure and, as specified, waiver of effective dates. If we do not specify that the effective date for a provision be waived, the date noted in the section should be considered the effective date.

A. Waiver of Notice-and-Comment Procedure

1. Marketing Provisions (Several Sections, Subpart V)

All of the marketing sections included in this regulation and listed below with the exception of the requirement that plans must include the plan type in the plan's name, and that plans report the termination of agents or brokers to States, must be implemented, according to MIPPA, by a date specified by the Secretary, but no later than November 15, 2008. Under section 1871(b)(1)(B) of the Act, prior notice and comment is not required when ''a statute establishes a specific deadline for the implementation of a provision and the deadline is less than 150 days after the date of the enactment of the statute in which the deadline is contained. The deadline for the marketing provisions that must be in effect by November 15th is less than 150 days after enactment of HIPAA, and these provisions thus may be published in final form without prior notice and comment.

2. Other Provisions

The remainder of the provisions in this IFC either update or revise existing regulations or add new regulations to conform to the statutory changes made by MIPAA. Since these provisions are set in law without regard to what public commenters might say, seeking public comment is unnecessary and contrary to the public interest.

B. Waiver of Delay of Effective Date

In addition, for those provisions discussed above which were required by statute to be in effect by a date specified by the Secretary, but in no case later than November 15, 2008, we find good cause to waive the 30-day delay in effective date that would otherwise apply under section 1871(e)(1)(B)(i) of the Act and section 553(d) of the Administrative Procedure Act (APA).

Section 553(d) of the APA and section 1871(e)(1)(B)(i) of the Act ordinarily require that a regulation be effective no earlier than 30 days after publication. Under section 553(d)(3) this requirement can be waived for good cause, and under section 1871(e)(1)(B)(ii) this requirement can be waived if necessary to comply with statutory requirements, or if a delay is contrary to the public interest.

As noted above, Congress enacted MIPPA on July 15, 2008 and directed that many of the marketing provisions in this rule be effective on a date specified by the Secretary, but in no event later than November 15, 2008, so that they could be implemented in time for this fall's marketing for the 2009 plan year. As a result, we find good cause to waive the APA delay of effective date, and find that a delay under section 1871 is contrary to the public interest.

In addition, 5 U.S.C. section 801 generally requires that agencies submit major rules to the Congress 60 days before the rules are scheduled to become effective. This delay does not apply, however, when there has been a finding of good cause for waiver of prior notice and comment as set forth above.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-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 Paperwork

Reduction Act of 1995 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.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

Section 422.101 Requirements Relating to Basic Benefits

Section 422.101(f)(1) states that MA organizations offering special needs plans must implement a model of care with care management as a centerpiece designed to meet the specialized needs of the plan's targeted enrollees.

The burden associated with this requirement is the time and effort put forth by the special needs plan to establish a model that meets the requirements under Section 422.101(f). In the initial year of development, we estimate it would take one special needs plan 80 hours per year to meet this requirement. In subsequent years, we estimate that it would take 10 hours per year to revise the model of care based on performance data analysis through the plan's quality improvement program. Existing SNPs already have models of care and will need to revise, not develop, models of care. We estimate the 335 existing SNPs would have a cumulative annual burden of 3,350 hours to revise their model of care. In January 2010, we anticipate that CMS will approve 150 new SNPs. We estimate the 150 new SNPs would have a cumulative initial year burden of 12,000 hours to develop their model of care, and a cumulative annual burden of 1,500 hours to revise their model of care in subsequent years. In summary, we project the total annual burden in calendar year 2009 to be 3,350 hours. In calendar year 2010, we project the total annual burden to be 13,500 hours (12,000 hours for SNPs approved to begin operating January 1, 2010 and 1,500 hours for SNPs approved prior to January 1, 2010).

Section 422.107 Special Needs Plans and Dual-Eligibles: Arrangements With States

Section 422.107(a) requires that an MA organization seeking to offer a special needs plan serving beneficiaries eligible for both Medicare and Medicaid (dual-eligible SNPs) must have a contract with the State Medicaid agency. The MA organization retains responsibility under the contract for providing benefits, or arranging for benefits to be provided, for individuals entitled to receive medical assistance under Title XIX. Such benefits may include long-term care services consistent with State policy.

Section 422.107 also allows MA organizations with an existing dual-eligible SNP without a State Medicaid agency contract to continue to operate through 2010 provided they meet all other statutory requirements, that is, care management and quality improvement requirements, and do not expand their service areas.

The burden associated with this requirement is the time and effort put forth by each dual-eligible special needs plan to contract with the State Medicaid agency. We estimate it would take one special needs plan 18 hours for 6 months to comply with this requirement. We estimate 460 special needs plans would be affected annually by this requirement; therefore, the total annual burden associated with this requirement is 16,560 hours.

Section 422.111 Disclosure Requirements

Section 422.111(b)(2)(iii) states that each special needs plan must provide for prospective dual-eligible individuals, prior to enrollment, a comprehensive written statement describing cost-sharing protections and benefits that the individual is entitled to under title XVIII and the State Medicaid program under title XIX. This may be developed by the special needs plans and distributed by the agents selling Medicare products.

The burden associated with this requirement is the time and effort put forth by each SNP to develop and provide such written statement. We estimate that it would take one special needs plan 10 hours for 6 months to comply with this requirement. We estimate 460 special needs plans would be affected annually by this requirement; therefore the total annual burden associated with this requirement is 4,600 hours.

Section 422.114 Access to Services Under an MA Private Fee-for-Service Plan

a. Clarification Regarding Utilization

The revised section 422.114(a)(2)(ii)(A) requires that for plan year 2010 and subsequent plan years, a PFFS plan that meets access requirements, with respect to a particular category of provider, by establishing contracts or agreements with a sufficient number and range of providers must meet the network accessibility and adequacy requirements described in Section 1852(d)(1) of the Act. This section of the statute describes the network adequacy requirements that coordinated care plans currently must meet when contracting with providers to furnish benefits covered under the plan.

CMS currently uses the network adequacy standards established for coordinated care plans in order to determine whether PFFS plans who want to meet access requirements under section 422.114(a)(2)(ii) satisfactorily meet those requirements. Therefore, we believe that there will be no additional burden on PFFS plans in order to comply with section 422.114(a)(2)(ii)(A).

b. Requirement for Certain Non-Employer PFFS Plans To Use Contract Providers

Section 422.114(a)(3) requires that for plan year 2011 and subsequent plan years, an MA organization that offers a PFFS plan that is operating in a network area as defined in section 422.114(a)(3)(i) meets the access requirements in section 422.114(a)(1) only if the MA organization has contracts or agreements with providers in accordance with the network accessibility and availability requirements described in Section 1852(d)(1) of the Act.

The burden associated with this requirement is that beginning in plan year 2011, an MA organization offering a PFFS plan will be required to create separate plans within its existing service area based on whether the counties located in that service area are considered network areas or not. We have 77 MA organizations currently offering 838 non-employer MA PFFS plans. We estimate that an additional 300 plans will be created as a result of organizations creating separate plan benefit packages for their network area and non-network area plans. We estimate that it will take 2 hours to create a new plan benefit package for a total of 600 hours to create 300 plan benefit packages.

c. Requirement for all Employer/Union-Sponsored PFFS Plans To Use Contracts With Providers

Section 422.114(a)(4) requires that an employer/union sponsored PFFS plan operating on or after plan year 2011 must establish written contracts or agreements with a sufficient number

and range of health care providers in its service area for all categories of services in accordance with the network accessibility and availability requirements described in Section 1852(d)(1) of the Act.

The burden associated with this requirement is the time and effort necessary for an organization offering an employer/union sponsored PFFS plan to submit the required application to CMS according to section 422.501. We estimate that approximately 100 hours would be required to complete an application. We project approximately 5 organizations will submit applications for a year, requiring 1000 hours of time by all applicants on an annual basis. This burden associated with the requirement under section 422.501 is captured in OMB #0938–0935.

Section 422.152 Quality Improvement Program

Section 422.152(g) states that MA organizations offering special needs plans must conduct a quality improvement program that (1) provides for the collection, analysis, and reporting of data that measures health outcomes and indices of quality at the plan level; (2) measures the effectiveness of its model of care; and (3) makes available to CMS information on quality and outcomes measures that will enable (i) beneficiaries to compare health coverage options, and (ii) CMS to monitor the plan's model of care performance.

The burden associated with this requirement is the time and effort put forth by the special needs plan to develop, collect, and analyze the quality and health outcomes measures that meet the requirements under Section 422.152(g). In the initial year of development, we estimate it would take one special needs plan 120 hours per year to meet this requirement. In subsequent years, we estimate that it would take 40 hours per year to revise the quality and health outcomes measures based on performance data analysis through the plan's quality improvement program.

The cumulative burden on SNPs is reflected in two parts: The burden on existing plans; and the burden on new SNPs approved to operate beginning on January 1, 2010. First, we estimate that, in calendar year 2009, the 335 existing SNPs would have a cumulative annual burden of 40,200 hours (120 hours × 335 plans) to develop the quality and health outcomes measures needed to evaluate their model of care and overall plan performance. In calendar year 2010 and subsequent years, the existing SNPs would have a cumulative annual burden of 13,400 hours (40 hours × 335 plans) to revise the quality and health outcomes measures based on performance data analysis through the plan's quality improvement program. Second, by January 1, 2010, we anticipate that CMS will approve 150 new SNPs. We estimate the 150 new SNPs would have a cumulative initial year (calendar year 2010) burden of 18,000 hours (120 hours × 150 plans) to develop their quality and health outcomes measures needed to evaluate their model of care and overall plan performance, and a cumulative annual burden of 6,000 hours (40 hours × 150 plans) to revise their model of care in subsequent years.

In summary, we project the cumulative annual burden in calendar year 2009 to be 40,200 hours. In calendar year 2010, we project the total annual burden to be 31,400 hours (13,400 hours for existing SNPs revising their measures, and 18,000 hours for new SNPs developing their measures).

Section 163 of MIPPA, as codified in new § 422.152(h), newly applies a general rule for quality improvement programs at § 422.152(a) to PFFS and MSA plans in 2010. Each MA organization that offers one or more MA plans must have, for each of those plans, an ongoing quality improvement program that meets the applicable requirements of this section for the services it furnishes to its MA enrollees. As part of its ongoing quality improvement program, a plan must—

- (1) Have a chronic care improvement program that meets the requirements of paragraph (c) of this section concerning elements of a chronic care program;
- (2) Conduct quality improvement projects that can be expected to have a favorable effect on health outcomes and enrollee satisfaction, and meet the requirements of paragraph (d) of this section; and
- (3) Encourage its providers to participate in CMS and HHS quality improvement initiatives.

Section 163 of MIPPA, as codified in § 422.152(h), also newly applies § 422.152(e)(2) to PFFS and MSA plans in 2011. Section 422.152(e)(2) are requirements that are currently applicable to local PPO organizations with contracted networks: § 422.152(e)(2) requires that MA organizations offering an MA regional plan or local PPO plan as defined in this section—

- (i) Measure performance under the plan using standard measures required by CMS and report its performance to CMS. The standard measures may be specified in uniform data collection and reporting instruments required by CMS.
- (ii) Evaluate the continuity and coordination of care furnished to enrollees.
- (iii) If the organization uses written protocols for utilization review, the organization must—
- (A) Base those protocols on current standards of medical practice; and
- (B) Have mechanisms to evaluate utilization of services and to inform enrollees and providers of services of the results of the evaluation.

These requirements relate to measuring of performance under the plans using standard measures required by CMS and to reporting this performance to CMS. The standard measures may be specified in uniform data collection and reporting instruments required by CMS and will relate to clinical areas including effectiveness of care, enrollee perception of care, and use of services and to non-clinical areas including access to and availability of services, appeals and grievances, and organizational characteristics.

The burden associated with this new reporting provision is the time it takes affected MA organizations to gather and submit the information. Reporting is usually required annually. Currently, the standard measures that will be required will most likely be those already captured in HEDIS and CAHPS, approved under OMB # 0938–0701. Note that CMS administers the CAHPS survey, and so the burden for CAHPS is minimal on plans.

The currently approved annual burden, per plan, for § 422.152 is estimated to be 400.53 hours.

Therefore, the total hours burden associated with this requirement, as estimated based on current numbers for each plan type = 400 hours for 1028 PFFS (employer and non-employer) plans and 400 hours for 10 MSA plans for 2010 and thereafter for a total of 415,200 hours.

Section 422.504 Contract Provisions

Section 422.504(g)(1) states that each MA organization must adopt and maintain arrangements satisfactory to CMS to protect its enrollees from incurring liability for payment of fees that are the legal obligation of the MA organization. This may be done by the establishment of identified liaison staff of the MA plan and the State Medicaid agency, and by conducting regular meetings for the purpose of enrollee review.

The burden associated with this requirement is the time and effort put forth by the each MA plan to adopt and

maintain arrangements. We estimate it would take one MA plan 208 hours to comply with this requirement. We estimate 3400 plans would be affected annually by this requirement; therefore, the total annual burden associated with this requirement is 707,200 hours.

Section 422.2268 Standards for MA Organization Marketing

Section 422.2268(g) states MA organizations cannot market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan, prior to the appointment.

The burden associated with this requirement is the time and effort put forth by the MA organization to document a beneficiary's signed acknowledgement confirming the specific types of choices that the marketing representative is authorized to discuss. While there is burden associated with this requirement, we feel the burden associated with these requirements is exempt from the requirements of the Paperwork Reduction Act of 1995 (PRA) as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

Section 422.2272 Licensing of Marketing Representatives and Confirmation of Marketing Resources

Section 422.2272(d) states that MA organizations must report to the State in which the MAO appoints an agent or broker, the termination of any such agent or broker, including the reasons for such termination if State law requires that the reasons for the termination be reported.

The burden associated with this requirement is the time and effort put forth by the MA organization to comply with the State requests for information. While there is burden associated with this requirement, we feel the burden associated with these requirements is exempt from the requirements of the Paperwork Reduction Act of 1995 (PRA) as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

Section 422.2274 Broker and Agent Compensation and Training of Sales Agents

Section 422.2274(b) states that if a MA organization markets through independent brokers or agents, they must train and test agents selling Medicare products concerning Medicare rules and regulations specific to the plan products they intend to sell.

The burden associated with this requirement is the time and effort put forth by the MA organization to provide training and test agents. While there is burden associated with this requirement, we feel the burden associated with these requirements is exempt from the requirements of the Paperwork Reduction Act of 1995 (PRA) as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

Section 422.2274(d) states that upon CMS' request, the organization must provide to CMS the information necessary for it to conduct oversight of marketing activities.

The burden associated with this requirement is the time and effort put forth by the organization to provide the requested information to CMS. We anticipate it would take 1 organization 480 minutes/8 hours to fulfill this requirement. We estimate 670 MA organizations would be affected annually by this requirement, therefore the total annual burden associated with this requirement is 5360 hours.

Section 423.520 Prompt Payment for Part D Sponsors

Section 423.520(a)(ii)(2) requires the Part D sponsor to notify the submitting network pharmacy that a submitted claim is not a clean claim. Such notification must specify all defects or improprieties in the claim and must list all additional information necessary for the proper processing and payment of the claim.

The burden associated with this requirement is the time and effort put forth by the Part D sponsor to provide proper notification to the network pharmacy. While there is burden associated with this requirement, we believe the burden associated with these requirements is exempt from the requirements of the Paperwork Reduction Act (PRA) of 1995, as defined in 5 CFR 1320.3(b)(2), because the time, effort, and financial resources necessary to comply with this requirement would be incurred by persons in the normal course of their activities.

Section 423.2268 Standards for Part D Marketing

Section 423.2268(g) states Part D organizations cannot market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan, prior to the appointment.

The burden associated with this requirement is the time and effort put forth by the Part D organization to document a beneficiary's signed acknowledgement confirming the specific types of choices that the marketing representative is authorized to discuss. While there is burden associated with this requirement, we feel the burden associated with these requirements is exempt from the requirements of the Paperwork Reduction Act of 1995 (PRA) as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

Section 423.2272 Licensing of Marketing Representatives and Confirmation of Marketing Resources

Section 423.2272(d) states that Part D sponsors must report to the State in which the Part D sponsor appoints an agent or broker, the termination of any such agent or broker, including the reasons for such termination if State law requires that the reasons for the termination be reported.

The burden associated with this requirement is the time and effort put forth by the Part D sponsor to comply with the State requests for information. While there is burden associated with this requirement, we feel the burden associated with these requirements is exempt from the requirements of the Paperwork Reduction Act of 1995 (PRA) as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

Section 423.2274 Broker and Agent Compensation and Training of Sales Agents

Section 423.2274(b) requires the Part D sponsor to ensure agents selling Medicare products are trained on Medicare rules and regulations specific to the plan products they intend to sell.

The burden associated with this requirement is the time and effort put forth by the Part D sponsor to provide training and test agents. While there is burden associated with this requirement, we feel the burden associated with these requirements is exempt from the requirements of the Paperwork Reduction Act of 1995 (PRA) as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the

requirement would be incurred by persons in the normal course of their activities.

Section 423.2274(d) states that the Part D sponsor provide information for it to conduct oversight of marketing activities upon CMS' request.

The burden associated with this requirement is the time and effort put forth the by the Part D sponsor to provide information to CMS. We anticipate it would take 1 Part D sponsor 480 minutes/8 hours to fulfill this requirement. We estimate 87 Part D sponsors would be affected annually by this requirement; therefore the total annual burden associated with this requirement is 696 hours.

Please note, CMS will revise the currently OMB approved PRA packages that contain Part 422—Medicare Advantage Program and Part 423—Voluntary Medicare Prescription Drug Benefit to include any new and/or revised burden requirements. The OMB approval numbers for those PRA packages are 0938–0753 and 0938–0964.

As reflected in the table that follows, the aggregate annual burden associated with the collection of information section for this rule totals 1,194,766.

TABLE 2—AGGREGATE ANNUAL BURDEN

OMB No.	Requirements	Number of respondents	Burden hours	Total annual burden
0938–0753	422.101(f)(1)	335	24	[1] 3,350
0938–0753	422.107(a)	460	20	16,560
0938–0753	422.111(b)(2)	460	10	[1] 4,600
0938–0753	422.114(a)(3)	300	2	600
0938–0753	422.114(a)(4)	10	100	1,000
0938–0753	422.152(g)	335	120	[1] 40,200
0938–0753	422.152(h)	1,038	400	415,200
0938–0753	422.504(g)(1)	3,400	208	[1] 707,200
0938–0753	422.2268(a)	N/A	N/A	N/A
0938–0964	422.2272(d)	N/A	N/A	N/A
0938–0964	422.2274(b)(d)	670	8	5,360
0938–0964	423.520	N/A	N/A	N/A
0938–0964	423.2268(a)	N/A	N/A	N/A
0938–0964	423.2272(d)	N/A	N/A	N/A
0938–0964	423.2274(b)(d)	87	8	696
Total Aggregate Burden				[1] 1,194,766

[1] = hours.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this rule; or

2. Mail copies to the address specified in the **ADDRESSES** section of this rule and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: CMS Desk Officer, CMS–4138–IFC *Brenda_Aguilar@omb.eop.gov*. Fax (202) 395–6974.

VI. Regulatory Impact Analysis

A. Overall Impact

Executive Order 12866 (as amended) 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). We estimate the prompt payment provisions to have an impact to the federal budget in an amount exceeding $100 million as specified in Table 3 which indicates $670 million in costs to the Federal government associated with these provisions from calendar year (CY) 2010 through CY 2018. Costs for provisions not related to prompt payment, which are indicated in Table 5, total $26.7 million, and will affect MA organizations and prescription drug plan sponsors. In addition, we project an incurred savings (before the Part B premium offset) ranging from $780 million in CY 2011 to $1.59 billion in CY 2018, representing savings to the Federal government of $8.1 billion over this period, as the result of the requirement for certain non-employer and all employer private-fee-for-service plans to establish contracts with providers (see Table 4). Including both the costs and savings to the Federal government as a result of the provisions in this IFC, we estimate a net savings of $7.43 billion to the Federal government over the period estimated. As a result, this interim final rule meets the threshold of being economically significant and is consequently a major rule.

B. Regulatory Flexibility Analysis

1. General

The RFA requires agencies to analyze options for regulatory relief of small businesses, if a rule has significant impact on a substantial number of small entities. Under the RFA, we are not required to conduct an initial regulatory flexibility analysis for interim final rules. However, it is our longstanding policy to provide an analysis whenever we believe it would aid understanding of the effects of the IFC. As a result, we provide, in separate sections below, an analysis of the prompt payment provisions and other provisions in the IFC that are not associated with these. For purposes of RFA, a small business (as determined by the Small Business Administration (SBA)), is a non-profit entity of any size that is not dominant in its field, or a small government jurisdiction. HHS uses an impact change of 3 to 5 percent on revenues in its threshold measure of a significant economic impact on a substantial number of small entities. Individuals and States are not included in the definition of a small entity. Small entities affected include small retail pharmacies, which we believe will have positive cost impacts; pharmacy benefit managers, which we believe will have

some additional costs; and MA organizations and Part D sponsors, which are not typically considered small entities. Cost impacts for these entities are discussed in further detail below.

2. Prompt Payment Provisions

The Secretary has determined that this rule will have a significant impact on a substantial number of small entities and that the prompt payment revisions will positively impact retail pharmacies while adding some additional cost impacts to Part D sponsors and pharmacy benefit managers (PBMs).

With respect to the provisions contained in this interim final rule, we discuss in further detail impacts to retail pharmacies, Part D sponsors, and pharmacy benefit managers (PBMs). The Small Business Administration (SBA) considers pharmacies with firm revenues less than $6.5 million to be small businesses. The 2004 Business Census (the latest available detailed data) indicated that there were approximately 19,443 firms operating about 40,115 retail pharmacies and drug store establishments (NAICS code 44611). Of these firms, 17,835 had revenues under $6.5 million and operated a total of 17,835 establishments. As a result, we estimate that more than 90 percent of retail pharmacy firms are small businesses (as defined by the SBA size standards).

Given this assumption, we estimate that the prompt payment provisions will positively impact a substantial number of small retail pharmacies. Our conversations with retail pharmacies indicate that those pharmacies able to provide remittances to wholesalers for invoices for drugs within a contractual 14 day period will receive a rebate of 1–3% off the total invoice price. The new prompt payment provisions requiring the payment by Part D plan sponsors of clean claims from pharmacies within 14 days of electronic submission will facilitate the payment of pharmacies' wholesalers for drugs within their contractual window and receiving the related discount. We do not anticipate that there will be any additional costs to pharmacies related to this provision.

The other small businesses that may be impacted by the provisions in this interim final rule are pharmacy benefit managers (PBMs). In our 2005 Part D final rule, we estimated approximately one hundred PBM firms. Since that time we have seen continued consolidation in this industry and believe there to be even a small number of PBMs, even thought there have been a handful of new entrants in the industry. We have no information on the size of the smaller firms in the industry, but it is likely that none of them, or at most a very small number would fall below the $6.5 million annual revenue threshold used by the SBA for defining ''small entities'' in the insurance industry. We address the impact of these provisions on health plans and PBMs with revenues greater than the $6.5 million dollar threshold in section B. However, we do believe that the prompt payment provisions may put small PBMs at a disadvantage as more frequent payments may result in a shorter float on cash and a loss of investment income.

Section 1102(b) of the Social Security Act requires us to prepare a regulatory flexibility 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. This rule will not affect small rural hospitals since the program will be directed at outpatient prescription drugs, not drugs provided during a hospital stay. As required by law, prescription drugs provided during hospital stays are covered under a separate Medicare payment system. Therefore, we are not providing an analysis in this rule.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. That threshold level is currently approximately $130 million. We anticipate that this interim final rule would not impose costs above the $130 million UMRA threshold on State, local, tribal governments, in the aggregate or by the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. The changes and additions contained in this interim final rule do not impose new costs on states or local governments. Thus, there are no anticipated Federalism implications.

Anticipated Effects on Health Plans and Pharmacy Benefit Managers (PBM)

Part D sponsors and their PBM subcontractors will be significantly impacted by a number of provisions contained in this interim final rule. We estimate that the prompt payment provisions contained this interim final rule will impose significant costs to PDPs, MA–PD plans, and their subcontractors. The industry expects that the shortened payment period will likely require sponsors to hold more cash reserves and lose the opportunity for accumulating interest. We estimate the loss of investment income resulting from the prompt payment provisions to increase the costs of the Part D program by $670 million from CY 2010 through CY 2018.

CMS requests comments and information on the accuracy and completeness of our estimates.

3. Other Provisions

Although other provisions of this rule do not exceed $100 million, because there are costs to plans and sponsors associated with several provisions of this rule, we indicate in Table 5 general areas affected and specify the cost impacts associated with these other provisions of the rule. For specific burden associated with the proposed requirements and the bases for our estimates, see section IV, Collection of Information Requirements, of this rule.

For the cost impact estimates for provisions other than the prompt payment provisions, we use, as appropriate, the figures of $14.68 (based on the United States Department of Labor (DOL) statistics for the hourly wages of word processors and typists) and $37.15 (based on DOL statistics for a management analyst) [1] plus the added OMB figures of 12 percent for overhead and 36 percent for benefits, respectively, to represent average costs to plans, sponsors and downstream entities for the provisions discussed in this proposed rule with comment period (note that the wages cited for the provisions below include the hourly wage + an additional 48 percent to reflect overhead, benefit costs for total wages of $21.73 and $54.98, respectively). Also, it should be noted that while we believe there may be costs for special needs plans to hire medical personnel or senior staff not captured above for the state contracting and model of care provisions, we are unsure of the costs for these and thus are

[1] The hourly rates for the burden requirement were developed using the Department of Labor, Bureau of Labor Statistics for May 2006 (National Occupational Employment and Wage Estimates).

requesting comments on additional cost impacts for these provisions.

In the Regulatory Impact Analysis of the January 28, 2005 final rule (70 FR 4695) revising the Medicare Advantage program, we noted that costs associated with the MA program would be approximately $18.3 billion from 2004 through 2009, 10 percent of which we estimated will be administrative costs. The rule establishing the prescription drug benefit program published on January 28, 2005 (70 FR 4194) made a similar calculation in its Regulatory Impact Statement. Administrative costs associated with the provisions of this final rule, then, add negligibly to the total administrative costs of the MA or Part D programs.

With respect to economic benefits, we have no reliable basis for estimating the effects of these proposals. Many of the proposed changes clarify or codify existing policies though such clarification could contribute to greater plan efficiency and compliance with program regulations. Accordingly, we estimate that while there could be economic benefits associated with these proposals, they are difficult to gauge at this time.

Special Needs Plans (Part C)

Several of our provisions concern special needs plans and strengthening coordination between plans and States to better coordinate care, developing models of care, and ensuring that enrollees are not charged for costs that are the responsibility of the State. A breakdown of costs for each provision are as follows:

- Developing models of care ($54.98 × 3,350 hours = $184,183).
- Contracting with States ($54.98 × 16,560 hours = $910,469).
- Developing dual-eligible written information on both Medicare and Medicaid cost-sharing and benefits ($21.73 × 4,600 hours = $99,958).
- Collecting, analyzing, and reporting data that measures health outcomes and indices of quality on its model of care ($54.98 × 40,200 hours = $2,210,196).

Private Fee-for-Service Plans (Part C)

CMS estimates an incurred savings (before the Part B premium offset) of $780 million for CY 2011 to $1.59 billion in CY 2018 as a result of the requirement that certain non-employer and all employer PFFS plans establish contracts with providers.

To do the estimates, we considered the number of counties that had PFFS plans, and the number of members. We then saw how many coordinated care plans were currently operating in each of these counties (excluding regional PPOs). This gave us a basis to project how many PFFS plans and members would be subject to the new requirement to set up networks of providers by 2011.

Based on the information, as well as the level of payments that these plans receive from CMS, we estimated how many members would end up in PFFS plans that did not need to form networks; how many would be in plans that converted to network PFFS plans, how many would end up in a coordinated care plan; and how many would switch to original Medicare. We used different assumptions for individual plans and for group plans. However, for both group and individual plans, we assumed that most members would remain in a PFFS plan (either network or non-network).

For members who stayed in either a network or non-network PFFS plan, we assumed a higher plan bid and, therefore, cost to Medicare. In contrast, we assumed a savings for those that we estimate will go to a coordinated care plan, and a larger savings for those who go to original Medicare.

We indicate the estimated incurred savings over this period in Table 4.

Costs for each provision, as shown in Table 5, affecting private fee-for-service (PFFS) plans are as follows:

- Certain non-employer PFFS plans establishing contracts with providers ($54.98 × 600 hours = $32,988).
- Employer/union sponsored PFFS plans establishing contracts with providers ($54.98 × 1,000 hours = $54,980).
- PFFS and MSA plans developing quality improvement programs ($54.98 × 415,200 hours) = $22,827,696.

Marketing (Parts C and D)

Costs for each marketing provision, in the context of each program, are as follows:

- Training and testing of agents selling Medicare products, MA program ($54.98 × 5,360 hours = $294,692).
- Training and testing of agents selling Medicare products, Part D ($54.98 × 696 hours = $38,266)

CMS requests comments and information on the accuracy and completeness of our estimates.

TABLE 3—PROJECTED PART D (NON-MARKETING) COSTS FOR CY 2010–2018

[Millions of dollars]

	CY 2010	CY 2011	CY 2012	CY 2013	CY 2014	CY 2015	CY 2016	CY 2017	CY 2018	CY 2010–2018
Prompt payment by prescription drug plans and MA–PD plans under Part D	50	50	60	60	70	80	90	100	110	670

TABLE 4—PROJECTED INCURRED SAVINGS FOR NON-EMPLOYER AND EMPLOYER PFFS NETWORK PROVISION

[Millions of dollars]

	CY 2011	CY 2012	CY 2013	CY 2014	CY 2015	CY 2016	CY 2017	CY 2018	CY 2011–2018
Total HI (MC and FFS)	420	470	520	580	640	690	760	830	4,910
Total SMI (MC and FFS)	360	400	460	490	540	600	670	760	4,280
Total Medicare (before Part B premium offset)	780	870	980	1,070	1,180	1,290	1,430	1,590	9,190
Total Medicare (after Part B premium offset)	690	770	860	950	1,040	1,140	1,260	1,400	8,110

TABLE 5—PROJECTED ANNUAL COSTS TO MAOS AND PDP SPONSORS: OTHER PROVISIONS

Provision	CY effective	Projected costs
Special needs plan: developing models of care	2010	$184,183
Special needs plan: contracting with States	2010	910,469
Special needs plan: developing written information on both Medicare and Medicaid cost-sharing and benefits for dual-eligible beneficiaries.	2010	99,958
Special needs plan: collecting, analyzing, and reporting data related to model of care concerning health outcomes and indices of quality.	2010	2,210,196
Training and testing of agents and brokers (Part C and Part D programs)	October 2008	332,958
Certain non-employer PFFS plans establishing contracts with providers	2011	32,988
Employer/union sponsored PFFS plans establishing contracts with providers	2011	54,980
PFFS and MSA plans developing quality improvement programs	2010	22,827,696
Total		26,653,428

C. Alternatives Considered

All of the economically significant provisions in this interim final rule are a result of the recent passage of MIPPA and are self-implementing. While we had no discretion with these statutory provisions, we desired to make our resulting regulations available to industry and the public as soon as possible to facilitate continued, efficient operation of the Part C and D programs. Regarding the other provisions contained in this interim final rule, we considered not issuing further guidance in these areas, but we believed that in order to ensure public awareness of our policies, as well as to avoid potential confusion regarding them, we should codify our policies in this interim final rule.

D. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/index.html*), in Table 6 below, we have prepared an accounting statement showing the classification of the expenditures associated with the prompt payment provisions of this final rule and the benefits associated with the PFFS network provisions. This table provides our best estimate of the costs and savings as a result of the changes presented in this interim final rule. All costs are classified as transfers by the Federal Government to PDP sponsors or MAOs.

TABLE 6—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

Category	Transfers ($ millions)
Incurred savings for the Non-Employer and Employer PFFS Network Provision, CYs 2011–2018	
Undiscounted Annualized Monetized Transfers	$1,013.8.
Annualized Monetized Transfers Using 7% Discount Rate	$838.4.
Annualized Monetized Transfers Using 3% Discount Rate	$873.9.
From Whom to Whom? (Represents a reduction of transfers from the Federal Government to non-network/network PFFS Plans.).	PFFS Plans to the Federal Government.
Prompt payment by prescription drug plans and MA–PD plans under Part D, CYs 2010–2018	
Undiscounted Annualized Monetized Transfers	$74.4.
Annualized Monetized Transfers Using 7% Discount Rate	$71.0.
Annualized Monetized Transfers Using 3% Discount Rate	$72.9.
From Whom to Whom?	Federal Government to Part D Sponsors.
Costs for all other (non-marketing) provisions not related to Part D	
Undiscounted Annualized Monetized Costs	$26.7.
Who Is Affected?	MAOs/PDP Sponsors.

E. Conclusion

Given that we expect the cost of implementing a number of the provisions contained in this interim final rule, as specified in Table 3, will exceed the $100 million threshold within a single year between CY 2010 and CY 2018, we conducted an economic impact analysis with regard to those entities potentially impacted by these provisions. As we stated previously, we expect that entities such as pharmacies will benefit from these changes, whereas other entities, such as PBMs and Part D sponsors, will experience additional costs which they will pass on to CMS through direct subsidy payments and beneficiaries through additional premiums as reflected in their bids. The prompt payment provisions account for the primary cost impacts associated with this IFC, ranging from $50 million in CY 2010 to $110 million in CY 2018. Cost impacts for the other provisions of this IFC will total slightly more than $26.7 million in the years indicated when the provisions become effective. As discussed, we also estimate a savings ranging from $780 million in CY 2011 to $1.59 billion in CY 2018 as a result of the requirement that non-employer private-fee-for-service plans have networks beginning in 2011.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 417

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 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, 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 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

■ 1. The authority citation for part 417 continues to read as follows:

Authority: Sec. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), secs. 1301, 1306, and 1310 of the Public Health Service Act (42 U.S.C. 300e, 300e–5, and 300e–9), and 31 U.S.C. 9701.

Subpart J—Qualifying Conditions for Medicare Contracts

■ 2. Amend § 417.402 by—
■ A. Revising paragraph (c)(1).
■ B. Revising paragraph (c)(2).
■ C. Revising paragraph (c)(3).
The revisions read as follows:

§ 417.402 Effective date of initial regulations.

* * * * *

(c) * * *

(1) There were two or more coordinated care plan-model MA regional plans not offered by the same MA organization in the same service area or portion of a service area for the entire previous calendar year meeting the conditions in paragraph(c)(3) of this section; or

(2) There were two or more coordinated care plan-model MA local plans not offered by the same MA organization in the same service area or portion of a service area for the entire previous calendar year meeting the conditions in paragraph (c)(3) of this section.

(3) *Minimum enrollment requirements*. With respect to any service area or portion of a service area that is within a Metropolitan Statistical Area (MSA) with a population of more than 250,000 and counties contiguous to the MSA that are not in another MSA with a population of more than 250,000, 5000 enrolled individuals. If the service area includes a portion in more than one MSA with a population of more than 250,000, the minimum enrollment determination is made with respect to each such MSA and counties contiguous to the MSA.

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 3. 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

■ 4. Amend § 422.4 by—
■ A. Republishing paragraph (a) introductory text.
■ B. Revising paragraph (a)(3)(ii).
The revision reads as follows:

§ 422.4 Types of MA plans.

(a) *General rule*. An MA plan may be a coordinated care plan, a combination of an MA MSA plan and a contribution into an MA MSA established in accordance with § 422.262, or an MA private fee-for-service plan.

(3) * * *

(ii) Subject to paragraphs (a)(3)(ii)(A) and (B) of this section, does not vary the rates for a provider based on the utilization of that provider's services; and

(A) May vary the rates for a provider based on the specialty of the provider, the location of the provider, or other factors related to the provider that are not related to utilization and do not violate § 422.205 of this part.

(B) May increase the rates for a provider based on increased utilization of specified preventive or screening services.

* * * * *

Subpart C—Benefits and Beneficiary Protections

■ 5. Amend § 422.101 by adding paragraph (f) to read as follows:

§ 422.101 Requirements relating to basic benefits.

* * * * *

(f) *Special Needs Plan Model of Care*. (1) MA organizations offering special needs plans (SNP) must implement an evidence-based model of care with appropriate networks of providers and specialists designed to meet the specialized needs of the plan's targeted enrollees. The MA organization must, with respect to each individual enrolled—

(i) Conduct a comprehensive initial health risk assessment of the individual's physical, psychosocial, and functional needs as well as annual health risk reassessment, using a comprehensive risk assessment tool that CMS will review during oversight activities.

(ii) Develop and implement a comprehensive individualized plan of care through an interdisciplinary care team in consultation with the beneficiary, as feasible, indentifying goals and objectives including measurable outcomes as well as specific services and benefits to be provided.

(iii) Use an interdisciplinary team in the management of care.

(2) [Reserved]

■ 6. Add new section § 422.107 to read as follows:

§ 422.107 Special needs plans and dual-eligibles: Contract with State Medicaid Agency.

(a) *Definition*. For the purpose of this section, a contract with a State Medicaid agency means a formal written agreement between an MA organization and the State Medicaid agency documenting each entity's roles and responsibilities with regard to dual-eligible individuals.

(b) *General rule*. MA organizations seeking to offer a special needs plan serving beneficiaries eligible for both Medicare and Medicaid (dual-eligible) must have a contract with the State Medicaid agency. The MA organization retains responsibility under the contract for providing benefits, or arranging for benefits to be provided, for individuals entitled to receive medical assistance under title XIX. Such benefits may include long-term care services consistent with State policy.

(c) *Minimum contract requirements*. At a minimum, the contract must document—

(1) The MA organization's responsibility, including financial obligations, to provide or arrange for Medicaid benefits.

(2) The category(ies) of eligibility for dual-eligible beneficiaries to be enrolled under the SNP, as described under the Statute at sections 1902(a), 1902(f), 1902(p), and 1905.

(3) The Medicaid benefits covered under the SNP.

(4) The cost-sharing protections covered under the SNP.

(5) The identification and sharing of information on Medicaid provider participation.

(6) The verification of enrollee's eligibility for both Medicare and Medicaid.

(7) The service area covered by the SNP.

(8) The contract period for the SNP.

(d) *Date of Compliance.* (1) Effective January 1, 2010—

(i) MA organizations offering a new dual-eligible SNP must have a State Medicaid agency contract.

(ii) MA organizations with an existing dual-eligible SNP without a State Medicaid agency contract may continue to operate through 2010 provided they meet all other statutory requirements, that is, care management and quality improvement program requirements. However, they cannot expand their service areas during 2010.

(2) [Reserved]

■ 7.Amend § 422.111 by—

■ A. Redesignating paragraph (b)(2)(iii) as (b)(2)(iv).

■ B. Adding new paragraph (b)(2)(iii) to read as follows:

§ 422.111 Disclosure requirements.

* * * * *

(b) * * *

(2) * * *

(iii) For a Special Needs Plan for dual-eligible individuals, prior to enrollment, for each prospective enrollee, a comprehensive written statement describing cost sharing protections and benefits that the individual is entitled to under title XVIII and the State Medicaid program under title XIX.

* * * * *

■ 8. Amend § 422.114 by—

■ A. Revising paragraph (a)(2) introductory text.

■ B. Revising paragraph (a)(2)(ii).

■ C. Adding paragraph (a)(3).

■ D. Adding paragraph (a)(4).

The revisions and additions read as follows:

§ 422.114 Access to services under an MA private fee-for-service plan.

(a) * * *

(2) Subject to paragraphs (a)(3) and (a)(4) of this section, CMS finds that an MA organization meets the requirement in paragraph (a)(1) of this section if, with respect to a particular category of health care providers, the MA organization has—

(i) * * *

(ii) Subject to paragraph (A) of section (a)(2)(ii), contracts or agreements with a sufficient number and range of providers to furnish the services covered under the MA private fee-for-service plan; or

(A) For plan year 2010 and subsequent plan years, contracts or agreements with a sufficient number and range of providers to meet the access standards described in section 1852(d)(1) of the Act.

(B) [Reserved]

* * * * *

(3) For plan year 2011 and subsequent plan years, an MA organization that offers an MA private fee-for-service plan (other than a plan described in section 1857(i)(1) or (2) of the Act) that is operating in a network area (as defined in paragraph (a)(3)(i) of this section) meets the requirement in paragraph (a)(1) of this section only if the MA organization has contracts or agreements with providers in accordance with paragraph (a)(2)(ii)(A) of this section.

(i) Network area is defined, for a given plan year, as the area that the Secretary identifies in the announcement of the risk and other factors to be used in adjusting MA capitation rates for each MA payment area for the previous plan year as having at least 2 network-based plans (as defined in paragraph (a)(3)(ii) of this section) with enrollment as of the first day of the year in which the announcement is made.

(ii) Network-based plan is defined as a coordinated care plan as described in § 422.4(a)(1)(ii), a network-based MSA plan, or a section 1876 reasonable cost plan. A network-based plan excludes a MA regional plan that meets access requirements substantially through the authority of § 422.112(a)(1)(ii) instead of written contracts.

(4) For plan year 2011 and subsequent plan years, an MA organization that offers an MA private fee-for-service plan that is described in section 1857(i)(1) or (2) of the Act meets the requirement in paragraph (a)(1) of this section only if the MA organization has contracts or agreements with providers in accordance with paragraph (a)(2)(ii)(A) of this section.

* * * * *

Subpart D—Quality Improvement

■ 9. Amend § 422.152 by—

■ A. Revising paragraph (a) introductory text.

■ B. Adding paragraph (g).

■ C. Adding paragraph (h).

The revisions read as follows:

§ 422.152 Quality improvement program.

(a) *General rule.* Each MA organization that offers one or more MA plans must have, for each of those plans, an ongoing quality improvement program that meets applicable requirements of this section for the service it furnishes to its MA enrollees. As part of its ongoing quality improvement program, a plan must—

* * * * *

(g) *Special requirements for specialized MA Plans for special needs individuals.* A SNP must conduct a quality improvement program that—

(1) Provides for the collection, analysis, and reporting of data that measures health outcomes and indices of quality pertaining to its targeted special needs population (that is, dual-eligible, institutionalized, or chronic condition) at the plan level.

(2) Measures the effectiveness of its model of care through the collection, aggregation, analysis, and reporting of data that demonstrate the following:

(i) Access to care as evidenced by measures from the care coordination domain (for example, service and benefit utilization rates, or timeliness of referrals or treatment).

(ii) Improvement in beneficiary health status as evidenced by measures from functional, psychosocial, or clinical domains (for example, quality of life indicators, depression scales, or chronic disease outcomes).

(iii) Staff implementation of the SNP model of care as evidenced by measures of care structure and process from the continuity of care domain (for example, National Committee for Quality Assurance accreditation measures or medication reconciliation associated with care setting transitions indicators).

(iv) Comprehensive health risk assessment as evidenced by measures from the care coordination domain (for example, accuracy of acuity stratification, safety indicators, or timeliness of initial assessments or annual reassessments).

(v) Implementation of an individualized plan of care as evidenced by measures from functional, psychosocial, or clinical domains (for example, rate of participation by IDT members and beneficiaries in care planning).

(vi) A provider network having targeted clinical expertise as evidenced by measures from medication management, disease management, or behavioral health domains.

(vii) Delivery of services across the continuum of care.

(viii) Delivery of extra services and benefits that meet the specialized needs of the most vulnerable beneficiaries as evidenced by measures from the psychosocial, functional, and end-of-life domains.

(ix) Use of evidence-based practices and nationally recognized clinical protocols.

(x) Use of integrated systems of communication as evidenced by

measures from the care coordination domain (for example, call center utilization rates, rates of beneficiary involvement in care plan development, etc.).

(3) Makes available to CMS information on quality and outcomes measures that will—

(i) Enable beneficiaries to compare health coverage options; and

(ii) Enable CMS to monitor the plan's model of care performance.

(h) *Requirements for MA private-fee-for-service plans and Medicare medical savings account plans.* (1) Subject to paragraph (h)(2) of this section, MA PFFS and MSA plans are subject to requirements that may not exceed the requirements specified in § 422.152(e).

(2) For plan year 2010, MA PFFS and MSA plans are not subject to the limitations under § 422.152(e)(1)(i) and must meet the requirements using administrative claims data only.

Subpart E—Relationships With Providers

■ 10. Revise paragraph (a) of § 422.216 as follows:

§ 422.216 Special Rules for MA private-fee-for-service plans.

(a) *Payment to Providers*—(1) *Payment Rate.* (i) The MA organization must establish payment rates for plan covered items and services that apply to deemed providers. The MA organization may vary payment rates for providers in accordance with § 422.4(a)(3).

(ii) Providers must be reimbursed on a fee-for-service basis.

(iii) The MA organization must make information on its payment rates available to providers that furnish services that may be covered under the MA private fee-for-service plan.

(2) *Noncontract providers.* The organization pays for services of noncontract providers in accordance with § 422.100(b)(2).

(3) *Services furnished by providers of service.* Any provider of services as defined in section 1861(u) of the Act that does not have in effect a contract establishing payment amounts for services furnished to a beneficiary enrolled in an MA private fee-for-service plan must receive, and accept as payment in full, at least the amount (less any payments under §§ 412.105(g) and 413.76 of this chapter) that it could collect if the beneficiary were enrolled in original Medicare.

* * * * *

Subpart G—Payments to Medicare Advantage Organizations

■ 11. Amend § 422.306 by—

■ A. Revising the introductory text.

■ B. Adding paragraph (c).

The revisions and additions read as follows:

§ 422.306 Annual MA capitation rates.

Subject to adjustments at § 422.308(b) and § 422.308(g), the annual capitation rate for each MA local area is determined under paragraph (a) of this section for 2005 and each succeeding year, except for years when CMS announces under § 422.312(b) that the annual capitation rates will be determined under paragraph (b) of this section, and is then adjusted to exclude the applicable phase-in percentage of the standardized costs for payments under section 1886(d)(5)(B) of the Act in the area for the year under paragraph (c) of this section.

* * * * *

(c) *Phase-out of the indirect costs of medical education from MA capitation rates.* Beginning with 2010, after the annual capitation rate for each MA local area is determined under paragraph (a) or (b), the amount is adjusted in accordance with section 1853(k)(4) of the Act to exclude from such amount the phase-in percentage for the year of the estimated costs for payments under section 1886(d)(5)(B) of the Act in the area for the year.

Subpart K—Contracts With Medicare Advantage Organizations

■ 12. Amend § 422.504 by adding paragraph (g)(1)(iii) to read as follows:

§ 422.504 Contract provisions.

* * * * *

(g) * * *

(1) * * *

(iii) For full-benefit dual-eligible individuals or qualified Medicare beneficiaries, plans may not impose cost sharing exceeding the amount that would be permitted to the individual under title XIX if the individual were not enrolled in the SNP.

* * * * *

Subpart V—Medicare Advantage Marketing Requirements

■ 13. Amend § 422.2268 by—

■ A. Adding paragraph (b)

■ B. Adding paragraph (g).

■ C. Adding paragraph (h).

■ D. Adding paragraph (n).

■ E. Adding paragraph (q).

The additions to read as follows:

§ 422.2268 Standards for MA organization marketing.

* * * * *

(b) Offer gifts to potential enrollees, unless the gifts are of nominal (as defined in the CMS Marketing Guidelines) value, are offered to all potential enrollees without regard to whether or not the beneficiary enrolls, and are not in the form of cash or other monetary rebates.

* * * * *

(g) Market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan, prior to the appointment.

(h) Market additional health related lines of plan business not identified prior to an in-home appointment without a separate appointment that may not be scheduled until 48 hours after the initial appointment.

* * * * *

(n) Display the names and/or logos of co-branded network providers on the organization's member identification card, unless the provider names, and/or logos are related to the member selection of specific provider organizations (for example, physicians, hospitals). Other marketing materials (as defined in § 422.2260) that include names and/or logos of provider co-branding partners must clearly indicate that other providers are available in the network.

* * * * *

(q) Use a plan name that does not include the plan type. The plan type should be included at the end of the plan name.

■ 14. Amend § 422.2272 by adding paragraph (d) to read as follows:

§ 422.2272 Licensing of marketing representatives and confirmation of marketing resources.

* * * * *

(d) Report to the State in which the MAO appoints an agent or broker, the termination of any such agent or broker, including the reasons for such termination if State law requires that the reasons for the termination be reported.

■ 15. Add § 422.2274 to read as follows:

§ 422.2274 Broker and agent requirements.

If a Medicare Advantage organization markets through employed or independent brokers or agents—

(a) Agents and brokers must be compensated as follows:

(1) An MA plan (or other entity on its behalf) may provide compensation to a broker or agent for the sale of a MA product only if the aggregate of the first year compensation is no more than 200 percent of the aggregate of the compensation paid for selling or servicing the enrollee in each individual subsequent renewal year, of which there

must be a total of five renewal years (creating a 6-year compensation cycle). For purposes of this section, ''compensation''—

(i) Includes pecuniary or non-pecuniary remuneration of any kind relating to the sale or renewal of the policy including but not limited to commissions, bonuses, gifts, prizes, awards and finders fees.

(ii) Does not include salary or other benefits related to employment, except to the extent that the salary or other benefits are related to the volume of sales.

(iii) Does not include the payment of fees to comply with State appointment laws, training, certification, and testing costs; and reimbursement for mileage to and from appointments with beneficiaries and reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials.

(2) If compensation is paid in the first year, renewal compensation must be paid for no fewer than 5 renewal years (6-year compensation cycle), provided that the enrollee remains enrolled in the plan.

(3) No entity shall provide aggregate compensation to its agents or brokers and no agent or broker shall receive aggregate compensation greater than the renewal compensation payable by the replacing plan on renewal policies if an existing policy is replaced with a like plan type during the first year and 5 renewal years (6-year compensation cycle).

(i) For purposes of this section, ''like plan type'' means PDP replaced with another PDP, MA or MA–PD replaced with another MA or MA–PD, or cost plan replaced with another cost plan.

(ii) Replacements between different plan types (for which a new compensation is paid) include—PDP and MA–PD, PDP and cost plans, or MA–PD and cost plans.

(4) Compensation shall be earned for months 4 through 12 of the enrollment year.

(i) Plans may pay agents and brokers up-front or prorate compensation payments over 12 months or over months 4 through 12, but

(ii) When a beneficiary disenrolls from the plan, the plan must recover all compensation paid: for months in which the beneficiary is not enrolled; and during months 1 through 3 if the beneficiary disenrolls during the first three months.

(5) Organizations and sponsors must establish a compensation structure for new and replacement enrollments and renewals effective in a given plan year. Compensation structures must be in place by the beginning of the plan marketing period, October 1.

(6) Compensation structures must be available upon CMS request including for audits, investigations, and to resolve complaints.

(b) It must ensure agents selling Medicare products are trained annually on Medicare rules and regulations specific to the plan products they intend to sell.

(c) It must ensure agents selling Medicare products are tested annually, as specified in CMS guidance.

(d) Upon CMS' request, the organization must provide to CMS, in a form consistent with current CMS guidance, the information necessary for it to conduct oversight of marketing activities.

(e) It must comply with State requests for information about the performance of a licensed agent or broker as part of a state investigation into the individual's conduct. CMS will establish and maintain a memorandum of understanding (MOU) to share compliance and oversight information with States that agree to the MOU.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 16. 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 B—Eligibility and Enrollment

■ 17. Amend § 423.46 by revising paragraph (a) introductory text to read as follows:

§ 423.46 Late enrollment penalty.

(a) *General.* A Part D eligible individual must pay the late penalty described under § 423.286(d)(3), except as described at § 423.780(e), if there is a continuous period of 63 days or longer at any time after the end of the individual's initial enrollment period during which the individual meets all of the following conditions:

* * * * *

Subpart G—Payments to Part D Plan Sponsors for Qualified Prescription Drug Coverage

■ 18. Amend § 423.322 by revising paragraph (b) to read as follows:

§ 423.322 Requirement for disclosure of information.

* * * * *

(b) *Restrictions on use of information.* Officers, employees and contractors of the Department of Health and Human Services may use the information disclosed or obtained in accordance with the provisions of this subpart only for the purposes of, and to the extent necessary in, carrying out this subpart including, but not limited to, determination of payments, and payment-related oversight, and program integrity activities.

(1) This restriction does not limit OIG's authority to fulfill the Inspector General's responsibilities in accordance with applicable Federal law.

(2) This restriction does not limit CMS' ability to use data regarding drug claims in accordance with section 1848(m) of the Act.

Subpart K—Application Procedures and Contracts with Part D Plan Sponsors

■ 19. Amend § 423.505 by—
■ A. Adding paragraph (b)(19).
■ B. Adding paragraph (b)(20).
■ C. Adding paragraph (b) (21).
■ D. Adding paragraph (i)(3)(iv) through (vi).
■ E. Revising paragraph (m)(1) introductory text.
■ F. Revising (m)(1)(iii)(A).
■ G. Revising paragraph (m)(1)(iv).
■ H. Adding paragraph (m)(3).

The additions and revisions read as follows.

§ 423.505 Contract provisions.

* * * * *

(b) * * *

(19) Effective contract year 2010, include the prompt payment provisions described in § 423.520.

(20) Effective contract year 2010, provide that pharmacies located in, or having a contract with, a long-term care facility (as defined in § 423.100) must have not less than 30 days, nor more than 90 days, to submit to the Part D sponsor claims for reimbursement under the plan.

(21) Effective contract year 2009, update any prescription drug pricing standard for reimbursement of network pharmacies based on the cost of a drug used by the Part D sponsor on—

(i) January 1 of each contract year; and

(ii) Not less frequently than once every 7 days after the date in paragraph (b)(21)(i) of this section.

* * * * *

(i) * * *

(3) * * *

(iv) A provision requiring prompt payment of clean claims by the Part D sponsor, consistent with § 423.520.

(v) A provision that establishes timeframes, consistent with § 423.505(b)(20), for long-term care

pharmacies to submit claims to the Part D sponsor for reimbursement under the plan.

(vi) If applicable, a provision—

(A) Establishing regular updates of any prescription drug pricing standard used by the Part D sponsor consistent with § 423.505(b)(21); and

(B) Indicating the source used by the Part D sponsor for making any such pricing updates.

* * * * *

(m)(1) CMS may release the minimum data necessary for a given purpose from the data collected under paragraph (f)(3) of this section to Federal executive branch agencies, States, and external entities in accordance with the following:

* * * * *

(iii) * * *

(A) Subject to the restrictions in this paragraph, all elements on the claim are available to HHS.

* * * * *

(iv) For purposes of paragraph (m)(1)(iii) of this section, States and executive-branch Federal agencies are not considered to be external entities.

* * * * *

(3) CMS shall make available to Congressional support agencies (the Congressional Budget Office, the Government Accountability Office, the Medicare Payment Advisory Commission, and the Congressional Research Service when it is acting on behalf of a Congressional committee in accordance with 2 U.S.C. 166(d)(1)) all information collected under paragraph (f)(3) of this section for the purposes of conducting congressional oversight, monitoring, making recommendations, and analysis of the Medicare program.

■ 20. Add 423.520 to read as follows:

§ 423.520 Prompt payment by Part D sponsors.

(a) *Contract between CMS and the Part D sponsor.* (1) Effective contract year 2010, the contract between the Part D sponsor and CMS must provide that the Part D sponsor will issue, mail, or otherwise transmit payment with respect to all clean claims, as defined in paragraph (b) of this section, submitted by network pharmacies (other than mail-order and long-term care pharmacies) within—

(i) 14 days after the date on which the claim is received, as defined in paragraph (a)(2)(i) of this section, for an electronic claim; or

(ii) 30 days after the date on which the claim is received, as defined in paragraph (a)(2)(ii) of this section, for any other claim.

(2) *Date of receipt of claim.* A claim is considered to have been received—

(i) On the date on which the claim is transferred, for an electronic claim; or

(ii) On the 5th day after the postmark day of the claim or the date specified in the time stamp of the transmission, for any other claim, whichever is sooner.

(b) *Clean claim.* A clean claim means a claim that has no defect or impropriety (including any lack of any required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment of the claim from being made under this section.

(c) *Procedures involving claims*—(1) *Claims determined to be clean.* A claim is deemed to be a clean claim if the Part D sponsor receiving the claim does not provide notice to the submitting network pharmacy of any deficiency in the claim within—

(i) 10 days after the date on which the claim is received, as defined in paragraph (a)(2)(i) of this section, for an electronic claim; or

(ii) 15 days after the date on which the claim is received, as defined in paragraph (a)(2)(ii) of this section, for any other claim.

(2) *Claims determined not to be clean*—(i) *General.* If a Part D sponsor determines that a submitted claim is not a clean claim, as defined in paragraph (b) of this section, the Part D sponsor must notify the submitting network pharmacy of such determination within the period described in paragraph (c)(1) of this section. Such notification must specify all defects or improprieties in the claim and must list all additional information necessary for the proper processing and payment of the claim.

(ii) *Determination after submission of additional information.* A claim is deemed to be a clean claim under paragraph (b) of this section if the Part D sponsor that receives the claim does not provide notice to the submitting network pharmacy of any defect or impropriety in the claim within 10 days of the date on which additional information is received under paragraph (c)(2)(i) of this section.

(3) *Obligation to pay.* A claim submitted to a Part D sponsor that is not paid or contested by the Part D sponsor within the timeframes specified in paragraphs (a)(1)(i) and (ii) of this section must be deemed to be a clean claim and must be paid by the Part D sponsor in accordance with paragraph (a) of this section.

(d) *Date of payment of claim.* Payment of a clean claim under paragraph (c)(3) of this section is considered to have been made on the date on which—

(1) The payment is transferred, for an electronic claim; or

(2) The payment is submitted to the United States Postal Service or common carrier for delivery, for any other claim.

(e) *Interest payment*—(1) *General.* Subject to paragraph (e)(2) of this section, if payment is not issued, mailed or otherwise transmitted for a clean claim as required under paragraph (a) of this section, the Part D sponsor must pay interest to the network pharmacy that submitted the claim at a rate equal to the weighted average of interest on 3-month marketable Treasury securities determined for such period, increased by 0.1 percentage point for the period beginning on the day after the required payment date and ending on the date on which the payment is made, as determined under paragraph (d). Interest amounts paid under this paragraph will not count against the Part D sponsor's administrative costs, as defined in § 423.308, and will not be treated as allowable risk corridor costs, as defined in § 423.308.

(2) *Authority not to charge interest.* As CMS determines appropriate, including in exigent circumstances such as natural disasters and other unique and unexpected events that prevent the timely processing of claims, a Part D sponsor will not be charged interest under paragraph (e)(1) of this section.

(f) *Electronic transfer of funds.* A Part D sponsor must pay all clean claims submitted electronically by electronic transfer of funds provided the submitting network pharmacy so requests or has so requested previously that contract year. When such payment is made electronically, remittance may also be made electronically by the Part D sponsor.

(g) *Protecting the rights of the claimants.* (1) *General.* Nothing in this section may be construed to prohibit or limit a claim or action that any individual or organization has against a pharmacy, provider, or Part D sponsor that is not covered by the subject matter of this section.

(2) *Anti-retaliation.* Consistent with applicable Federal or State law, a Part D sponsor may not retaliate against an individual, pharmacy, or provider for exercising a right of action under paragraph (g)(1) of this section.

(h) *Construction.* A determination under this section that a claim submitted by a network pharmacy is a clean claim shall not be construed as a positive determination regarding eligibility for payment under title XVIII of the Act, nor is it an indication of government approval of, or acquiescence regarding, the claim submitted. The determination does not relieve any party of civil or criminal liability with respect to the claim, nor

does it offer a defense to any administrative, civil, or criminal action with respect to the claim.

Subpart P—Premiums and Cost-Sharing Subsidies for Low-Income Individuals

■ 21. Amend § 423.772 by revising the definitions of ''income'' and ''resources'' to read as follows:

§ 423.772 Definitions.

* * * * *

Income means income as described under section 1905(p)(1) of the Act without use of any more liberal disregards under section 1902(r)(2) of the Act (that is defined by section 1612 of the Act) and exempts support and maintenance furnished in kind. This definition includes the income of the applicant and spouse who is living in the same household, if any, regardless of whether the spouse is also an applicant.

* * * * *

Resources means liquid resources of the applicant (and, if married, his or her spouse who is living in the same household), such as checking and savings accounts, stocks, bonds, and other resources that can be readily converted to cash within 20 days, that are not excluded from resources in section 1613 of the Act, and real estate that is not the applicant's primary residence or the land on which the primary residence is located. It exempts the value of any life insurance policy.

* * * * *

■ 22. Amend § 423.780 by revising paragraph (e) to read as follows:

§ 423.780 Premium subsidy.

* * * * *

(e) *Waiver of Late Enrollment Penalty for Subsidy-Eligible Individuals.* Subsidy eligible individuals, as defined in § 423.773, are not subject to a late enrollment penalty, as defined in § 423.46.

* * * * *

Subpart V—Part D Marketing Requirements

■ 23. Amend § 423.2268 by—
■ A. Adding paragraph (b)
■ B. Adding paragraph (g).
■ C. Adding paragraph (h).
■ D. Adding paragraph (n).
■ E. Adding paragraph (q).

The additions and revisions read as follows:

§ 423.2268 Standards for Part D marketing.

* * * * *

(b) Offer gifts to potential enrollees, unless the gifts are of nominal (as defined in the CMS Marketing Guidelines) value, are offered to all potential enrollees without regard to whether or not the beneficiary enrolls, and are not in the form of cash or other monetary rebates.

* * * * *

(g) Market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan, prior to the appointment.

(h) Market additional health related lines of plan business not identified prior to an in-home appointment without a separate appointment that may not be scheduled until 48 hours after the initial appointment.

* * * * *

(n) Display the names and/or logos of co-branded network providers on the organization's member identification card. Other marketing materials (as defined in § 423.2260) that include names and/or logos of provider co-branding partners must clearly indicate that other providers are available in the network.

* * * * *

(q) Use a plan name that does not include the plan type. The plan type should be included at the end of the plan name.

■ 24. Amend § 423.2272 by adding new paragraph (d) to read as follows:

§ 423.2272 Licensing of marketing representatives and confirmation of marketing resources.

* * * * *

(d) Report to the State in which the MAO appoints an agent or broker, the termination of any such agent or broker, including the reasons for such termination if State law requires that the reasons for the termination be reported.

■ 25. Add new § 423.2274 to read as follows:

§ 423.2274 Broker and agent requirements.

If a Part D sponsor markets through employed or independent brokers or agents—

(a) Agents and brokers must be compensated as follows:

(1) A Part D sponsor (or other entity on its behalf) may provide compensation to a broker or agent for the sale of a Part D plan only if the aggregate of the first year compensation is no more than 200 percent of the aggregate of the compensation paid for selling or servicing the enrollee in each individual subsequent renewal year, of which there must be a total of five renewal years (creating a 6-year compensation cycle). For purposes of this section ''compensation''—

(i) Includes pecuniary or non-pecuniary remuneration of any kind relating to the sale or renewal of the policy including but not limited to commissions, bonuses, gifts, prizes, awards and finders fees.

(ii) Does not include salary or other benefits related to employment, except to the extent that the salary or other benefits are related to the volume of sales.

(iii) Does not include the payment of fees to comply with State appointment laws, training, certification, and testing costs; and reimbursement for mileage to and from appointments with beneficiaries and reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials.

(2) If compensation is paid in the first year, compensation must be paid for no fewer than 5 renewal years (6-year compensation cycle), provided that the enrollee remains enrolled in the plan.

(3) No entity shall provide aggregate compensation to its agents or brokers and no agent or broker shall receive aggregate compensation greater than the renewal compensation payable by the replacing plan on renewal policies if an existing policy is replaced with a like plan type during the first year and 5 renewal years (6-year compensation cycle).

(i) For purposes of this section, ''like plan type'' means PDP replaced with another PDP, MA or MA–PD replaced with another MA or MA–PD, or cost plan replaced with another cost plan.

(ii) Replacements between different plan types (for which a new compensation is paid) include—PDP and MA–PD, PDP and cost plans, or MA–PD and cost plans.

(iii) When a PDP is added to an MA-only plan, a new commission would be paid for the enrollment in the PDP during the first year.

(4) Compensation shall be earned for months 4 through 12 of the enrollment year.

(i) Plans may pay agents and brokers up-front or prorate compensation payments over 12 months or over months 4 through 12, but

(ii) When a beneficiary disenrolls from the plan, the plan must recover all compensation paid: for months in which the beneficiary is not enrolled; and during months 1 through 3 if the beneficiary disenrolls during the first three months.

(5) Organizations and sponsors must establish a compensation structure for new and replacement enrollments and renewals effective in a given plan year. Compensation structures must be in

place by the beginning of the marketing period, October 1.

(6) Compensation structures must be available upon CMS request including for audits, investigations, and to resolve complaints.

(b) It must ensure agents selling Medicare products are trained annually on Medicare rules and regulations specific to the plan products they intend to sell.

(c) It must ensure agents selling Medicare products are tested annually, as specified in CMS guidance.

(d) Upon CMS' request, the organization must provide to CMS, in a form consistent with current CMS guidance, the information necessary for it to conduct oversight of marketing activities.

(e) It must comply with State requests for information about the performance of a licensed agent or broker as part of a state investigation into the individual's conduct. CMS will establish and maintain a memorandum of understanding (MOU) to share compliance and oversight information with States that agree to the MOU.

Authority: (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: August 19, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: September 2, 2008.

Michael O. Leavitt,

Secretary.

[FR Doc. E8–21686 Filed 9–15–08; 9:00 am]

BILLING CODE 4120–01–P

Federal Register

Thursday,
September 18, 2008

Part IV

Election Assistance Commission

11 CFR Chapter II

Freedom of Information, Government in the Sunshine, and Privacy Act Requirements; Final Rule

ELECTION ASSISTANCE COMMISSION

11 CFR Chapter II

RIN 3265–AA00

Freedom of Information, Government in the Sunshine, and Privacy Act Requirements

AGENCY: United States Election Assistance Commission (EAC).

ACTION: Final rule.

SUMMARY: The U.S. Election Assistance Commission is publishing notice of its final rules implementing provisions of the Freedom of Information Act, the Government in the Sunshine Act, and the Privacy Act.

DATES: The rules promulgated today become effective September 18, 2008.

FOR FURTHER INFORMATION CONTACT: Tamar Nedzar, Attorney, U.S. Election Assistance Commission, 1225 New York Avenue NW., Suite 1100, Washington, DC 20005. Telephone (202) 566–3100.

SUPPLEMENTARY INFORMATION:

Preamble Table of Contents

The following is an outline of the preamble.

I. Disposition of Comments
II. Legal Basis for the Rulemaking
III. Discussion of the Rulemaking
IV. Rulemaking Analyses and Notices

I. Disposition of Comments

The EAC issued a notice of proposed rulemaking and requested public comment on these rules on June 30, 2008 (73 FR 36,807). The comment period ended on August 29, 2008. The EAC received no comments on this rulemaking activity, and therefore made no changes to the proposed rules. The regulations in this notice are the same in form and substance as those posted in the Notice of Proposed Rulemaking associated with this RIN.

II. Legal Basis for the Rulemaking

The U.S. Election Assistance Commission (EAC) is required to promulgate this final rule pursuant to the Freedom of Information Act (FOIA), 5 U.S.C. 552, as amended; the Government in the Sunshine Act (Sunshine Act), 5 U.S.C. 552b; and the Privacy Act, 5 U.S.C. 552a, as amended. The FOIA requires each federal agency to publish certain information in the **Federal Register**, to make available for public inspection and copying certain other information, and to make available certain information to any members of the public upon specific request for that information. The FOIA stipulates that an agency must promulgate regulations specifying the schedule of fees applicable to the processing of requests for information. The Government in the Sunshine Act requires meetings of a federal agency headed by a collegial body, a majority of whose members are appointed by the President with the advice and consent of the Senate, to be open to public observation. The EAC is a collegial body subject to the Act. The Act specifies certain exemptions from the open meeting requirement, and the procedures that an agency must follow to conduct or to close a meeting. The Privacy Act creates requirements that apply to systems of records pertaining to individuals that are established, maintained, or controlled by a federal agency, and prescribes rights and limits to access to such records.

III. Discussion of the Rulemaking

The United States Election Assistance Commission was created by Congress in the Help America Vote Act of 2002. The Commission's primary function is to serve as a national clearinghouse and resource for information on and procedures for federal elections. The EAC conducts studies on election administration and makes those studies available to the public. The EAC also has adopted Voluntary Voting System Guidelines; administers a voting system testing and certification program; allocates election-related federal funding to the States; and carries out administrative duties under the National Voter Registration Act of 1993 (the Motor Voter Law), including developing and maintaining a mail voter registration application form for elections to federal office.

The EAC is committed to operating transparently, competently, and subject to public scrutiny and accountability. To help implement these goals, the EAC is promulgating these regulations to implement three important federal statutes addressing access to information about the EAC and its activities—the Freedom of Information Act, as amended, including recent amendments found in the OPEN Government Act of 2007; the Government in the Sunshine Act; and the Privacy Act.

Many of the provisions in today's rules are identical to or closely resemble the requirements adopted by other federal agencies, and as such represent regulatory ''best practices'' on the topics of FOIA, open government, and protection of the privacy of information about individuals.

IV. Regulatory Analyses and Notices

Regulatory Flexibility Act, as Amended

The Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 (5 U.S.C. 601 *et seq.*) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small government jurisdictions. The EAC has considered the effects of this regulatory action on small entities and certifies that these rules will not have a significant impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4; 2 U.S.C. 1532) requires each agency to assess the effects of its regulatory actions on State, local, and tribal governments and the private sector. Any agency promulgating a rule likely to result in a federal mandate requiring expenditures by a State, local, or tribal government or by the private sector of $120.7 million or more in any one year must prepare a written statement incorporating various assessments, estimates, and descriptions that are delineated in the Act. The EAC has determined that these rules would create no unfunded mandates because they require no expenditures by a State, local, or tribal government and will not have an impact of $120.7 million or more in any one year.

Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as amended by SBREFA, 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. If the rule meets the definition of a major rule, as defined in SBREFA, the Comptroller General must provide a report to Congress and the rule may not take effect until 60 days after it has been published in the **Federal Register**. The current action is a Final Rule that does not meet the definition of a major rule. The EAC is submitting the necessary rule report to the Congress and the Comptroller General of the United States.

National Environmental Policy Act

The EAC analyzed these rules for the purpose of the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*) and determined that this action includes no circumstances that would have any effect on the quality of the environment. The rules pertain solely to the dissemination of information. Thus, these actions do not require an environmental assessment or an environmental impact statement.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires the EAC to consider the impact of paperwork and other information collection burdens imposed on the public. These rules do not impose any reporting or recordkeeping requirements. They pertain solely to the dissemination of information under the FOIA; access to information about meetings and the decision-making process of the EAC; and dissemination of information about what information is maintained about identifiable individuals by the EAC and how they may gain access to and correct or amend information about them.

Executive Order 12630 (Taking of Private Property)

These rules 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.''

Executive Order 12988 (Civil Justice Reform)

These rules meet 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)

Executive Order 13045, ''Protection of Children from Environmental Health Risks and Safety Risks'' (April 23, 1997, 62 FR 19885), requires that agencies issuing economically significant rules, which also concern an environmental health or safety risk that an agency has reason to believe may disproportionately affect children, must include an evaluation of the environmental health and safety effects of the regulation on children. Section 5 of Executive Order 13045 directs an agency to submit for a covered regulatory action an evaluation of its environmental health or safety effects on children. The EAC has determined that these rules are not covered regulatory actions as defined under Executive Order 13045. This determination is based upon the fact that these rules are not economically significant under Executive Order 12866, because the changes would not have an impact of $100 million or more in any one year, and do not constitute an environmental health risk or safety risk that would disproportionately affect children.

Executive Order 12372 (Intergovernmental Review)

The regulations implementing Executive Order 12372 regarding intergovernmental consultation on federal programs and activities do not apply to this rulemaking.

Executive Order 13211 (Energy Supply, Distribution, or Use)

The EAC has analyzed these rules under Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.'' This rule is not a significant energy action within the meaning of section 4(b) of the Executive Order. These rules involve internal procedures of and dissemination of information about the EAC, is not economically significant, and will not have a significant adverse effect on the supply, distribution, or use of energy.

List of Subjects

11 CFR Part 9405

Administrative practice and procedure, Confidential business information, Freedom of information, Government employees.

11 CFR Part 9407

Administrative practice and procedure, Government employees.

11 CFR Part 9410

Administrative practice and procedure, Freedom of information, Government employees.

■ For the reasons set forth in the preamble, the Election Assistance Commission establishes a new Chapter II, consisting of parts 9405, 9407, and 9410 in Title 11 of the code of Federal Regulations to read as follows:

CHAPTER II—ELECTION ASSISTANCE COMMISSION

PART 9405—PROCEDURES FOR DISCLOSURE OF RECORDS UNDER THE FREEDOM OF INFORMATION ACT

Sec.
9405.1 Purpose and scope.
9405.2 Definitions.
9405.3 Policy on disclosure of records.
9405.4 Availability of records.
9405.5 Categories of exemptions.
9405.6 Discretionary release of exempt records.
9405.7 Requests for records.
9405.8 Appeals of denials of requests for records.
9405.9 Fees in general.
9405.10 Fees to be charged—categories of requesters.
9405.11 Miscellaneous fee provisions.
9405.12 Waiver or reduction of charges.

Authority: 5 U.S.C. 552, as amended.

§ 9405.1 Purpose and scope.

The regulations in this part implement the provisions of the Freedom of Information Act (FOIA), 5 U.S.C. 552, as amended, with respect to the availability of records for inspection and copying.

§ 9405.2 Definitions.

As used in this part, the term—

Chief FOIA Officer means the person designated under § 9405.3(d) who has Commission-wide responsibility for the efficient and appropriate compliance with the FOIA.

Commercial use request means a FOIA request from or on behalf of a person who seeks information for a use or purpose that furthers his/her commercial, trade, or profit interests, which can include furthering those interests through litigation. The FOIA Officer will determine, whenever reasonably possible, the use to which a requester will put the requested documents. Where the FOIA Officer has reasonable cause to doubt the use for which the requester claims to have made the FOIA request or where that use is not clear from the FOIA request itself, the FOIA Officer will seek additional clarification before assigning the request to a specific category.

Commission means the U.S. Election Assistance Commission, established by the Help America Vote Act of 2002, 42 U.S.C. 15301 *et seq.*

Commissioner means an individual appointed to the Commission by the President and confirmed by the Senate under section 203 of the Help America Vote Act of 2002, 42 U.S.C. 15323.

Direct costs means those expenditures which the Commission actually incurs in searching for, duplicating, and, in the case of commercial use requesters, reviewing documents to respond to a FOIA request. Direct costs include, but are not limited to, the salary of the employee performing the work (the basic rate of pay for the employee plus 16 percent of that basic rate to cover benefits) and the cost of operating duplicating equipment. Direct costs do not include overhead expenses, such as the cost of space and heating or lighting the facility in which the records are stored.

Duplication means the process of making a copy of a document necessary to respond to a FOIA request. Examples of the form such copies can take include, but are not limited to, paper copy, microform, audio-visual materials, or machine readable documentation (*e.g.*, magnetic tape, DVD, or CD). The Commission will honor a requester's specified preference of form or format of disclosure if the records requested are reasonably reproducible with reasonable efforts in the requested form or format.

Educational institution means a preschool, a public or private elementary or secondary school, an institution of undergraduate higher education, an institute of graduate higher education, an institution of professional education, and an institution of vocational education, which operates a program or programs of scholarly research.

Executive Director means the Executive Director of the Commission or his or her designee.

FOIA means Freedom of Information Act, 5 U.S.C. 552, as amended.

FOIA Officer means a person designated by the Chief FOIA Officer under § 9405.3(d) to carry out day-to-day implementation of the FOIA activities of the Commission.

FOIA Public Liaison means a person designated by the Chief FOIA Officer under § 9405.3(d) to assist in the resolution of any disputes between the requester and the Commission.

FOIA request means to seek the release of records under 5 U.S.C. 552, as amended.

General Counsel means the General Counsel of the Commission or his or her designee.

Non-commercial scientific institution means an organization that is not operated on a commercial basis and which is operated solely for the purpose of conducting scientific research, the results of which are not intended to promote any particular product or industry.

Record means any information that would be a Commission record subject to the requirements of this part when maintained by the Commission in any format, including, but not limited to, an electronic format. Record includes information that is maintained for the Commission by an entity under Government contract for the purposes of records management.

Representative of the news media means any person or entity that gathers information of potential interest to a segment of the public, uses editorial skills to turn the raw materials into a distinct work, and distributes that work to an audience. As used in this paragraph, ''news'' means information that is about current events or that would be of current interest to the public. Examples of news media entities include, but are not limited to, television or radio stations broadcasting to the public at large, web logs, and publishers of periodicals (but only in those instances in which these entities can qualify as disseminators of news, as defined in this paragraph) who make their products available for purchase or subscription by the general public. As used in this paragraph, a ''web log'' means a publicly available Web site, usually maintained by an individual, with regular entries of commentary, descriptions of events, or other material. A freelance journalist may be regarded as working for a news media entity and therefore, considered a representative of the news media if that person can demonstrate a solid basis for expecting publication by a news organization (whether or not the journalist is actually employed by the entity). A publication contract would present a solid basis for such an expectation. The Commission may also consider the past publication record of the requester in making this determination.

Requester is any person who submits a FOIA request to the Commission for release of a record under 5 U.S.C. 552, as amended.

Review means the process of examining a document located in response to a commercial use request to determine whether any portion of the document located is exempt from disclosure. Review also refers to processing any document for disclosure, *i.e.*, doing all that is necessary to excise exempt portions of the document or otherwise prepare the document for release. Review time includes time spent considering any formal objection to disclosure made by a business submitter requesting confidential treatment but does not include time spent resolving general legal or policy issues regarding the application of exemptions.

Search means all time spent reviewing, manually or by automated means, Commission records for the purpose of locating those records that are responsive to a FOIA request, including, but not limited to, page-by-page or line-by-line identification of material within documents and also includes reasonable efforts to locate and retrieve information from records maintained in electronic form or format. Search time does not include review of material to determine whether the material is exempt from disclosure.

§ 9405.3 Policy on disclosure of records.

(a) The Commission will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the rights of individuals and other entities with respect to trade secrets and commercial or financial information entitled to privileged and confidential treatment, and the need for the Commission to promote free internal policy deliberations and to pursue its official activities without undue disruption.

(b) All Commission records shall be available to the public unless they are specifically exempt under this part.

(c) In the interest of efficiency and economy, the Commission's preference is to furnish records to requesters in electronic format, when possible.

(d) To carry out this policy, the Commission shall designate a Chief Freedom of Information Act Officer (Chief FOIA Officer). The Chief FOIA Officer shall designate one or more Commission officials, as appropriate, as FOIA Public Liaison and/or as FOIA Officers. A FOIA Public Liaison shall serve as a supervisory official to whom a FOIA requester can raise questions about the service the FOIA requester has received. A FOIA Officer shall have the authority, subject to the direction and supervision of the Chief FOIA Officer, the requirements of this part, and the FOIA, to make decisions concerning disclosure of records to the public.

§ 9405.4 Availability of records.

(a) The FOIA and its provisions apply only to existing Commission records; the FOIA does not require the creation of new records.

(b) In accordance with 5 U.S.C. 552(a)(2), the Commission shall make the following materials available for public inspection and copying:

(1) Statements of policy and interpretation that have been adopted by the Commission but have not been published in the **Federal Register**;

(2) Administrative staff manuals and instructions to staff that affect a member of the public;

(3) Copies of all records, regardless of form or format, that have been released to any person under this paragraph and that, because of their nature or subject matter, the Commission determines have become or are likely to become the subject of subsequent requests for substantially the same records; and

(4) A general index of the records referred to in paragraph (b)(3) of this section.

(c) In accordance with 5 U.S.C. 552(a)(3), the Commission shall make available, upon proper request, all non-exempt Commission records, or portions

of records, not previously made public under 5 U.S.C. 552(a)(1) and (a)(2).

(d) The Commission shall maintain and make available current indexes and supplements providing identifying information regarding any matter issued, adopted, or promulgated after July 4, 1967. These indexes and supplements shall be published and made available on at least a quarterly basis for public distribution unless the Commission determines by Notice in the **Federal Register** that publication would be unnecessary, impracticable, or not feasible due to budgetary considerations. Nevertheless, copies of any index or supplement shall be made available upon request at a cost not to exceed the direct cost of duplication.

(e) If documents or files contain both disclosable and non-disclosable information, the non-disclosable information will be deleted and the disclosable information released, unless the disclosable portions cannot be reasonably segregated from the other portions in a manner which will allow meaningful information to be disclosed.

(f) All records created in the process of implementing provisions of 5 U.S.C. 552 will be maintained by the Commission in accordance with the authority granted by the National Archives and Records Service of the General Services Administration.

(g) The Commission encourages the public to explore the information available on the Commission's Web site, located at *http://www.eac.gov*.

§ 9405.5 Categories of exemptions.

(a) No FOIA requests under 5 U.S.C. 552 shall be denied release unless the record contains, or its disclosure would reveal, matters that are:

(1) Specifically authorized under criteria established by an Executive Order to be kept secret in the interest of national defense or foreign policy and are, in fact, properly classified under such Executive Order;

(2) Related solely to the internal personnel rules and practices of the Commission;

(3) Specifically exempted from disclosure by statute, provided that such statute:

(i) Requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue, or

(ii) Establishes particular criteria for withholding or refers to particular types of matters to be withheld;

(4) Trade secrets and commercial or financial information obtained from a person that are privileged or confidential. Such information includes confidential business information which concerns or relates to the trade secrets, processes, operations, style of works, or apparatus, or to the production, sales, shipments, purchases, transfers, identification of customers, inventories, or amount of source of income, profits, losses, or expenditures of any person, firm, partnership, corporation, or other organization, if the disclosure is likely to have the effect of either impairing the Commission's ability to obtain such information as is necessary to perform its statutory functions or causing substantial harm to the competitive position of the person, firm, partnership, corporation, or other organization from which the information was obtained, unless the Commission is required by law to disclose such information. For purposes of this section, trade secret means a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Examples of trade secrets may include, but are not limited to, plans, schematics, specifications of materials used in production, source code used to develop software, technical descriptions of manufacturing process, quality control methodology, and test results. The following procedures shall be used for submitting business information in confidence:

(i) Clearly mark any portion of any data or information being submitted that in the submitter's opinion is a trade secret or commercial and financial information that the submitter is claiming should be treated as privileged and confidential and submit such data or information separately from other material being submitted to the Commission;

(ii) A request for confidential treatment shall be addressed to the Chief FOIA Officer, U.S. Election Assistance Commission, 1225 New York Avenue, NW., Suite 1100, Washington, DC 20005 and shall indicate clearly on the envelope that it is a request for confidential treatment.

(iii) With each submission of, or offer to submit, business information which a submitter desires to be treated as confidential under paragraph (a)(4) of this section, the submitter shall provide the following, which may be disclosed to the public:

(A) A written description of the nature of the subject information and a justification for the request for its confidential treatment, and

(B) A certification in writing under oath that substantially identical information is not available to the public.

(iv) Approval or denial of requests shall be made only by the Chief FOIA Officer or his or her designees. A denial shall be in writing, shall specify the reason for the denial, and shall advise the submitter of the right to appeal to the Commission.

(v) For good cause shown, the Commission may grant an appeal from a denial by the Chief FOIA Officer or his or her designee if the appeal is filed within 15 days after receipt of the denial. An appeal shall be addressed to the Chief FOIA Officer, U.S. Election Assistance Commission, 1225 New York Avenue, NW., Suite 1100, Washington, DC 20005 and shall clearly indicate that it is a confidential submission appeal. An appeal will be decided within 20 days after its receipt (excluding Saturdays, Sundays, and legal holidays) unless an extension, stated in writing with the reasons therefore, has been provided to the person making the appeal.

(vi) Any business information submitted in confidence and determined to be entitled to confidential treatment shall be maintained in confidence by the Commission and not disclosed except as required by law. In the event that any business information submitted to the Commission is not entitled to confidential treatment, the submitter will be permitted to withdraw the tender unless it is the subject of a request under the FOIA or of judicial discovery proceedings.

(5) Interagency or intra-agency memoranda or letters that would not be available by law to a party in litigation with the Commission;

(6) Personnel and medical files and similar files, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;

(7) Records or information compiled for law enforcement purposes, but only to the extent that the production of such law enforcement records or information:

(i) Could reasonably be expected to interfere with enforcement proceedings;

(ii) Would deprive a person of a right to a fair trial or an impartial adjudication;

(iii) Could reasonably be expected to constitute an unwarranted invasion of personal privacy;

(iv) Could reasonably be expected to disclose the identity of a confidential source, including a State, local, or foreign agency or authority or any private institution that furnished information on a confidential basis, and, in the case of a record or information compiled by a criminal law enforcement authority in the course of a criminal

investigation, or by an agency conducting a lawful national security intelligence investigation, information furnished by a confidential source;

(v) Would disclose techniques and procedures for law enforcement investigations or prosecutions or would disclose guidelines for law enforcement investigations or prosecutions if such disclosure could reasonably be expected to risk circumvention of the law; or

(vi) Could reasonably be expected to endanger the life or physical safety of any individual.

(b) Any portion of a record that reasonably can be segregated from the balance of the record shall be provided to any individual requesting such record after deletion of the portions which are exempt. The amount of information deleted and the exemption under which the deletion is made shall be indicated on the released portion of the record, unless including that indication would harm an interest protected by an exemption in paragraph (a) of this section under which the deletion is made. If technically feasible, the amount of the information deleted shall be indicated at the place in the record where such deletion is made.

(c) If a requested record is one of another government agency or deals with subject matter to which a government agency other than the Commission has exclusive or primary responsibility, the request for such a record shall be promptly referred by the Commission to that agency for disposition or guidance as to disposition.

(d) Nothing in this part authorizes withholding of information or limiting the availability of records to the public, except as specifically provided; nor is this part authority to withhold information from Congress.

§ 9405.6 Discretionary release of exempt records.

The Commission may, in its discretion, release requested records despite the applicability of the exemptions in § 9405.5, if it determines that it is in the public interest and that the rights of third parties would not be prejudiced. The Executive Director will have the authority to determine that requested records may be released despite otherwise applicable exemptions.

§ 9405.7 Requests for records.

(a) Requests for copies of Commission records under the FOIA shall be made in writing and addressed to the Chief FOIA Officer, U.S. Election Assistance Commission, 1225 New York Avenue, NW., Suite 1100, Washington, DC 20005. The request shall reasonably describe the records sought with sufficient specificity with respect to names, dates, and subject matter to permit the records to be located. A requester will be promptly advised if the records cannot be located on the basis of the description given and that further identifying information must be provided before the request can be satisfied.

(b) Requests for Commission records and copies thereof shall specify the preferred form or format (including electronic formats) of the response. The Commission shall accommodate requesters as to form or format if the record is readily available in that form or format. When requesters do not specify the form or format of the response, the Commission shall respond in the form or format in which the document is most accessible to the Commission. In the interest of efficiency and economy, the Commission's preference is to furnish records to requesters in electronic format, whenever possible.

(c) The Commission shall determine within 20 working days after receipt of a request, or 20 working days after an appeal is granted, whether to comply with such request, unless in unusual circumstances the time is extended. The 20-day period shall commence on the date on which the request was first received by the appropriate component of the Commission, but in any event, not later than 10 days after the request is first received by the component of the Commission designated to receive requests under this part. The 20-day period shall not be tolled by the Commission except—

(1) The Commission may make one request of the requester for information and toll the 20-day period while it is awaiting such information that it has reasonably requested from the requester.

(2) If it is necessary to clarify with the requester issues regarding fee assessment.

(3) Under paragraphs (c)(1) or (2) of this section, the Commission's receipt of the requester's response to the Commission's request for information or clarification ends the tolling period.

(d) In the event the time is extended under paragraph (c) of this section, the requester shall be notified of the reasons for the extension and the date on which a determination is expected to be made. An extension may be made if it is—

(1) Necessary to locate records or transfer them from physically separate facilities; or

(2) Necessary to search for, collect, and appropriately examine a large quantity of separate and distinct records that are the subject of a single request; or

(3) Necessary for consultation with another agency that has a substantial interest in the determination of the request.

(e) If the Commission determines that an extension of time is necessary to respond to a request satisfying the unusual circumstances specified in paragraph (c) of this section, the Commission shall so notify the requester and give the requester an opportunity to limit the scope of the request so that it may be processed within the time limit prescribed in paragraph (c) of this section or arrange with the Commission an alternative time frame for processing the request or a modified request.

(f) The Commission may aggregate and process as a single request requests by the same requester, or a group of requesters acting in concert, if the Commission reasonably believes that the requests actually constitute a single request that would otherwise satisfy the unusual circumstances specified in paragraph (c) of this section, and the requests involve clearly related matters.

(g) The Commission will process requests under the FOIA based on the order they are received.

(h) The Commission shall consider requests for the expedited processing of requests in cases where the requester demonstrates a compelling need for such processing.

(1) The term ''compelling need'' means, with respect to a request made by a person primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal government activity.

(2) Requesters for expedited processing must include in their requests a statement setting forth the basis for the claim that a ''compelling need'' exists for the requested information, certified by the requester to be true and correct to the best of his or her knowledge and belief.

(3) The Commission shall determine whether to grant a request for expedited processing and notify the requester of such determination within 10 days of receipt of the request. Denials of requests for expedited processing may be appealed as set forth in § 9405.8. The Commission shall expeditiously determine any such appeal. As soon as practicable, the Commission shall process the documents responsive to a request for which expedited processing is granted.

(i) Any person denied access to records by the Commission shall be notified immediately of the denial, including the reasons for the decision

and notified of his or her right to appeal the adverse determination to the Commission.

(j) The date of receipt of a request under this part shall be the date on which the Chief FOIA Officer actually receives the request.

(k) Each request received by the Chief FOIA Officer will be assigned an individualized tracking number. Requesters may call (866) 747–1471 and, using the tracking number, obtain information about the request, including the date on which the Commission originally received the request and an estimated date on which the Commission will complete action on the request.

§ 9405.8 Appeals of denials of requests for records.

(a) Any person who has been notified under § 9405.7(i) that his/her request for inspection of a record or for a copy of a record has been denied, or who has received no response within 20 working days (or within such extended period as is permitted under § 9405.7(d)) after the request has been received by the Commission, or who has received no response within 20 days after a request for expedited processing has been received by the Commission, may appeal the adverse determination or the failure to respond by requesting the Commission to direct that the record be made available or that the expedited processing shall occur.

(b) The appeal request shall be in writing, shall clearly and prominently state on the envelope or other cover and at the top of the first page ''FOIA Appeal,'' and shall identify the record in the form in which it was originally requested.

(c) The appeal request should be delivered or addressed to the Chief FOIA Officer, U.S. Election Assistance Commission, 1225 New York Avenue, NW., Suite 1100, Washington, DC 20005.

(d) The requester may state facts and cite legal or other authorities as he or she deems appropriate in support of the appeal request.

(e) The Commission will make a determination with respect to any appeal within 20 working days after receipt of the appeal (or within such extended period as is permitted under § 9405.7). If, on appeal, the denial of the request for a record or a copy is in whole or in part upheld, the Commission shall advise the requester of the denial and shall notify him or her of the provisions for judicial review of that determination as set forth in 5 U.S.C. 552(a)(4).

(f) Because of the risk of misunderstanding inherent in oral communications, the Commission will not entertain any appeal from an alleged denial or failure to comply with an oral request. Any person who has orally requested a copy of a record that he or she believes to have been improperly denied should resubmit the request in writing as set forth in § 9405.7.

§ 9405.9 Fees in general.

(a) *Generally.* The Commission will charge fees that recoup the full allowable direct costs it incurs. The Commission will use the most efficient and least costly means to comply with requests for documentation.

(b) *Manual searches for records.* The Commission will charge fees at the salary rate(s) (basic pay plus 16 percent) of the employee(s) making the search.

(c) *Computer searches for records.* The Commission will charge the actual direct cost of operating the central processing unit (CPU) for that portion of operating time that is directly attributable to searching for records responsive to a FOIA request and operator/programmer salary apportionable to the search.

(d) *Review of records.* Only requesters who are seeking documents for commercial use may be charged for time spent reviewing records to determine whether they are exempt from mandatory disclosure. Charges may be assessed only for the initial review (*i.e.*, the review undertaken the first time the Commission analyzes the applicability of a specific exemption to a particular record or portion of a record). Records or portions of records withheld in full under an exemption that is subsequently determined not to apply may be reviewed again to determine the applicability of other exemptions not previously considered. The costs for such a subsequent review are assessable. The Commission will charge at the salary rate(s) (basic pay plus 16 percent) of the employee(s) reviewing records.

(e) *Duplication of records.* Records will be duplicated at a rate of fifteen (15) cents per page. For copies prepared by computers, such as tapes, CDs, DVDs, or printouts, the Commission shall charge the actual cost, including operator time, of production. For other methods of reproduction or duplication, the Commission will charge the actual direct costs of producing the document(s). If the Commission estimates that duplication charges are likely to exceed $25, it shall notify the requester of the estimated amount of fees, unless the requester has indicated in advance a willingness to pay fees as high as those anticipated. Such a notice shall offer a requester the opportunity to confer with agency personnel with the object of reformulating the request to meet his or her needs at a lower cost.

(f) *Other charges.* The Commission will recover the full costs of providing services such as those enumerated below when it provides them in response to a direct request for such services:

(1) Certifying that records are true copies; or

(2) Sending records by special methods such as express mail.

(g) *Payment of fees.* Remittance shall be in the form either of a personal check or bank draft drawn on a bank in the United States or a postal money order. Remittance shall be made payable to the order of the Treasury of the United States and mailed to the Chief FOIA Officer, U.S. Election Assistance Commission, 1225 New York Avenue, NW., Suite 1100, Washington, DC 20005.

(h) *Receipt of fees.* A receipt for fees paid will be given upon request. Refund of fees paid for services actually rendered will not be made.

(i) *Restrictions on assessing fees.* The Commission shall not assess search fees or duplication fees under this paragraph if the Commission fails to comply with any time limit in these regulations. The Commission will not charge fees to any requester, including commercial use requesters, if the cost of collecting a fee would be equal to or greater than the fee itself. With the exception of requesters seeking documents for a commercial use, the Commission will not charge fees for the first 100 pages of duplication and the first two hours of search time.

(1) The elements to be considered in determining the ''cost of collecting a fee'' are the administrative costs of receiving and recording a requester's remittance and processing the fee for deposit in the Treasury Department's special account.

(2) For purposes of these restrictions on assessment of fees, the word ''pages'' means paper copies of 8.5″ x 11″ or 11″ x 14.″ Thus, requesters are not entitled to 100 computer disks, for example.

(3) For purposes of these restrictions on assessment of fees, the term ''search time'' means manual search. To apply this term to searches made by computer, the Commission will determine the hourly cost of operating the CPU and the operator's hourly salary plus 16 percent. When the cost of such search (including operator time and the cost of operating the computer to process a request) equals the equivalent dollar amount of two hours of salary of the person performing the search (*i.e.*, the

operator), the Commission will begin assessing charges for computer search.

§ 9405.10 Fees to be charged—categories of requesters.

There are four categories of FOIA requesters: Commercial use requesters; educational and non-commercial scientific institutions; representatives of the news media; and all other requesters.

(a) *Commercial use requesters.* When the Commission receives a request for documents for commercial use, it will assess charges that recover the full direct costs of searching for, reviewing for release, and duplicating the record sought. Commercial use requesters are neither entitled to two hours of free search time nor 100 free pages of duplication. The Commission may recover the cost of searching for and reviewing records even if there is ultimately no disclosure of records (see § 9405.11(b)).

(b) *Educational and non-commercial scientific institution requesters.* The Commission shall provide documents to requesters in this category for the cost of reproduction alone, excluding charges for the first 100 pages. To be eligible for inclusion in this category, requesters must show that the record is being made as authorized by and under the auspices of a qualifying institution and that the records are not sought for a commercial use but are sought in the furtherance of scholarly (if the request is from an educational institution) or scientific (if the request is from a non-commercial scientific institution) research.

(c) *Representatives of the news media.* The Commission shall provide documents to requesters in this category for the cost of reproduction alone, excluding charges for the first 100 pages. To be eligible for inclusion in this category, the requester must fit the definition of a representative of the news media as stated in § 9405.2, and the request must not be made for commercial use. For purposes of this paragraph, a request for records supporting the news dissemination function of the requester shall not be considered to be a request that is for commercial use.

(d) *All other requesters.* The Commission shall charge requesters who do not fit into any of the categories above fees that recover the full reasonable direct cost of searching for and reproducing records that are responsive to the request, except that the first 100 pages of reproduction and the first two hours of search time shall be furnished without charge.

§ 9405.11 Miscellaneous fee provisions.

(a) *Charging Interest—notice and rate.* The Commission may begin assessing interest charges on an unpaid bill starting on the 31st day following the day on which the billing was sent. The fact that the fee has been received by the Commission within the 30-day grace period, even if it is not processed, will suffice to stay the accrual of interest. Interest will be at the rate prescribed in section 3717 of title 31 of the United States Code and will accrue from the date of the billing.

(b) *Charges for unsuccessful search.* The Commission may assess charges for time spent searching, even if it fails to locate the records or if the records located are determined to be exempt from disclosure. If the Commission estimates that search charges are likely to exceed $25, it shall notify the requester of the estimated amount of fees, unless the requester has indicated in advance his willingness to pay fees as high as those anticipated. Such a notice shall offer the requester the opportunity to confer with agency personnel with the object of reformulating the request to meet his or her needs at a lower cost.

(c) *Aggregating requests.* A requester may not file multiple requests at the same time, each seeking portions of a document or documents, solely in order to avoid payment of fees. When the Commission reasonably believes that a requester or a group of requestors acting in concert has submitted requests that constitute a single request involving clearly related matters, the Commission may aggregate those requests and charge accordingly. One element to be considered in determining whether a belief would be reasonable is the time period over which the requests have occurred.

(d) *Advance payments.* The Commission may not require a requester to make an advance payment (*i.e.*, payment before work is commenced or continued on a request) unless:

(1) The Commission estimates or determines that allowable charges that a requester may be required to pay are likely to exceed $250. Then, the Commission will notify the requester of the likely cost and obtain satisfactory assurance of full payment where the requester has a history of prompt payment of FOIA fees or require an advance payment of an amount up to the full estimated charges in the case of requesters with no history of payment; or

(2) A requester has previously failed to pay a fee charged in a timely fashion (*i.e.*, within 30 days of the date of the billing). Then, the Commission may require the requester to:

(i) Pay the full amount owed plus any applicable interest as provided above or demonstrate that he or she has, in fact, paid the fee, and

(ii) Make an advance payment of the full amount of the estimated fee before the agency begins to process a new request or a pending request from that requester.

(3) When the Commission acts under paragraphs (d)(1) or (2) of this section, the administrative time limits prescribed in 5 U.S.C. 552(a)(6) will begin only after the Commission has received payments described in paragraphs (d)(1) and (2) of this section.

(e) *Effect of Debt Collection Act of 1982.* The Commission shall comply with the provisions of the Debt Collection Act, including disclosure to consumer reporting agencies and use of collection agencies, where appropriate, to encourage repayment.

§ 9405.12 Waiver or reduction of charges.

Records responsive to a request will be furnished without charge when the Chief FOIA Officer determines, based on all available information, that disclosure of the requested information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester.

PART 9407—IMPLEMENTATION OF THE GOVERNMENT IN THE SUNSHINE ACT

Sec.

9407.1 Purpose and scope.
9407.2 Definitions.
9407.3 Open meetings.
9407.4 Notice of meetings.
9407.5 Closed meetings.
9407.6 Procedures for closing meetings.
9407.7 Recordkeeping requirements.
9407.8 Public availability of records.

Authority: 5 U.S.C. 552b.

§ 9407.1 Purpose and scope.

This part contains the regulations of the U.S. Election Assistance Commission implementing the Government in the Sunshine Act (5 U.S.C. 552b). Consistent with the Act, it is the policy of the Commission that the public is entitled to the fullest practicable information regarding its decision making processes. This part sets forth the basic responsibilities of the Commission with regard to this policy and offers guidance to members of the public who wish to exercise the rights established by the Act. These regulations also fulfill the requirement

of 5 U.S.C. 552b(g) that each agency subject to the Act promulgates regulations to implement the open meeting requirements of paragraphs (b) through (f) of section 552b.

§ 9407.2 Definitions.

As used in this part, the term—

Commission means the U.S. Election Assistance Commission, established by the Help America Vote Act of 2002, 42 U.S.C. 15301 *et seq.*

Commissioner means an individual appointed to the Commission by the President and confirmed by the Senate under section 203 of the Help America Vote Act of 2002, 42 U.S.C. 15323.

Executive Director means the Executive Director of the Commission or his or her designee.

General Counsel means the General Counsel of the Commission or his or her designee.

Meeting means the deliberations of at least three Commissioners where such deliberations determine or result in the joint conduct or disposition of official Commission business. A deliberation conducted through telephone or similar communications equipment in which all persons participating can hear each other shall be considered a meeting. For the purposes of this section, ''joint conduct'' does not include situations where the requisite number of members is physically present in one place but not conducting agency business as a body. In addition, the term ''meeting'' does not include a process of notation voting by circulated memorandum for the purpose of expediting consideration of official Commission business. The term ''meeting'' also does not include deliberations on whether to:

(1) Schedule a meeting;

(2) Hold a meeting with less than seven days notice, as provided in § 9407.4(e);

(3) Change the subject matter of a publicly announced meeting or the determination of the Commission to open or close a meeting or portions of a meeting to public observation, as provided in § 9407.4(f);

(4) Change the time or place of an announced meeting, as provided in § 9407.4(g);

(5) Close a meeting or portions of a meeting, as provided in § 9407.5; or

(6) Withhold from disclosure information pertaining to a meeting or portions of a meeting, as provided in § 9407.5.

Public observation means attendance by one or more members of the public at a meeting of the Commission but does not include participation in the meeting.

Public participation means the presentation or discussion of information, raising of questions, or other manner of involvement in a meeting of the Commission by one or more members of the public in a manner that contributes to the disposition of Commission business.

§ 9407.3 Open meetings.

(a) The Commissioners shall not jointly conduct, determine, or dispose of agency business other than in accordance with this section.

(b) Except as otherwise provided in this part, every portion of every Commission meeting shall be open to public observation.

(c) No additional right to participate in Commission meetings is granted to any person by this part. Meetings of the Commission, or portions of a meeting, shall be open to public participation only when an announcement to that effect is issued under § 9407.4(b)(4). Public participation shall be conducted in an orderly, non-disruptive manner and in accordance with any procedures as the chairperson of the meeting may establish. Public participation may be terminated at any time for any reason.

(d) When holding open meetings, the Commission shall make a diligent effort to provide appropriate space, sufficient visibility, and adequate acoustics to accommodate the public attendance anticipated for the meeting. When open meetings are conducted through telephone or similar communications equipment, the Commission shall make an effort to provide sufficient access to the public in a manner which allows the public to clearly hear, see, or otherwise follow the proceedings. The meeting room or other forum selected shall be sufficient to accommodate a reasonable number of interested members of the public. The Commission shall ensure that public meetings are held at a reasonable time and are readily accessible to individuals with disabilities.

(e) Members of the public attending open Commission meetings may use small electronic audio recording devices to record the proceedings. The use of any other recording equipment and cameras requires advance coordination with and notice to the Commission's Communications Office. The chair or acting chair of the Commission may prohibit, at any time, the use of any recording equipment during a public meeting if he or she determines that such recording would disrupt the orderly conduct of the meeting.

§ 9407.4 Notice of meetings.

(a) Except as otherwise provided in this section, the Commission shall make a public announcement at least seven days prior to a meeting.

(b) The public announcement shall include:

(1) The time and place of the meeting;

(2) The subject matter of the meeting;

(3) Whether the meeting is to be open, closed, or portions of a meeting will be closed;

(4) Whether public participation will be allowed; and

(5) The name and telephone number of the person who will respond to requests for information about the meeting.

(c) The public announcement requirement shall be implemented by:

(1) Publishing the announcement on the Commission's Web site; and

(2) Distributing the announcement to affected government entities and persons and organizations that the Executive Director determines may have an interest in the subject matter of the meeting.

(d) The announcement will be submitted for publication in the **Federal Register** immediately following the public posting and distribution noted in paragraph (c) of this section.

(e) A meeting may be held with less than seven days notice if a majority of the Commission determines by recorded vote that the business of the Commission so requires. The Commission shall make a public announcement to this effect at the earliest practicable time. The announcement shall include the information required by paragraph (b) of this section and shall be issued in accordance with those procedures set forth in paragraphs (c) and (d) of this section that are practicable given the available period of time.

(f) The subject matter of an announced meeting or the determination of the Commission to open or close a meeting or portions of a meeting to public observation may be changed only if:

(1) A majority of the Commissioners determine by a recorded vote that agency business so requires and that no earlier announcement of the change was possible,

(2) The Commission publicly announces the change and the vote of each Commissioner upon such change at the earliest practicable time.

(3) The announcement of the change noted in paragraph (f)(2) of this section is issued in accordance with those procedures set forth in paragraphs (c) and (d) of this section that are practicable given the available period of time.

(g) The time or place of an announced meeting may be changed only if a public

announcement of the change is made at the earliest practicable time. The announcement shall be issued in accordance with those procedures set forth in paragraphs (c) and (d) of this section that are practicable given the available period of time.

§ 9407.5 Closed meetings.

(a) A meeting or portions of a meeting may be closed and information pertaining to such meeting or portions of a meeting may be withheld from the public only if the Commission determines that such meeting or portions of a meeting or the disclosure of such information is likely to:

(1) Disclose matters that are:

(i) Specifically authorized under criteria established by an Executive Order to be kept secret in the interest of national defense or foreign policy, and

(ii) To be properly classified under that Executive Order;

(2) Relate solely to the internal personnel rules and practices of the Commission;

(3) Disclose matters specifically exempted from disclosure by statute (other than the Freedom of Information Act, 5 U.S.C. 552) provided that the statute:

(i) Requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue, or

(ii) Establishes particular criteria for withholding or refers to particular types of matters to be withheld;

(4) Disclose the trade secrets and commercial or financial information obtained from a person and privileged or confidential;

(5) Involve either accusing any person of a crime or formally censuring any person;

(6) Disclose information of a personal nature, if disclosure would constitute a clearly unwarranted invasion of personal privacy;

(7) Disclose either investigatory records compiled for law enforcement purposes or information which, if written, would be contained in such records but only to the extent that the production of the records or information would:

(i) Interfere with enforcement proceedings,

(ii) Deprive a person of a right to either a fair trial or an impartial adjudication,

(iii) Constitute an unwarranted invasion of personal privacy,

(iv) Disclose the identity of a confidential source or sources and, in the case of a record compiled either by a criminal law enforcement authority in the course of a criminal investigation or by an agency conducting a lawful national security intelligence investigation, confidential information furnished only by the confidential source or sources,

(v) Disclose investigative techniques and procedures, or

(vi) Endanger the life or physical safety of law enforcement personnel;

(8) Disclose information contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions;

(9) Disclose information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed action of the Commission. This exception shall not apply in any instance where the Commission has already disclosed to the public the content or nature of the proposed action or where the Commission is required by law to make such disclosure on its own initiative prior to taking final action on the proposal; or

(10) Specifically concern the issuance of a subpoena by the Commission; or the participation of the Commission in a civil action or proceeding, an action in a foreign court or international tribunal, or an arbitration; or the initiation, conduct, or disposition by the Commission of a particular case of formal adjudication under the procedures in 5 U.S.C. 554 or otherwise involving a determination on the record after opportunity for a hearing.

(b) Before a meeting or portions of a meeting may be closed to public observation, the Commission shall determine, notwithstanding the exemptions set forth in paragraph (a) of this section, whether the public interest requires that the meeting or portions of a meeting be open consistent with Federal law. The Commission may open a meeting or portions of a meeting that could be closed under paragraph (a) of this section if the Commission finds it to be in the public interest to do so and the disclosure is not otherwise prohibited by Federal law.

§ 9407.6 Procedures for closing meetings.

(a) A meeting or portions of a meeting may be closed and information pertaining to a meeting or portions of a meeting may be withheld under § 9407.5(a) only when a majority of the members of the Commission vote to take the action.

(b) A separate vote of the Commissioners shall be taken with respect to each meeting or portion of a meeting proposed to be closed and with respect to information which is proposed to be withheld. A single vote may be taken with respect to a series of meetings or portions of a meeting that are proposed to be closed, so long as each meeting or portion of a meeting in the series involves the same particular matter and is scheduled to be held no more than 30 days after the initial meeting in the series. The vote of each participating Commission member shall be recorded, and no proxies shall be allowed.

(c) A person whose interests may be directly affected by a portion of a meeting may request in writing that the Commission close that portion of the meeting for any of the reasons referred to in § 9407.5(a)(5), (6), or (7) . Upon the request of a Commissioner, a recorded vote shall be taken whether to close such meeting or a portion of a meeting.

(d) Before the Commission may hold a meeting that is closed, in whole or part, a certification shall be obtained from the General Counsel that, in his or her opinion, the meeting may properly be closed. The certification shall be in writing and shall state each applicable exemption provision from § 9407.5(a).

(e) Within one day of a vote taken under this section, the Commission shall make publicly available a written copy of such vote reflecting the vote of each Commissioner.

(f) In the case of the closure of a meeting or portions thereof, the Commission shall make publicly available within one day of the vote on such action a full written explanation of the reasons for the closing with a list of all persons expected to attend the meeting and their affiliation.

§ 9407.7 Recordkeeping requirements.

(a) The Commission shall maintain either a complete transcript or electronic recording of the proceedings of each meeting.

(b) In the case of either a meeting or portions of a meeting closed to the public under § 9407.5(a)(8) or (10), the Commission shall maintain a complete transcript, an electronic recording, or a set of minutes of the proceedings. If minutes are maintained, they shall fully and clearly describe all matters discussed and shall provide a full and accurate summary of any actions taken and the reasons for which such actions were taken, including a description of the views expressed on any item and a record reflecting the vote of each Commissioner. All documents considered in connection with any action shall be identified in the minutes.

(c) The transcript, electronic recording, or copy of the minutes of a meeting shall disclose the identity of each speaker.

(d) The Commission shall maintain a complete verbatim copy of the transcript, a complete electronic recording, or a complete copy of the minutes of the proceedings of each meeting for at least two years, or for one year after the conclusion of any Commission proceeding with respect to which the meeting was held, whichever occurs later.

§ 9407.8 Public availability of records.

The Commission shall make available to the public the transcript, electronic recording, or minutes of a meeting, except for items of discussion or testimony that relate to matters the Commission has determined to contain information that may be withheld under § 9407.5(a). This information shall be made available as soon as practicable after each meeting on the Commission's Web site. Otherwise, requests to receive or review transcripts, electronic recordings, or minutes of a meeting should be addressed to the Communications Director, U.S. Election Assistance Commission, 1225 New York Avenue, Suite 1100, Washington, DC 20005. Copies of a transcript, a transcription of the electronic recording, or the minutes of a meeting (except for items of discussion or testimony that relate to matters withheld under § 9407.5) shall be furnished at cost to any person upon written request pursuant to the requirements of 11 CFR part 9405.

PART 9410—IMPLEMENTATION OF THE PRIVACY ACT OF 1974

Sec.

9410.1 Purpose and scope.
9410.2 Definitions.
9410.3 Procedures for requests pertaining to individual records in a record system.
9410.4 Times, places, and requirements for identification of individuals making requests.
9410.5 Disclosure of requested information to individuals.
9410.6 Request for correction or amendment to record.
9410.7 Commission review of request for correction or amendment of record.
9410.8 Appeal of initial adverse determination on amendment or correction.
9410.9 Disclosure of record to person other than the individual to whom it pertains.
9410.10 Fees.
9410.11 Penalties.

Authority: 5 U.S.C. 552a.

§ 9410.1 Purpose and scope.

(a) This part sets forth rules that inform the public as to what information is maintained by the U.S. Election Assistance Commission about identifiable individuals and that inform those identifiable individuals how they may gain access to and correct or amend information about them.

(b) The regulations in this part carry out the requirements of the Privacy Act of 1974 (Pub. L. 93–579) and in particular 5 U.S.C. 552a as added by that Act.

(c) The regulations in this part apply only to records disclosed or requested under the Privacy Act of 1974 and not to requests for information made under 5 U.S.C. 552, the Freedom of Information Act, or requests for reports and statements filed with the Election Assistance Commission which are public records and available for inspection and copying.

§ 9410.2 Definitions.

As used in this part, the term—

Commission means the U.S. Election Assistance Commission, established by the Help America Vote Act of 2002, 42 U.S.C. 15301 *et seq.*

Commissioner means an individual appointed to the Commission by the President and confirmed by the Senate under section 203 of the Help America Vote Act of 2002, 42 U.S.C. 15323.

Individual means a citizen of the United States or an alien lawfully admitted for permanent residence.

Maintain includes maintain, collect, use, or disseminate.

Record means any item, collection, or grouping of information about an individual that is maintained by the Commission including, but not limited to, his or her education, financial transactions, medical history, and criminal or employment history and that contains his or her name or the identifying number, symbol, or other identifying information particularly assigned to the individual, such as finger or voice print or a photograph.

Systems of records means a group of any records under the control of the Commission from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying information particularly assigned to the individual.

§ 9410.3 Procedures for requests pertaining to individual records in a record system.

(a) Any individual may request the Commission to inform him or her whether a particular record system named by the individual contains a record pertaining to him or her. The request may be made in person or in writing at the location of the record system and to the person specified in the notice describing that record system.

(b) An individual, who believes that the Commission maintains records pertaining to him or her but cannot determine which record system contains those records, may request assistance by mail or in person from the Executive Director, U.S. Election Assistance Commission, 1225 New York Avenue, Suite 1100, Washington, DC 20005 during the hours of 9 a.m. to 5:30 p.m.

(c) Requests under paragraphs (a) or (b) of this section shall be acknowledged by the Commission within 15 working days from the date of receipt of the request. If the Commission is unable to locate the information requested under paragraphs (a) or (b) of this section, it shall so notify the individual within 15 working days after receipt of the request. The notification may request additional information to assist the Commission in locating the record, or it may advise the individual that no record or document exists about that individual.

§ 9410.4 Times, places, and requirements for identification of individuals making requests.

(a) After being informed by the Commission that a record system contains a record pertaining to him or her, an individual may request that the Commission disclose that record in the manner described in this section. Each request for the disclosure of a record or a copy of a record it shall be made in person or by written correspondence to the U.S. Election Assistance Commission, 1225 New York Avenue, Suite 1100, Washington, DC 20005 and to the person identified in the notice describing the systems of records. Requests can also be made by specifically authorized agents or by parents or guardians of individuals.

(b) Each individual requesting the disclosure of a record or copy of a record shall furnish the following information with his or her request:

(1) The name of the record system containing the record;

(2) Proof as described in paragraph (c) of this section that he or she is the individual to whom the requested record relates; and

(3) Any other information required by the notice describing the record system.

(c) Proof of identity as required by paragraph (b)(2) of this section shall be provided as described in paragraphs (c)(1) and (c)(2) of this section. Requests made by an agent, parent, or guardian shall be in accordance with the procedures described in § 9410.9.

(1) Requests made in writing shall include a statement affirming the individual's identity, signed by the individual and either notarized or witnessed by two persons (including witnesses' addresses). If the individual

appears before a notary, he or she shall submit adequate proof of identification in the form of a driver's license, birth certificate, passport, or other identification acceptable to the notary. If the statement is witnessed, it shall include a sentence above the witnesses' signatures that they personally know the individual or that the individual has submitted proof of his or her identification to their satisfaction. In cases involving records of extreme sensitivity, the Commission may determine that the identification is not adequate and may request the individual to submit additional proof of identification.

(2) If the request is made in person, the requester shall submit proof of identification similar to that described in paragraph (c)(1) of this section, acceptable to the Commission.

§ 9410.5 Disclosure of requested information to individuals.

(a) Upon submission of proof of identification as required by § 9410.4, the Commission shall allow the individual to see and/or obtain a copy of the requested record or shall send a copy of the record to the individual by registered mail. If the individual requests to see the record, the Commission may make the record available either at the location where the record is maintained or at a place more suitable to the requestor, if possible. The record shall be made available as soon as possible, but in no event later than 15 working days after proof of identification. The individual may have a person or persons of his or her own choosing accompany him or her when the record is disclosed.

(b) The Commission must furnish each record requested by an individual under this part in a form intelligible to that individual.

(c) If the Commission denies access to a record to an individual, he or she shall be advised of the reason for the denial and advised of the right to judicial review.

(d) Upon request, an individual will be provided access to the accounting of disclosures from his or her record under the same procedures as provided above and in § 9410.4.

§ 9410.6 Request for correction or amendment to record.

(a) Any individual who has reviewed a record pertaining to him or her that was furnished under this part may request that the Commission correct or amend all or any part of that record.

(b) Each individual requesting a correction or amendment shall send or provide in person the written request to the Commission through the person who furnished the record.

(c) Each request for a correction or amendment of a record shall contain the following information:

(1) The name of the individual requesting the correction or amendment;

(2) The name of the system of records in which the record sought to be amended is maintained;

(3) The location of the system of records from which the individual record was obtained;

(4) A copy of the record sought to be amended or corrected or a sufficiently detailed description of that record;

(5) A statement of the material in the record that the individual desires to correct or amend; and

(6) A statement of the basis for the requested correction or amendment including any material that the individual can furnish to substantiate the reasons for the correction or amendment sought.

§ 9410.7 Commission review of request for correction or amendment of record.

(a) The Commission shall, not later than 10 working days after the receipt of the request for a correction or amendment of a record under § 9410.6, acknowledge receipt of the request and inform the individual whether additional information is required before the correction or amendment can be considered.

(b) If no additional information is required, within 10 working days from receipt of the request, the Commission shall either make the requested correction or amendment or notify the individual of its refusal to do so, including in the notification the reasons for the refusal and the appeal procedures provided in § 9410.8.

(c) The Commission shall make each requested correction or amendment to a record if that correction or amendment will negate inaccurate, irrelevant, untimely, or incomplete information in the record.

(d) The Commission shall inform prior recipients of a record of any amendment or correction or notation of dispute of the individual's record if an accounting of the disclosure was made. The individual may request a list of prior recipients if an accounting of the disclosure was made.

§ 9410.8 Appeal of initial adverse determination on amendment or correction.

(a) Any individual whose request for a correction or amendment has been denied in whole or in part may appeal that decision to the Commissioners no later than 180 days after the adverse decision is rendered.

(b) The appeal shall be in writing and shall contain the following information:

(1) The name of the individual making the appeal;

(2) Identification of the record sought to be amended;

(3) The record system in which that record is contained;

(4) A short statement describing the amendment sought; and

(5) The name and location of the Commission official who initially denied the correction or amendment.

(c) Not later than 30 working days after the date on which the Commission receives the appeal, the Commissioners shall complete their review of the appeal and make a final decision thereon. However, for good cause shown, the Commissioners may extend that 30-day period. If the Commissioners extend the period, the individual requesting the review shall be promptly notified of the extension and the anticipated date of a decision.

(d) After review of an appeal, the Commission shall send a written notice to the requestor containing the following information:

(1) The decision and, if the denial is upheld, the reasons for the decision;

(2) The right of the requestor to institute a civil action in a Federal District Court for judicial review of the decision; and

(3) The right of the requestor to file with the Commission a concise statement setting forth the reasons for his or her disagreement with the Commission's denial of the correction or amendment. The Commission shall make this statement available to any person to whom the record is later disclosed, together with a brief statement, if appropriate, of the Commission's reasons for denying the requested correction or amendment. The Commission shall also send a copy of the statement to prior recipients of the individual's record if an accounting of the disclosures was made.

§ 9410.9 Disclosure of record to person other than the individual to whom it pertains.

(a) Any individual who desires to have a record covered by this part disclosed to or mailed to another person may designate such person and authorize the person to act as his or her agent for that specific purpose. The authorization shall be in writing, signed by the individual, and notarized or witnessed as provided in § 9410.4(c).

(b) The parent of any minor individual or the legal guardian of any individual who has been declared by a court of competent jurisdiction to be incompetent due to physical or mental

incapacity or age may act on behalf of that individual in any matter covered by this part. A parent or guardian who desires to act on behalf of such an individual shall present suitable evidence of parentage or guardianship, by birth certificate, certified copy of a court order, or similar documents, and proof of the individual's identity in a form that complies with § 9410.4(c).

(c) An individual to whom a record is to be disclosed in person under this part may have a person or persons of his or her own choosing accompany him or her when the record is disclosed.

§ 9410.10 Fees.

(a) The Commission shall not charge an individual for the cost of making a search for a record or the cost of reviewing the record. When the Commission makes a copy of a record as a necessary part of the process of disclosing the record to an individual, the Commission shall not charge the individual for the cost of making that copy. When the Commission makes a copy of a record in response to a request from an individual, the Commission may charge the individual for the reasonable cost of making the copy.

(b) If an individual requests that the Commission furnish a copy of the record, the Commission shall charge the individual for the cost of making the copy. The fee that the Commission has established for making a copy is fifteen (15) cents per page.

§ 9410.11 Penalties.

Any person who makes a false statement in connection with any request for a record or an amendment or correction thereto under this part is subject to the penalties prescribed in 18 U.S.C. 494 and 495 and 5 U.S.C. 552a (i)(3).

Thomas R. Wilkey,

Executive Director, U.S. Election Assistance Commission.

[FR Doc. E8–21801 Filed 9–17–08; 8:45 am]

BILLING CODE 6820–KF–P

Federal Register

Thursday,
September 18, 2008

Part V

Election Assistance Commission

11 CFR Parts 9409, 9411, and 9420

Testimony by Commission Employees Relating to Official Information and Production of Official Records in Legal Proceedings, Standards of Conduct for Commission Employees, and Nondiscrimination on the Basis of Handicap in Programs or Activities Conducted by the U.S. Election Assistance Commission; Final Rule

ELECTION ASSISTANCE COMMISSION

11 CFR Parts 9409, 9411, and 9420

RIN 3265–AA01

Testimony by Commission Employees Relating to Official Information and Production of Official Records in Legal Proceedings, Standards of Conduct for Commission Employees, and Nondiscrimination on the Basis of Handicap in Programs or Activities Conducted by the U.S. Election Assistance Commission

AGENCY: United States Election Assistance Commission (EAC).

ACTION: Final rule.

SUMMARY: The U.S. Election Assistance Commission is promulgating administrative regulations to implement standards of conduct for Commission employees, requirements on testimony by Commission employees and production of Commission records in legal proceedings, and requirements for nondiscrimination on the basis of handicap in programs or activities conducted by the Commission.

DATES: The rules promulgated today become effective September 18, 2008.

FOR FURTHER INFORMATION CONTACT: Tamar Nedzar, Attorney, U.S. Election Assistance Commission, 1225 New York Avenue, NW., Suite 1100, Washington, DC 20005. Telephone (202) 566–3100.

SUPPLEMENTARY INFORMATION:

Preamble Table of Contents

The following is an outline of the preamble.

I. Legal Basis for the Rulemaking
II. Discussion of the Rulemaking
III. Rulemaking Analyses and Notices

I. Legal Basis for the Rulemaking

This rulemaking action is taken to establish administrative requirements necessary for the proper functioning of the Election Assistance Commission (EAC). The Office of Government Ethics, established by the Ethics in Government Act of 1978, which is responsible for exercising leadership in the federal government for the prevention of conflicts of interest and the fostering of high ethical standards for government employees, has promulgated regulations on the standards of conduct for federal government employees. The EAC, pursuant to 1 CFR 21.21, is cross referencing the Office of Government Ethics regulations in its own regulations in part 9411 of 11 CFR Chapter II to ensure that all employees of the EAC are aware of the standards of ethical conduct applicable to them as employees of the Commission. Similarly, the Office of Personnel Management, under the Hatch Act Reform Amendments of 1993, has promulgated regulations defining what political activities are permitted and prohibited for federal government employees. The EAC, pursuant to 1 CFR 21.21, is cross referencing the Office of Personnel Management regulations in its own regulations in part 9411 of 11 CFR Chapter II to ensure that all employees of the EAC are aware of the political activities permitted and prohibited to them as employees of the Commission.

The U.S. Supreme Court, in *United States ex rel Touhy* v. *Ragen,* 340 U.S. 462 (1951), established limits on the power of legal tribunals to require agencies of the federal government to produce official records or allow their employees to provide testimony relating to official information in connection with legal proceedings in which the federal agency is not a named party. The EAC is adopting regulations (sometimes referred to as ''Touhy'' procedures) in part 9409 of 11 CFR Chapter II to provide guidance for the internal operations of the Commission and to inform the public about Commission procedures concerning the service of process and responses to demands or requests for the production of official Commission documents or the testimony of Commission employees in proceedings in which the Commission is not a named party.

Finally, in the Rehabilitation, Comprehensive Services, and Developmental Disabilities Act of 1978, 29 U.S.C. 794, Congress provided that each federal agency shall promulgate such regulations as may be necessary to carry out the provisions of the act relating to nondiscrimination under federal grants and programs. The EAC is adopting regulations in part 9420 of 11 CFR Chapter II to prohibit discrimination on the basis of handicap in programs or activities conducted by the Commission.

The EAC is promulgating 11 CFR parts 9409, 9411, and 9420 as final rules, under the exemption in 5 U.S.C. 553(b)(3)(a) for interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice.

II. Discussion of the Rulemaking

The United States Election Assistance Commission was created by Congress in the Help America Vote Act of 2002. The Commission's primary function is to serve as a national clearinghouse and resource for information on and procedures for federal elections. The EAC conducts studies on election administration and makes those studies available to the public. The EAC also has adopted Voluntary Voting System Guidelines; administers a voting system testing and certification program; allocates election-related federal funding to the States; and carries out administrative duties under the National Voter Registration Act of 1993 (the Motor Voter Law), including developing and maintaining a mail voter registration application form for elections to federal office.

The rules being adopted address the internal administration of the EAC. By establishing standards of conduct for EAC personnel, rules governing when and how internal EAC documents may be released and EAC personnel may testify in legal matters in which the EAC is not a named party, and rules ensuring nondiscrimination on the basis of handicap in programs and activities conducted by the EAC, the Commission is satisfying the requirement in the Administrative Procedure Act, 5 U.S.C. 552, that federal agencies publish in the **Federal Register** statements of the general course and method of how the agencies' functions are channeled and determined. In addition, the EAC is either adopting by cross reference or modeling the three sets of regulatory requirements it is adopting on regulations addressing the same topics previously adopted by other federal agencies. Thus, many of the provisions in these rules are identical to or closely resemble the requirements adopted by other federal agencies, and as such represent regulatory ''best practices'' on the topics of standards of conduct, ''Touhy'' procedures, and nondiscrimination on the basis of handicap.

Although not required by law, the EAC posted these regulations on its Web site for the period from August 5, 2008 to September 4, 2008. The EAC received no comments during that period. Accordingly, no changes were made to the regulations and they are being submitted to the **Federal Register** with the same content they contained when posted on the EAC's Web site.

III. Regulatory Analyses and Notices

Regulatory Flexibility Act, as Amended

The Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 (5 U.S.C. 601 *et seq.*) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any

other statute, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small government jurisdictions. Because the rules adopted today are administrative in nature and exempt from notice and comment rulemaking under § 553(b)(3)(a) of the Administrative Procedure Act, the EAC has concluded that a regulatory flexibility analysis is not required.

Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4; 2 U.S.C. 1532) requires each agency to assess the effects of its regulatory actions on State, local, and tribal governments and the private sector. Any agency promulgating a rule likely to result in a federal mandate requiring expenditures by a State, local, or tribal government or by the private sector of $120.7 million or more in any one year must prepare a written statement incorporating various assessments, estimates, and descriptions that are delineated in the Act. The EAC has determined that these administrative rules will create no unfunded mandates because they require no expenditures by a State, local, or tribal government and will not have an impact of $120.7 million or more in any one year.

Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as amended by SBREFA, 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. If the rule meets the definition of a major rule, as defined in SBREFA, the Comptroller General must provide a report to Congress and the rule may not take effect until 60 days after it has been published in the **Federal Register**. The current action is a Final Rule that does not meet the definition of a major rule. The EAC is submitting the necessary rule report to the Congress and the Comptroller General of the United States.

National Environmental Policy Act

The EAC analyzed these rules for the purpose of the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*) and determined that this action includes no circumstances that would have any effect on the quality of the environment. The rules pertain solely to the dissemination of information. Thus, these actions do not require an environmental assessment or an environmental impact statement.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires the EAC to consider the impact of paperwork and other information collection burdens imposed on the public. The regulations in part 9409 and part 9411 pertain solely to the internal administration of the EAC. These rules do not impose any reporting or recordkeeping requirements. The regulations in part 9420 also pertain to internal administrative procedures, but may result in complaints filed with the EAC. The EAC anticipates that only a very small number of such complaints, if any, will be submitted on an annualized basis and the paperwork burden of such complaints will also be very small, amounting to fewer than eight hours per year.

Executive Order 12630 (Taking of Private Property)

These rules would 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.''

Executive Order 12988 (Civil Justice Reform)

These rules meet 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)

Executive Order 13045, ''Protection of Children from Environmental Health Risks and Safety Risks'' (April 23, 1997, 62 FR 19885), requires that agencies issuing economically significant rules, which also concern an environmental health or safety risk that an agency has reason to believe may disproportionately affect children, must include an evaluation of the environmental health and safety effects of the regulation on children. Section 5 of Executive Order 13045 directs an agency to submit for a covered regulatory action an evaluation of its environmental health or safety effects on children. The EAC has determined that these rules are not covered regulatory actions as defined under Executive Order 13045. This determination is based upon the fact that these rules do not constitute an environmental health risk or safety risk that would disproportionately affect children.

Executive Order 12372 (Intergovernmental Review)

The regulations implementing Executive Order 12372 regarding intergovernmental consultation on federal programs and activities do not apply to this rulemaking.

Executive Order 13211 (Energy Supply, Distribution, or Use)

The EAC has analyzed these rules under Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.'' These rules are not a significant energy action within the meaning of section 4(b) of the Executive Order. They involve internal procedures of the EAC, are not economically significant, and will not have a significant adverse effect on the supply, distribution, or use of energy.

List of Subjects

11 CFR Part 9409

Administrative practice and procedure, Courts, Government employees, Practice and procedure.

11 CFR Part 9411

Administrative practice and procedure, Conduct standards, Conflict of interest, Government employees.

11 CFR Part 9420

Administrative practice and procedure, Grants and administration, Individuals with disabilities, Nondiscrimination.

■ In consideration of the foregoing, EAC amends title 11, Code of Federal Regulations, Chapter II, as follows:

■ 1. Add part 9409 to read as follows:

PART 9409—TESTIMONY BY COMMISSION EMPLOYEES RELATING TO OFFICIAL INFORMATION AND PRODUCTION OF OFFICIAL RECORDS IN LEGAL PROCEEDINGS

Sec.

9409.1 Purpose and scope.
9409.2 Applicability.
9409.3 Definitions.
9409.4 Production or disclosure prohibited unless approved by appropriate Commission official.
9409.5 Procedures for demand for testimony or production of documents.
9409.6 Service of subpoenas or requests.
9409.7 Factors to be considered by the General Counsel.
9409.8 Processing demands or requests.
9409.9 Final determination.
9409.10 Restrictions that apply to testimony.
9409.11 Restrictions that apply to released records.
9409.12 Procedure when a decision is not made prior to the time a response is required.

9409.13 Procedures when the General Counsel directs an employee not to testify or provide documents.
9409.14 Fees.
9409.15 Penalties.

Authority: 44 U.S.C. 3102.

§ 9409.1 Purpose and scope.

(a) This part sets forth policies and procedures you must follow when you submit a demand or request to an employee of the United States Election Assistance Commission to produce official records and information, or provide testimony relating to official information, in connection with a legal proceeding. You must comply with these requirements when you request the release or disclosure of official records and information.

(b) The Commission intends these provisions to:

(1) Promote economy and efficiency in its programs and operations;

(2) Minimize the possibility of involving the Commission in controversial issues not related to its functions;

(3) Maintain the Commission's impartiality among private litigants where the Commission is not a named party; and

(4) Protect sensitive, confidential information and the deliberative processes of the Commission.

(c) In providing for these requirements, the Commission does not waive the sovereign immunity of the United States.

(d) This part is intended only to provide guidance for the internal operations of the Commission and to inform the public about Commission procedures concerning the service of process and responses to demands or requests. The procedures specified in this part, or the failure of any Commission employee to follow the procedures specified in this part, are not intended to create, do not create, and may not be relied upon to create a right or benefit, substantive or procedural, enforceable at law by a party against the United States.

§ 9409.2 Applicability.

(a) This part applies to demands and requests to employees for factual or expert testimony relating to official information, or for production of official records or information, in legal proceedings in which the Commission is not a named party. However, it does not apply to:

(1) Demands upon or requests for a Commission employee to testify as to facts or events that are unrelated to his or her official duties or that are unrelated to the functions of the Commission;

(2) Demands upon or requests for a former Commission employee to testify as to matters in which the former employee was not directly or materially involved while at the Commission;

(3) Requests for the release of records under the Freedom of Information Act, 5 U.S.C. 552, or the Privacy Act, 5 U.S.C. 552a; and

(4) Congressional demands and requests for testimony or records.

§ 9409.3 Definitions.

As used in this part, the term—

Commission means the U.S. Election Assistance Commission, established by the Help America Vote Act of 2002, 42 U.S.C. 15301 *et seq.*

Commission employee or employee means:

(a) Any current or former officer or employee of the Commission;

(b) Any other individual hired through contractual agreement by or on behalf of the Commission or who has performed or is performing services under an agreement for the Commission; and

(c) Any individual who served or is serving in any consulting or advisory capacity to the Commission, whether formal or informal.

(d) This definition does not include persons who are no longer employed by the Commission and who are retained or hired as expert witnesses or who agree to testify about general matters, matters available to the public, or matters with which they had no specific involvement or responsibility during their employment with the Commission.

Demand means a subpoena, or an order or other command of a court or other competent authority, for the production, disclosure, or release of records or for the appearance and testimony of a Commission employee that is issued in a legal proceeding.

General Counsel means the General Counsel of the Commission or a person to whom the General Counsel has delegated authority under this part.

Legal proceeding means any matter before a court of law, administrative board or tribunal, commission, administrative law judge, hearing officer, or other body that conducts a legal or administrative proceeding. Legal proceeding includes all phases of litigation.

Records or official records and information means:

(a) All documents and materials that are Commission records under the Freedom of Information Act (5 U.S.C. 552);

(b) All other documents and materials contained in files of the Commission; and

(c) All other information or materials acquired by a Commission employee in the performance of his or her official duties or because of his or her official status.

Request means any informal request, by whatever method, for the production of records and information or for testimony that has not been ordered by a court or other competent authority.

Testimony means any written or oral statements, including depositions, answers to interrogatories, affidavits, declarations, interviews, and statements made by an individual in connection with a legal proceeding.

§ 9409.4 Production or disclosure prohibited unless approved by appropriate Commission official.

(a) No employee or former employee of the Commission shall, in response to a demand of a court or other authority, produce a record or disclose any information relating to any record of the Commission, or disclose any information or produce any material acquired as part of the performance of his official duties or because of his official status without the prior, written approval of the General Counsel of the Commission.

(b) Any expert or opinion testimony by a former employee of the Commission shall be excepted from the requirements of this part where the testimony involves only general expertise gained while employed at the Commission.

§ 9409.5 Procedures for demand for testimony or production of documents.

(a) A demand directed to the Commission for the testimony of a Commission employee or for the production of documents shall be served in accordance with the Federal Rules of Civil Procedure, Federal Rules of Criminal Procedure, or applicable State procedures and shall be directed to the General Counsel, U.S. Election Assistance Commission, 1225 New York Avenue, NW., Suite 1100, Washington, DC 20005. Acceptance of a demand shall not constitute an admission or waiver with respect to jurisdiction, propriety of service, improper venue, or any other defense in law or equity available under the applicable laws or rules.

(b) If a subpoena is served on the Commission or a Commission employee before submitting a written request and receiving a final determination, the Commission will oppose the subpoena on grounds that the request was not submitted in accordance with this part.

(c) A written request must contain the following information:

(1) The caption of the legal proceeding, docket number, name and address of the court or other authority involved; and the procedural posture of the legal proceeding.

(2) A copy of the complaint or equivalent document setting forth the assertions in the case and any other pleading or document necessary to show relevance;

(3) A list of categories of records sought, a detailed description of how the information sought is relevant to the issues in the legal proceeding, and a specific description of the substance of the testimony or records sought;

(4) A statement as to how the need for the information outweighs the need to maintain any confidentiality of the information and outweighs the burden on the Commission to produce the records or provide testimony;

(5) A statement indicating that the information sought is not available from another source, from other persons or entities, or from the testimony of someone other than a Commission employee, such as a retained expert;

(6) If testimony is requested, the intended use of the testimony, a general summary of the desired testimony, and a showing that no document could be provided and used in lieu of testimony;

(7) A description of all prior decisions, orders, or pending motions in the case that bear upon the relevance of the requested records or testimony;

(8) The name, address, and telephone number of counsel to each party in the case;

(9) An estimate of the amount of time that the requester and other parties will require of each Commission employee for time spent by the employee to prepare for testimony, in travel, and for attendance in the legal proceeding; and

(10) Whether travel by the Commission employee is required to provide the testimony; or, in lieu of in-person testimony, whether a deposition may be taken at the employee's duty station.

(d) The Commission reserves the right to require additional information to complete a request where appropriate.

(e) A request should be submitted at least 45 days before the date that records or testimony is required. Requests submitted in less than 45 days before records or testimony is required must be accompanied by a written explanation stating the reasons for the late request and the reasons for expedited processing.

(f) Failure to cooperate in good faith to enable the General Counsel to make an informed decision may serve as the basis for a determination not to comply with a request.

(g) Notification to the General Counsel:

(1) Employees shall immediately refer all inquiries and demands made on the Commission to the General Counsel.

(2) An employee who receives a subpoena shall immediately forward the subpoena to the General Counsel. The General Counsel will determine the manner in which to respond to the subpoena.

§ 9409.6 Service of subpoenas or requests.

Subpoenas or requests for official records or information or testimony must be served on the General Counsel, U.S. Election Assistance Commission, 1225 New York Avenue, NW., Suite 1100, Washington, DC 20005.

§ 9409.7 Factors to be considered by the General Counsel.

The General Counsel, in his or her sole discretion, may grant an employee permission to testify on matters relating to official information, or produce official records and information, in response to a demand or request. Among the relevant factors that the General Counsel may consider in making this decision are whether:

(a) The purposes of this part are met;

(b) Allowing such testimony or production of records would be necessary to prevent a miscarriage of justice;

(c) The Commission has an interest in the decision that may be rendered in the legal proceeding;

(d) Allowing such testimony or production of records would assist or hinder the Commission in performing its statutory duties or use Commission resources where responding to the demand or request will interfere with the ability of Commission employees to do their work;

(e) Allowing such testimony or production of records would be in the best interest of the Commission or the United States;

(f) The records or testimony can be obtained from other sources;

(g) The demand or request is unduly burdensome or otherwise inappropriate under the applicable rules of discovery or the rules of procedure governing the case or matter in which the demand or request arose;

(h) Disclosure would violate a statute, Executive order or regulation;

(i) Disclosure would reveal confidential, sensitive, or privileged information, trade secrets or similar, confidential commercial or financial information, otherwise protected information, or information which would otherwise be inappropriate for release;

(j) Disclosure would impede or interfere with an ongoing law enforcement investigation or proceedings, or compromise constitutional rights;

(k) Disclosure would result in the Commission appearing to favor one litigant over another;

(l) Disclosure relates to documents that were produced by another agency;

(m) A substantial Government interest is implicated;

(n) The demand or request is within the authority of the party making it; and

(o) The demand or request is sufficiently specific to be answered.

§ 9409.8 Processing demands or requests.

(a) After service of a demand or request to testify, the General Counsel will review the demand or request and, in accordance with the provisions of this part, determine whether, or under what conditions, to authorize the employee to testify on matters relating to official information and/or produce official records and information.

(b) The Commission will process requests in the order in which they are received. Absent exigent or unusual circumstances, the Commission will respond within 45 days from the date a request is received. The time for response will depend upon the scope of the request.

(c) The General Counsel may grant a waiver of any procedure described by this part where a waiver is considered necessary to promote a significant interest of the Commission or the United States or for other good cause.

§ 9409.9 Final determination.

The General Counsel will make the final determination on demands and requests to employees for production of official records and information or testimony. All final determinations are within the sole discretion of the General Counsel. The General Counsel will notify the requester and the court or other authority of the final determination, the reasons for the grant or denial of the demand or request, and any conditions that the General Counsel may impose on the release of records or information, or on the testimony of a Commission employee.

§ 9409.10 Restrictions that apply to testimony.

(a) The General Counsel may impose conditions or restrictions on the testimony of Commission employees including, for example, limiting the areas of testimony or requiring the requester and other parties to the legal proceeding to agree that the transcript of the testimony will be kept under seal or

will only be used or made available in the particular legal proceeding for which testimony was requested. The General Counsel may also require a copy of the transcript of testimony at the requester's expense.

(b) The Commission may offer the employee's written declaration in lieu of testimony.

(c) If authorized to testify under this part, an employee may testify as to facts within his or her personal knowledge, but, unless specifically authorized to do so by the General Counsel, the employee shall not:

(1) Disclose confidential or privileged information; or

(2) For a current Commission employee, testify as an expert or opinion witness with regard to any matter arising out of the employee's official duties or the functions of the Commission unless testimony is being given on behalf of the United States.

§ 9409.11 Restrictions that apply to released records.

(a) The General Counsel may impose conditions or restrictions on the release of official records and information, including the requirement that parties to the proceeding obtain a protective order or execute a confidentiality agreement to limit access and any further disclosure. The terms of the protective order or confidentiality agreement must be acceptable to the General Counsel. In cases where protective orders or confidentiality agreements have already been executed, the Commission may condition the release of official records and information on an amendment to the existing protective order or confidentiality agreement.

(b) If the General Counsel so determines, original Commission records may be presented for examination in response to a demand or request, but they are not to be presented as evidence or otherwise used in a manner by which they could lose their identity as official Commission records, nor are they to be marked or altered. In lieu of the original records, certified copies will be presented for evidentiary purposes (see 28 U.S.C. 1733).

§ 9409.12 Procedure when a decision is not made prior to the time a response is required.

If a response to a demand or request is required before the General Counsel's decision is received, a U.S. attorney or a Commission attorney designated for the purpose shall appear with the employee or former employee of the Commission upon whom the demand has been made and shall furnish the court or other authority with a copy of the regulations contained in this part and inform the court or other authority that the demand has been, or is being, as the case may be, referred for the prompt consideration of the appropriate Commission official and shall respectfully request the court or authority to stay the demand pending receipt of the requested instructions.

§ 9409.13 Procedures when the General Counsel directs an employee not to testify or provide documents.

(a) If the General Counsel determines that an employee or former employee should not comply with a subpoena or other request for testimony or the production of documents, the General Counsel will so inform the employee and the party who submitted the subpoena or made the request.

(b) If, despite the determination of the General Counsel that testimony should not be given and/or documents not be produced, a court of competent jurisdiction or other appropriate authority orders the employee or former employee to testify and/or produce documents; the employee shall notify the General Counsel of such order.

(1) If the General Counsel determines that no further legal review of, or challenge to, the order will be sought, the employee or former employee shall comply with the order.

(2) If the General Counsel determines to challenge the order, or that further legal review is necessary, the employee or former employee should not comply with the order. Where necessary, the employee should appear at the time and place set forth in the subpoena. If legal counsel cannot appear on behalf of the employee, the employee should produce a copy of this part and respectfully inform the legal tribunal that he/she has been advised by counsel not to provide the requested testimony and/or produce documents. If the legal tribunal rules that the subpoena must be complied with, the employee shall respectfully decline to comply, citing this section and *United States ex rel. Touhy* v. *Ragen,* 340 U.S. 462 (1951).

§ 9409.14 Fees.

(a) *Generally.* The General Counsel may condition the production of records or appearance for testimony upon advance payment of a reasonable estimate of the costs to the Commission.

(b) *Fees for records.* Requesters will reimburse the Commission for the actual costs of time and resources spent searching, reviewing and duplicating records. Fees for producing records will include fees for searching, reviewing, and duplicating records, costs of attorney time spent in reviewing the demand or request, and expenses generated by materials and equipment used to search for, produce, and copy the responsive information. The Commission will charge fees at the salary rate(s) (basic pay plus 16 percent) of employee time spent searching, reviewing, and duplicating records. Fees for duplication will be the same as those charged by the Commission for records disclosed under the Freedom of Information Act (11 CFR 9405), except that the Commission will charge for the actual costs for each page of duplication and will not provide the first 100 pages for free.

(c) *Witness fees.* Fees for attendance by a witness will include fees, expenses, and allowances prescribed by the court's rules. If no such fees are prescribed, witness fees will be determined based upon the rule of the Federal district court closest to the location where the witness will appear. The fees will include cost of time spent by the witness to prepare for testimony, in travel, and for attendance in the legal proceeding.

(d) *Payment of fees.* Witness fees shall be paid for current Commission employees and any records certification fees by submitting to the General Counsel a check or money order for the appropriate amount made payable to the Treasury of the United States. In the case of testimony by former Commission employees, applicable fees shall be paid directly to the former employee in accordance with 28 U.S.C. 1821 or other applicable statutes.

(e) *Certification (authentication) of copies of records.* The Commission may certify that records are true copies to facilitate their use as evidence. To obtain certification a request for certified copies shall be made to the Commission at least 45 days before the date the copies will be needed. The request should be sent to the General Counsel, U.S. Election Assistance Commission, 1225 New York Avenue, NW., Washington, DC 20005.

(f) *Waiver or reduction of fees.* The General Counsel, in his or her sole discretion, may, upon a showing of reasonable cause, waive or reduce any fees in connection with the testimony, production, or certification of records.

§ 9409.15 Penalties.

(a) An employee who discloses official records or information or gives testimony relating to official information, except as expressly authorized by the Commission or as ordered by a Federal court after the Commission has had the opportunity to be heard, may face the penalties provided in 18 U.S.C. 641 and other

applicable laws. Former Commission employees are subject to the restrictions and penalties of 18 U.S.C. 207 and 216.

(b) A current Commission employee who testifies or produces official records and information in violation of this part shall be subject to disciplinary action in addition to any penalties assessed under paragraph (a) of this section.

■ 2. Add part 9411 to read as follows:

PART 9411—STANDARDS OF CONDUCT

Authority: 5 CFR parts 2634 through 2638; 5 CFR part 2641; 5 CFR parts 734 and 735.

§ 9411.1 Cross-reference to executive branch-wide regulations.

(a) Employees of the U.S. Election Assistance Commission are subject to the following standards of conduct and ethical requirements:

(1) Executive Branch Financial Disclosure, Qualified Trusts, and Certificates of Divestiture as provided in 5 CFR part 2634;

(2) Standards of Ethical Conduct for Employees of the Executive Branch as provided in 5 CFR part 2635;

(3) Limitations on Outside Earned Income, Employment and Affiliations for Certain Noncareer Employees as provided in 5 CFR part 2636;

(4) Regulations Concerning Post-Employment Conflict of Interest as provided in 5 CFR part 2637;

(5) Interpretation, Exemptions and Waiver Guidance Concerning 18 U.S.C. 208 (Acts Affecting a Personal Financial Interest) as provided in 5 CFR part 2638;

(6) Post-Employment Conflict of Interest Restrictions as provided in 5 CFR part 2641;

(7) Political Activities of Federal Employees as provided in 5 CFR part 734; and

(8) Employee Responsibilities and Conduct as provided in 5 CFR part 735.

(b) For purposes of this part, employee shall have the definition given to it by each standard of conduct or ethical requirement in paragraph (a) of this section.

■ 3. Add part 9420 to read as follows:

PART 9420—NONDISCRIMINATION ON THE BASIS OF HANDICAP IN PROGRAMS OR ACTIVITIES CONDUCTED BY THE U.S. ELECTION ASSISTANCE COMMISSION

Sec.

9420.1 Purpose and scope.
9420.2 Definitions.
9420.3 General prohibitions against discrimination.
9420.4 Program accessibility: Discrimination prohibited.
9420.5 Program accessibility: Existing facilities.
9420.6 Program accessibility: New construction and alterations.
9420.7 Communications.
9420.8 Compliance procedures.

Authority: 29 U.S.C. 794.

§ 9420.1 Purpose and scope.

This part sets forth the nondiscrimination policy of the U.S. Election Assistance Commission to prohibit discrimination on the basis of handicap in programs or activities conducted by the Commission.

§ 9420.2 Definitions.

As used in this part, the term—

Auxillary aids means services, including attendant services, or devices that enable handicapped persons, including those with impaired sensory, manual, or speaking skills to have an equal opportunity to participate in, and enjoy the benefits of, programs or activities conducted by the Commission. For example, auxiliary aids useful for disabled persons with impaired vision include readers, brailled materials, audio recordings, telecommunications devices and other similar services and devices. Auxiliary aids useful for disabled persons with impaired hearing include telephone handset amplifiers, telephones compatible with hearing aids, telecommunication devices for deaf persons (TDDs), interpreters, notetakers, written materials, and other similar services and devices.

Commission means the U.S. Election Assistance Commission, established by the Help America Vote Act of 2002, 42 U.S.C. 15301 *et seq.*

Complete complaint means a written statement that contains the complainant's name and address and describes the complaintant's name and address and describes the Commission's actions in sufficient detail to inform the Commission of the nature and date of the alleged violation of section 504, as defined in this part. It shall be signed by the complainant or by someone authorized to do so on his or her behalf. Complaints filed on behalf of classes or third parties shall describe or identify (by name if possible) the alleged victims of discrimination.

Facility means all or any portion of buildings, structures, equipment, roads, walks, parking lots, rolling stock or other conveyances, or other real or personal property whether owned, leased or used on some other basis by the Commission.

Handicapped person means any person who has a physical or mental impairment that substantially limits one or more major life activities, has a record of such impairment, or is regarded as having such impairment. As used in this definition, the phrase:

(1) *Physical or mental impairment* includes:

(i) Any physiological disorder or condition, cosmetic disfigurement, or anatomical loss affecting one of more of the following body systems: Neurological; musculoskeletal; special sense organs; respiratory, including speech organs; cardiovascular; reproductive; digestive; genitourinary; hemic and lymphatic; skin; and endocrine; or

(ii) Any mental or psychological disorder, such as mental retardation, organic brain syndrome, emotional or mental illness, and specific learning disabilities. The term ''physical or mental impairment'' includes, but is not limited to, such diseases and conditions as orthopedic; visual, speech, and hearing impairments; cerebral palsy; epilepsy; muscular dystrophy; multiple sclerosis; cancer; heart disease; diabetes; mental retardation; emotional illness; and drug addition and alcoholism.

(2) *Major life activities* include functions such as caring for one's self, performing manual tasks, walking, seeing, hearing, speaking, breathing, learning, and working.

(3) *Has a record of such an impairment* means has a history of or has been misclassified as having a mental or physical impairment that substantially limits one or more major life activities.

(4) *Is regarded as having an impairment* means:

(i) Has a physical or mental impairment that does not substantially limit major life activities, but is treated by the Commission as constituting such a limitation;

(ii) Has a physical or mental impairment that substantially limits major life activities only as a result of the attitudes of others toward the impairment; or

(iii) Has none of the impairments defined in paragraph (1) of this definition, but is treated by the Commission as having an impairment.

Qualified handicapped person means (1) with respect to any Commission program or activity under which a person is required to perform services or to achieve a level of accomplishment, a handicapped person who, with reasonable accommodation, meets the essential eligibility requirements and who can achieve the purpose of the program or activity; and

(2) With respect to any other program or activity, a handicapped person who meets essential eligibility requirements

for participation in, or receipt of benefits from, that program or activity.

Section 504 means section 504 of the Rehabilitation Act of 1973 (Pub. L. 93–112, 87 Stat. 394), as amended by the Rehabilitation Act Amendments of 1974 (Pub. L. 93–516, 88 Stat. 1617) and the Rehabilitation, Comprehensive Services, and Developmental Disabilities Act of 1978 (Pub. L. 95–602, 92 Stat. 2955). As used in this part, section 504 applies only to programs or activities conducted by the Commission and not to any federally assisted programs or activities that it administers.

§ 9420.3 General prohibitions against discrimination.

(a) No qualified handicapped person shall, on the basis of handicap, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any program or activity conducted by the Commission.

(b)(1) The Commission, in providing any aid, benefit, or service, may not, directly or through contractual, licensing, or other arrangement, on the basis of handicap—

(i) Deny a qualified handicapped person the opportunity to participate in or benefit from the aid, benefit, or service;

(ii) Afford a qualified handicapped person an opportunity to participate in or benefit from the aid, benefit, or service that is not equal to that afforded others;

(iii) Provide a qualified handicapped person with an aid, benefit, or service that is not as effective in affording equal opportunity to obtain the same result, to gain the same benefit, or to reach the same level of achievement as that provided to others;

(iv) Provide different or separate aids, benefits, or services to handicapped persons or to any class of handicapped persons than is provided to others unless such action is necessary to provide qualified handicapped persons with aids, benefits, or services that are as effective as those provided to others;

(v) Deny a qualified handicapped person the opportunity to participate as a member of planning or advisory boards; or

(vi) Otherwise limit a qualified handicapped person in the enjoyment of any right, privilege, advantage, or opportunity enjoyed by others receiving aid, benefit, or service.

(2) The Commission may not deny a qualified handicapped person the opportunity to participate in programs or activities that are not separate or different, despite the existence of permissibly separate or different programs or activities.

(3) The Commission may not, directly or through contractual or other arrangements, utilize criteria or methods of administration the purpose or effect of which would—

(i) Subject qualified handicapped persons to discrimination on the basis of handicap; or

(ii) Defeat or substantially impair accomplishment of the objectives of a program or activity with respect to handicapped persons.

(4) The Commission may not, in determining the site or location of a facility, make selections the purpose or effect of which would—

(i) Exclude handicapped persons from, deny them the benefits of, or otherwise subject them to discrimination under any program or activity conducted by the Commission; or

(ii) Defeat or substantially impair the accomplishment of objectives of a program or activity with respect to handicapped persons.

(5) The Commission, in selection of procurement contractors, may not use criteria that subject qualified handicapped persons to discrimination on the basis of handicap.

(6) The Commission may not administer a certification program in a manner that subjects qualified handicapped persons to discrimination on the basis of handicap, nor may the Commission establish requirements for the programs or activities of certified entities that subject qualified handicapped persons to discrimination on the basis of handicap. The programs or activities of entities that are certified by the Commission are not, themselves, covered by this part.

(c) The exclusion of non-handicapped persons from the benefits of a program limited by Federal statute or Executive Order to handicapped persons or the exclusion of a specific class of handicapped persons from a program limited by Federal statute or Executive Order to a different class of handicapped persons is not prohibited by this part.

(d) The Commission will administer programs and activities in the most integrated setting appropriate to the needs of qualified handicapped persons.

§ 9420.4 Program accessibility: Discrimination prohibited.

Except as otherwise provided in 11 CFR 9420.6 and 11 CFR 9420.7, no qualified handicapped person shall be denied the benefits of, be excluded from participation in, or otherwise be subjected to discrimination under any program or activity conducted by the Commission because its facilities are inaccessible to or unusable by handicapped persons.

§ 9420.5 Program accessibility: Existing facilities.

(a) *General.* The Commission will operate each program or activity so that the program or activity, when viewed in its entirety, is readily accessible to and usable by handicapped persons. This paragraph does not—

(1) Necessarily require the Commission to make each of its existing facilities accessible to and usable by handicapped persons;

(2) Require the Commission to take any action that it can demonstrate would result in a fundamental alteration in the nature of a program or activity or in undue financial and administrative burdens. The Commission has the burden of proving that compliance with 11 CFR 9420.6(a) would result in such alterations or burdens. The decision that compliance would result in such alteration or burdens must be made by the Commission after considering all agency resources available for use in the funding and operation of the conducted program or activity, and must be accompanied by a written statement of the reasons for reaching that conclusion. If an action would result in such an alteration or such burdens, the Commission will take any other action that would not result in such an alteration or such a burden but would nevertheless ensure that handicapped person receive the benefits and services of the program or activity.

(b) *Methods.* The Commission may comply with the requirements of this section through such means as redesign of equipment, reassignment of services to accessible buildings, assignment of aides to beneficiaries, home visits, delivery of services at alternate accessible sites, alteration of existing facilities and construction of new facilities, use of accessible rolling stock, or any other methods that result in making its programs or activities readily accessible to and usable by handicapped persons. The Commission is not required to make structural changes in existing facilities where other methods are effective in achieving compliance with this section. The Commission, in making alterations to existing buildings will meet accessibility requirements to the extent compelled by the Architectural Barriers Act of 1968, as amended, 42 U.S.C. 4151–4157, and any regulations implementing it. In choosing among available methods for meeting the requirements of this section, the Commission will give priority to those

methods that offer programs and activities to qualified handicapped persons in the most integrated setting appropriate.

(c) *Time period for compliance.* The Commission shall comply with the obligations established under this section within sixty days of the effective date of this part except that where structural changes in facilities are undertaken, such changes will be made within three years of the effective date of this part, but in any event as expeditiously as possible.

(d) *Transition plan.* In the event that structural changes to facilities will be undertaken to achieve program accessibility, the Commission will develop, within six months of the effective date of this part, a transition plan setting forth the steps necessary to complete such changes. The plan will be developed with the assistance of interested persons, including handicapped persons and organizations representing handicapped persons. A copy of the transition plan will be made available for public inspection. The plan will, at a minimum—

(1) Identify physical obstacles in the Commission's facilities that limit the accessibility of its programs or activities to handicapped persons;

(2) Describe in detail the methods that will be used to make the facilities accessible;

(3) Specify the schedule for taking the steps necessary to achieve compliance with this section and, if the time period of the transition plan is longer than one year, identify steps that will be taken during each year of the transition period;

(4) Indicate the official responsible for implementation of the plan; and

(5) Identify the person or groups with whose assistance the plan was prepared.

§ 9420.6 Program accessibility: New construction and alterations.

Each building or part of a building that is constructed or altered by, on behalf of, or for the use of the Commission shall be designed, constructed, or altered so as to be readily accessible to and usable by handicapped persons. The definitions, requirements, and standards of the Architectural Barriers Act, 42 U.S.C. 4151–4157 apply to buildings covered by this section.

§ 9420.7 Communications.

(a) The Commission will take appropriate steps to ensure effective communication with applicants, participants, personnel of other Federal entities, and members of the public.

(1) The commission will furnish appropriate auxiliary aids when necessary to afford a handicapped person an equal opportunity to participate in, and enjoy the benefits of, a program or activity conducted by the Commission.

(i) In determining what type of auxiliary aid is necessary, the Commission will give primary consideration to the requests of the handicapped person.

(ii) Where the Commission communicates with applicants and beneficiaries by telephone, telecommunication devices for deaf persons (TDDs) or equally effective telecommunication systems will be used.

(b) The Commission will ensure that interested persons, including persons with impaired vision or hearing can obtain information as to the existence and location of accessible services, activities, and facilities.

(c) To the extent that the Commission controls signage at its facilities, the Commission will provide signage at a primary entrance to each of its inaccessible facilities, directing users to a location at which they can obtain information about accessible facilities. To the extent practicable, the international symbol for accessibility shall be used at each primary entrance of an accessible facility.

(d) The Commission will take appropriate steps to provide handicapped persons with information regarding their section 504 rights under the Commission's programs or activities.

(e) This section does not require the Commission to take any action that it can demonstrate would result in a fundamental alteration in the nature of a program or activity or in undue financial and administrative burdens. The Commission has the burden of proving that compliance with this section would result in such alterations or burdens. The decision that compliance would result in such alteration or burdens must be made by the Commission after considering all agency resources available for use in the funding and operation of the conducted program or activity, and must be accompanied by a written statement of the reasons for reaching that conclusion. If an action required to comply with this section would result in such an alteration or such burdens, the Commission will take any other action that would not result in such an alteration or such a burden but would nevertheless ensure that, to the maximum extent possible, handicapped persons receive the benefits and services of the program or activity.

§ 9420.8 Compliance procedures.

(a) Except as provided in paragraph (b) of this section, this section applies to all allegations of discrimination on the basis of handicap in programs or activities conducted by the Commission.

(b) The Commission will process complaints alleging violations of section 504 with respect to employment according to the procedures established in 29 CFR 1614.101 et seq. pursuant to section 501 of the Rehabilitation Act of 1973 (29 U.S.C. 791).

(c) Responsibility for implementation and operation of this section shall be vested in the Rehabilitation Act Officer.

(d)(1) Requirement to file complaint with the Rehabilitation Act Officer.

(i) Any person who believes that he or she or any specific class of persons of which he or she is a member has been subjected to discrimination prohibited by this part may file a complaint with the Rehabilitation Act Officer.

(ii) Any person who believes that a denial of his or her services will result or has resulted in discrimination prohibited by this part may file a complaint with the Rehabilitation Act Officer.

(2) Timing of filing of complaint. All complete complaints must be filed within 180 days of the alleged act of discrimination. The Commission may extend this period for good cause.

(3) Complaints filed under this part shall be addressed to the Rehabilitation Act Officer, U.S. Election Assistance Commission, 1225 New York Avenue, NW., Suite 1100, Washington, DC 20005.

(e) The Commission will notify the Architectural and Transportation Barriers Compliance Board upon receipt of any complaint alleging that a building or facility that is subject to the Architectural Barriers Act of 1968, as amended (42 U.S.C. 4151–4157), or section 502 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 792), are not readily accessible and usable to handicapped persons.

(f) Review of complaints.

(1) The Commission will accept and investigate a complete complaint that is filed in accordance with paragraph (d) of this section and over which it has jurisdiction. The Rehabilitation Act Officer will notify the complainant and the respondent of receipt and acceptance of the complaint.

(2) If the Rehabilitation Act Officer receives a complaint that is not complete, he or she will notify the complainant within 30 days of receipt of the incomplete complaint, that additional information is needed. If the complainant fails to complete the complaint within 30 days of receipt of

this notice, the Rehabilitation Act Officer will dismiss the complaint without prejudice.

(3) If the Rehabilitation Act Officer receives a complaint over which the Commission does not have jurisdiction, the Commission will promptly notify the complainant and will make reasonable efforts to refer the complaint to the appropriate government entity.

(g) Within 180 days of receipt of a complete complaint for which it has jurisdiction, the Commission will notify the complainant of the results of the investigation in a letter containing—

(1) Findings of fact and conclusions of law.

(2) A description of a remedy for each violation found; and

(3) A notice of the right to appeal.

(h) Appeals of the findings of fact and conclusions of law or remedies must be filed by the complainant within 90 days of receipt from the Commission of a letter required by § 9420.9(g). The Commission may extend this time for good cause.

(i) Timely appeals to the Commission shall be addressed to the Rehabilitation Act Officer, U.S. Election Assistance Commission, 1225 New York Avenue, NW., Suite 1100, Washington, DC 20005.

(j) The Commission will notify the complainant of the results of the appeal within 60 days of the receipt of the request. If the Commission determines it needs additional information from the complainant, it shall have 60 days from the date it receives the additional information to make its determination on the appeal.

(k) The Commission may extend the time limits in paragraphs (g) and (j) of this section for good cause.

(l) The Commission may delegate its authority for conducting complaint investigations to other Federal agencies, except that the authority for making the final determination may not be delegated.

Thomas R. Wilkey,

Executive Director, U.S. Election Assistance Commission.

[FR Doc. E8–21795 Filed 9–17–08; 8:45 am]

BILLING CODE 6820–KF–P

Federal Register

Thursday,
September 18, 2008

Part VI

The President

Presidential Determination No. 2008–23 of July 25, 2008—Emergency Fund Drawdown to Assist Zimbabwean Refugees in South Africa, Botswana, Mozambique, and Zambia

Presidential Determination No. 2008–24 of August 15, 2008—Continuation of U.S. Drug Interdiction Assistance to the Government of Colombia

Presidential Determination No. 2008–25 of August 28, 2008—Emergency Fund Drawdown to Assist Georgian Victims of Conflict

Presidential Determination No. 2008–26 of September 10, 2008—Proposed Agreement for Cooperation Between the Government of the United States of America and the Government of India Concerning Peaceful Uses of Nuclear Energy

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Presidential Documents

Title 3—

The President

Presidential Determination No. 2008–23 of July 25, 2008

Memorandum for the Secretary of State

Emergency Fund Drawdown to Assist Zimbabwean Refugees in South Africa, Botswana, Mozambique, and Zambia

By the authority vested in me by the Constitution and the laws of the United States, including sections 2 and 4(a)(1) of the Migration and Refugee Assistance Act of 1962 (the ''Act''), as amended (22 U.S.C. 2601 and 2603) and section 301 of title 3, United States Code:

(1) I hereby determine, pursuant to 2(c)(1) of the Act, that it is important to the national interest to furnish assistance under the Act, in an amount not to exceed $2.5 million from the United States Emergency Refugee and Migration Assistance Fund, for the purpose of meeting unexpected and urgent refugee and migration needs, including by contributions to international, governmental, and nongovernmental organizations and payment of administrative expenses of the Bureau of Population, Refugees, and Migration of the Department of State, related to humanitarian needs of Zimbabwean refugees and asylum seekers; and

(2) the functions of the President in relation to this memorandum under section 2(d) of the Act, and of establishing terms and conditions under section 2(c)(1) of the Act, are assigned to you, and you may further assign such functions to any of your subordinates, consistent with applicable law.

You are authorized and directed to publish this memorandum in the *Federal Register*.

THE WHITE HOUSE,
Washington, July 25, 2008

[FR Doc. E8–21964
Filed 9–17–08; 8:45 am]
Billing code 4710–10–P

Federal Register
Vol. 73, No. 182
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Presidential Documents

Title 3—

The President

Presidential Determination No. 2008–24 of August 15, 2008

Memorandum for the Secretary of State [and] the Secretary of Defense

Continuation of U.S. Drug Interdiction Assistance to the Government of Colombia

Pursuant to the authority vested in me by section 1012 of the National Defense Authorization Act for Fiscal Year 1995, as amended (22 U.S.C. 2291–4), I hereby certify, with respect to Colombia, that (1) interdiction of aircraft reasonably suspected to be primarily engaged in illicit drug trafficking in that country's airspace is necessary because of the extraordinary threat posed by illicit drug trafficking to the national security of that country; and (2) that country has appropriate procedures in place to protect against innocent loss of life in the air and on the ground in connection with such interdiction, which shall at a minimum include effective means to identify and warn an aircraft before the use of force is directed against the aircraft.

The Secretary of State is authorized and directed to publish this determination in the *Federal Register* and to notify the Congress of this determination.

THE WHITE HOUSE,
Washington, August 15, 2008

[FR Doc. E8–21974
Filed 9–17–08; 8:45 am]
Billing code 4710–10–P

Federal Register
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Presidential Documents

Title 3—

The President

Presidential Determination No. 2008–25 of August 28, 2008

Memorandum for the Secretary of State

Emergency Fund Drawdown to Assist Georgian Victims of Conflict

By the authority vested in me by the Constitution and the laws of the United States, including sections 2 and 4(a)(1) of the Migration and Refugee Assistance Act of 1962 (the ''Act''), as amended, (22 U.S.C. 2601 and 2603) and section 301 of title 3, United States Code:

(1) I hereby determine, pursuant to section 2(c)(1) of the Act, that it is important to the national interest to furnish assistance under the Act, in an amount not to exceed $5.75 million from the United States Emergency Refugee and Migration Assistance Fund, for the purpose of meeting unexpected and urgent refugee and migration needs, including by contributions to international, governmental, and nongovernmental organizations and payment of administrative expenses of the Bureau of Population, Refugees, and Migration of the Department of State, related to the humanitarian needs of conflict victims and those displaced by recent violence in Georgia.

(2) I hereby assign to you the functions of the President in relation to this memorandum under section 2(d) of the Act, and of establishing terms and conditions under section 2(c)(1) of the Act, and you may further assign such functions to your subordinates, consistent with applicable law.

You are authorized and directed to publish this memorandum in the *Federal Register* .

THE WHITE HOUSE,
Washington, August 28, 2008

[FR Doc. E8–21975
Filed 9–17–08; 8:45 am]
Billing code 4710–10–P

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Presidential Documents

Title 3—

The President

Presidential Determination No. 2008–26 of September 10, 2008

Memorandum for the Secretary of State [and] the Secretary of Energy

Proposed Agreement for Cooperation Between the Government of the United States of America and the Government of India Concerning Peaceful Uses of Nuclear Energy

I have considered the Proposed Agreement for Cooperation Between the Government of the United States of America and the Government of India Concerning Peaceful Uses of Nuclear Energy, along with the views, recommendations, and statements of interested agencies.

I have determined that the performance of the Agreement will promote, and will not constitute an unreasonable risk to, the common defense and security. Pursuant to section 123 b. of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2153(B)), I hereby approve the proposed agreement and authorize the Secretary of State to arrange for its execution.

In addition, pursuant to the authority vested in me by the Constitution and the laws of the United States of America, including the Henry J. Hyde United States-India Peaceful Atomic Energy Cooperation Act of 2006 (Public Law 109–401), I hereby determine that:

1. India has provided the United States and the IAEA with a credible plan to separate civil and military nuclear facilities, materials, and programs, and has filed a declaration regarding its civil facilities and materials with the IAEA;

2. India and the IAEA have concluded all legal steps required prior to signature by the parties of an agreement requiring the application of IAEA safeguards in perpetuity in accordance with IAEA standards, principles, and practices (including IAEA Board of Governors Document GOV/1621 (1973)) to India's civil nuclear facilities, materials, and programs as declared in the plan described in paragraph (1), including materials used in or produced through the use of India's civil nuclear facilities;

3. India and the IAEA are making substantial progress toward concluding an Additional Protocol consistent with IAEA principles, practices, and policies that would apply to India's civil nuclear program;

4. India is working actively with the United States for the early conclusion of a multilateral treaty on the cessation of the production of fissile materials for use in nuclear weapons or other nuclear explosive devices;

5. India is working with and supporting United States and international efforts to prevent the spread of enrichment and reprocessing technology to any state that does not already possess full-scale, functioning enrichment or reprocessing plants;

6. India is taking the necessary steps to secure nuclear and other sensitive materials and technology, including through (A) the enactment and effective enforcement of comprehensive export control legislation and regulations; (B) harmonization of its export control laws, regulations, policies, and practices with the guidelines and practices of the Missile Technology Control Regime (MTCR) and the Nuclear Suppliers Group (NSG); and (C) adherence to the MTCR and the NSG in accordance with the procedures of those regimes for unilateral adherence; and

7. The NSG has decided by consensus to permit supply to India of nuclear items covered by the guidelines of the NSG.

I therefore hereby (1) exempt the proposed Agreement for Cooperation Between the Government of the United States of America and the Government of India Concerning Peaceful Uses of Nuclear Energy arranged pursuant to section 123 of the Atomic Energy Act of 1954 (42 U.S.C. 2153) from the requirement of subsection 123 a.(2) of such section; (2) waive the application of section 128 of the Atomic Energy Act of 1954 (42 U.S.C. 2157) with respect to exports to India; and (3) waive with respect to India the application of:

(A) subsection 129 a.(1)(D) of the Atomic Energy Act of 1954 (42 U.S.C. 2158(a)(1)(D)); and

(B) section 129 of the Atomic Energy Act of 1954 (42 U.S.C. 2158) regarding any actions that occurred before July 18, 2005.

The Secretary of State is authorized and directed to publish this determination in the *Federal Register*.

THE WHITE HOUSE,
Washington, September 10, 2008

[FR Doc. E8–21978
Filed 9–17–08; 8:45 am]
Billing code 4710–10–P

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LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with "P L U S" (Public Laws Update Service) on 202–741–6043. This list is also available online at *http://www.archives.gov/federal-register/laws.html*.

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H.R. 6532/P.L. 110–318

To amend the Internal Revenue Code of 1986 to restore the Highway Trust Fund balance. (Sept. 15, 2008; 122 Stat. 3532)

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