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9 a.m.-12:30 p.m.

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Washington, DC 20002

RESERVATIONS: (202) 741-6008



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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.

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

2 CFR Part 1880

RIN 2700-AD81

Commercial Acquisition; Extension of Suspension and Debarment Exclusions, Grants and Cooperative Agreements

AGENCY: National Aeronautics and Space Administration.

ACTION: Final rule.

SUMMARY: NASA has adopted as final, with no change, a proposed rule to extend coverage of non-procurement suspension and debarment to all tiers of procurement and non-procurement actions under all grants and cooperative agreements. The revisions herein are part of NASA's retrospective plan under EO 13563 completed in August 2011. NASA's full plan can be accessed at: http://www.nasa.gov/pdf/581545main_Final%20Plan%20for%20Retrospective%20Analysis%20of%20Existing%20Regulations.pdf.

DATES: *Effective Date:* March 29, 2013.

FOR FURTHER INFORMATION CONTACT: Leigh Pomponio, NASA, Office of Procurement, Contract Management Division (Suite 5G84); (202) 358-0592; email: leigh.pomponio@nasa.gov.

SUPPLEMENTARY INFORMATION:

A. Background

On August 31, 2005 (70 FR 51865), the Office of Management and Budget promulgated guidelines to Federal agencies on the governmentwide debarment and suspension system for nonprocurement programs. The OMB guidance to Federal Agencies was amended on November 15, 2006 (71 FRN 664320). These two notices resulted in the governmentwide regulation at 2 CFR part 180. Specifically, at § 180.220(c), OMB

offered Federal agencies flow down options for application of nonprocurement suspension and debarment regulations to procurement actions under covered transactions. OMB permitted Agencies to flow down requirements to just the first-tier or to all lower-tier participants.

On April 20, 2007, NASA promulgated a final rule (72 FR 19783) which established a new Part 1880 in Title 2 of the Code of Federal Regulations (CFR) on nonprocurement debarment and suspension. This rule implemented and supplemented the Office of Management and Budget's (OMB) guidance provided at 2 CFR part 180. It included agency-specific regulations related to nonprocurement suspension and debarment. At the time of that action, NASA elected to limit the flow down of nonprocurement suspension and debarment applicability to only first-tier procurement contacts thereunder. However, NASA has since reconsidered its position on flow down and this final rule revises 2 CFR 1880.220 to apply to all participants at all tiers, and to procurement and non-procurement actions at any dollar amount, under Agency grants and cooperative agreements. NASA will not permit any subawards to individuals or entities that are listed on the Excluded Parties List Service (EPLS).

To extend the suspension and debarment exclusions, NASA published a proposed rule on October 29, 2012. The due date for public comments in response to the proposed rule was December 28, 2012. NASA did not receive any comments.

B. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct 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). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866. This rule is not a major rule under 5 U.S.C. 804.

C. Regulatory Flexibility Act

NASA certifies that this rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* Small entities are already required to check the Excluded Parties List System (EPLS) prior to making first-tier, procurement subawards under a grant or cooperative agreement. They will now be required to ensure that none of their potential subrecipients are on the EPLS. The EPLS is an easy-to-access and easy-to-use on-line resource.

D. Paperwork Reduction Act

The Paperwork Reduction Act (Pub. L. 104-13) is not applicable because the changes do not impose information collection requirements that require the approval of the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

List of Subjects in 2 CFR Part 1880

Government procurement; Federal Grant program.

Ronald A. Poussard,

Acting Assistant Administrator for Procurement.

Accordingly, 2 CFR part 1880 is amended as follows:

PART 1880—NONPROCUREMENT DEBARMENT AND SUSPENSION

■ 1. The authority citation for part 1880 continues to read as follows:

Authority: Sec. 2455, Pub. L. 103-355, 108 Stat. 3327; E.O. 12549, 3 CFR, 1986 Comp., p. 189; E.O. 12689, 3 CFR, 1989 Comp., p. 235; 42 U.S.C. 2473(c)(1). 2

■ 2. Section 1880.220 is revised to read as follows:

§ 1880.220 What contracts and subcontracts, in addition to those listed in 2 CFR 180.220, are covered transactions?

NASA extends coverage of nonprocurement suspension and debarment requirements beyond first-tier procurement contracts under a covered nonprocurement action, to all lower tier subcontracts, at all dollar values, consistent with OMB guidance at 2 CFR 180.220(c) and the figure in the appendix at 2 CFR part 180. NASA does not permit subcontracting to suspended

or debarred entities at any tier, at any dollar amount.

[FR Doc. 2013-04569 Filed 2-26-13; 8:45 am]

BILLING CODE 7510-01-P

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 703

RIN 3133-AE06

Investment and Deposit Activities

AGENCY: National Credit Union Administration (NCUA).

ACTION: Final rule.

SUMMARY: The NCUA Board (Board) is amending its investment regulation to allow federal credit unions (FCUs) to purchase Treasury Inflation Protected Securities (TIPS). This final rule adds TIPS to the list of permissible investments for FCUs in part 703. TIPS will provide FCUs with an additional investment portfolio risk management tool that can be useful in an inflationary economic environment.

DATES: The final rule is effective on March 29, 2013.

FOR FURTHER INFORMATION CONTACT: John H. Brolin, Staff Attorney, or Frank Kressman, Associate General Counsel, Office of General Counsel, at 1775 Duke Street, Alexandria, VA 22314 or telephone: (703) 518-6438; or J. Owen Cole, Jr., Director, Division of Capital Markets, Office of Examination and Insurance, at the above address or telephone: (703) 518-6360.

SUPPLEMENTARY INFORMATION:

- I. Background
- II. September 2012 Proposal
- III. Final Rule
- IV. Regulatory Procedures

I. Background

TIPS are securities issued by the U.S. Department of the Treasury, Bureau of Public Debt, and are readily available to investors. TIPS differ from other securities by providing protection against inflation. The principal amount of TIPS increases with inflation and decreases with deflation, as measured by the Bureau of Labor Statistic's Consumer Price Index (CPI). When TIPS mature, holders are paid the adjusted principal or original principal, whichever is greater. TIPS pay interest twice a year at a fixed rate. The rate is applied to the adjusted principal, so, like the principal, interest payments rise with inflation and fall with deflation. In a deflationary period, it is possible to experience a contractual decline in the

principal balance, which is not an event of default.¹

TIPS are currently a prohibited investment under part 703 because they reprice their value in response to changes in the CPI, and the CPI is a prohibited index for variable rate instruments. Under § 703.14(a), an FCU is permitted to invest in a variable rate instrument as long as the rate is tied to a domestic interest rate.² The purpose of this provision is to reduce the basis risk between the interest earned on assets and the dividends paid on shares.³ Generally, deposit/share rates for financial institutions, including credit unions, are responsive to market interest rates. As market rates change, so do the deposit/share rates. Thus, if an FCU invests in a variable rate instrument with an index tied to market rates, the spread between the asset's income stream and the share dividends paid should remain relatively constant. This protects the FCU's earnings in times of rate volatility, especially in periods of rising rates. However, there is not always a perfect correlation between market interest rates and deposit/share rates. This can result in greater volatility for an FCU if it does not take action to manage this basis risk.

II. September 2012 Proposal

A. Summary of the September 2012 Proposal

The Board issued a proposed rule in September 2012 to amend § 703.14(a) to add TIPS to the list of permissible investments for FCUs in part 703.⁴ The Board issued the proposal after research and analysis demonstrated that TIPS would be a valuable risk management tool for FCUs. In addition to analyzing the nature and performance of TIPS in the marketplace, NCUA also monitored FCU usage of TIPS through a long-term investment pilot program. The results of the pilot program are consistent with the Board's research demonstrating that TIPS are an appropriate investment for

¹ To learn more about TIPS, see the U.S. Department of the Treasury, Bureau of Public Debt Web site at: http://www.treasurydirect.gov/indiv/research/indepth/tips/res_tips.htm.

² 12 CFR 703.14(a) states that an FCU may invest in a variable rate investment, as long as the index is tied to domestic interest rates and not, for example, to foreign currencies, foreign interest rates, or domestic or foreign commodity prices, equity prices, or inflation rates. For purposes of part 703, the U.S. dollar-denominated London Interbank Offered Rate (LIBOR) is a domestic interest rate.

³ Basis risk is a common form of risk incurred by financial institutions, including credit unions. Basis risk is the variability between two or more indices (e.g., equity barometers such as the S&P 500 and interest rate indices such as the 1 year Treasury rate) that serve as benchmarks for valuing financial institution assets and liabilities.

⁴ 77 FR 59144 (Sept. 26, 2012).

FCUs and can be a valuable portfolio management tool when there are inflationary risks in the economy.

B. Summary of Comments on the September 2012 Proposal

The NCUA received eight comment letters on the September 2012 proposal: two from FCU trade associations and six from state credit union leagues. The Board has considered these comments in adopting this final rule.

All of the commenters agreed that the authority to invest in TIPS will help FCUs manage inflation risk. Several commenters noted that TIPS are guaranteed by the U.S. Government, and the benefits to TIPS investors are widely recognized. One state credit union league noted that certain state-chartered institutions already have the authority to invest in TIPS, which they argued demonstrates that such securities can be utilized safely. Moreover, several commenters noted that FCUs now have greater access to advanced asset-liability management tools that can help identify and measure basis risk.

In addition to supporting the proposal, several commenters also made other recommendations that were outside the scope of the proposal. In general, the commenters asked the Board to take additional steps in the future to provide increased flexibility and additional investment powers to FCUs. Several commenters also urged NCUA to work closely with state regulators to facilitate the ability of well-managed state credit unions to invest in TIPS, where permissible under state law.

III. Final Rule

A. Why is the board adopting this rule?

As discussed, the Board is adopting this final rule to provide FCUs with an additional investment portfolio risk management tool that can be useful in an inflationary economic environment.

Historically, the Board has prohibited FCUs from investing in variable rate instruments tied to non-domestic rate indices, such as TIPS, because of the basis risk for FCUs. The Board remains concerned about basis risk. However, the Board generally agrees with commenters who noted that FCUs now have greater access to advanced asset-liability management tools that can identify and measure basis risk, and are, therefore, better equipped to manage the risks associated with investing in TIPS. Moreover, the Board agrees with commenters that allowing FCUs to hold TIPS in their investment portfolios adds no credit risk and allows them the option of minimizing the need for

accurate inflation forecasting as a way to maintain the real value of their investment portfolios. Accordingly, the Board is adopting the September 2012 proposal without substantive change. However, the Board has amended the language of the section slightly to better incorporate the amendment into the existing language of the rule.

B. Does this rule impose any new regulatory burdens on FCUs?

While the Board believes the authority to invest in TIPS can be a valuable part of an effective risk management program for those FCUs that understand the risks, TIPS may not be appropriate for all FCUs. As with any investment, the decision to purchase TIPS should be based on sound due diligence and a demonstrated effectiveness in managing risk. However, other than the due diligence and risk management requirements already required by NCUA for investments under § 703.14(a), this final rule does not impose any new TIPS-specific due diligence or risk management requirements on FCUs.

This final rule authorizes FCUs to purchase TIPS only. Other similar securities based on inflation indices currently available or available in the future that are not issued by the United States Treasury Department are not authorized by this rule. While several commenters requested the Board provide increased flexibility and additional investment powers to qualified FCUs, such requests are outside the scope of this rulemaking and will be considered separately by the Board.

C. What happens to the TIPS pilot program?

The TIPS pilot program will be terminated as of the effective date of this final rule.

IV. Regulatory Procedures

Regulatory Flexibility Act

The Regulatory Flexibility Act requires NCUA to prepare an analysis to describe any significant economic impact a rule may have on a substantial number of small entities (primarily those under \$50 million in assets). This final rule extends regulatory relief while maintaining existing safety and soundness standards. NCUA has determined this final rule will not have a significant economic impact on a substantial number of small credit unions.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) applies to rulemakings in which

an agency by rule creates a new paperwork burden on regulated entities or modifies an existing burden.⁵ For purposes of the PRA, a paperwork burden may take the form of either a reporting or a recordkeeping requirement, both referred to as information collections. As noted above, this final rule extends regulatory relief while maintaining existing safety and soundness standards. NCUA has determined that the requirements of this rule do not increase the paperwork requirements under the Paperwork Reduction Act of 1995 and regulations of the Office of Management and Budget.

Executive Order 13132

Executive Order 13132 encourages independent regulatory agencies to consider the impact of their actions on state and local interests. NCUA, an independent regulatory agency as defined in 44 U.S.C. 3502(5), voluntarily complies with the executive order to adhere to fundamental federalism principles. This final rule 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. The rule only adds to the list of permissible investments for FCUs. NCUA has determined that this final rule does not constitute a policy that has federalism implications for purposes of the executive order.

Assessment of Federal Regulations and Policies on Families

NCUA has determined that this final rule will not affect family well-being within the meaning of Section 654 of the Treasury and General Government Appropriations Act, 1999.⁶

Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act of 1996⁷ (SBREFA) provides generally for congressional review of agency rules. A reporting requirement is triggered in instances where NCUA issues a final rule as defined by Section 551 of the Administrative Procedure Act.⁸ The Office of Management and Budget has determined that the final rule is not a "major rule" for purposes of SBREFA.

List of Subjects in 12 CFR Part 703

Credit unions, Investments.

By the National Credit Union Administration Board on February 21, 2013.

Mary Rupp,

Secretary of the Board.

For the reasons discussed above, the Board amends 12 CFR part 703 as follows:

PART 703—INVESTMENT AND DEPOSIT ACTIVITIES

■ 1. The authority citation for part 703 continues to read as follows:

Authority: 12 U.S.C. 1757(7), 1757(8), 1757(15).

■ 2. Revise § 703.14(a) to read as follows:

§ 703.14 Permissible investments.

(a) *Variable rate investment.* A federal credit union may invest in a variable rate investment, as long as the index is tied to domestic interest rates. Except in the case of Treasury Inflation Protected Securities, the variable rate investment cannot, for example, be tied to foreign currencies, foreign interest rates, domestic or foreign commodity prices, equity prices, or inflation rates. For purposes of this part, the U.S. dollar-denominated London Interbank Offered Rate (LIBOR) is a domestic interest rate.

* * * * *

[FR Doc. 2013-04619 Filed 2-26-13; 8:45 am]

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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 40

[Docket No. RM12-12-000; Order No. 775]

Regional Reliability Standard PRC-006-NPCC-1—Automatic Underfrequency Load Shedding

AGENCY: Federal Energy Regulatory Commission.

ACTION: Final rule.

SUMMARY: Under section 215 of the Federal Power Act (FPA), the Federal Energy Regulatory Commission (Commission) approves regional Reliability Standard PRC-006-NPCC-1 (Automatic Underfrequency Load Shedding), submitted to the Commission for approval by the North American Electric Reliability Corporation (NERC). Regional Reliability Standard PRC-006-NPCC-1 applies to generator owners, planning coordinators, distribution providers, and transmission owners in the Northeast Power Coordinating Council

⁵ 44 U.S.C. 3507(d); 5 CFR part 1320.

⁶ Public Law 105-277, 112 Stat. 2681 (1998).

⁷ Public Law 104-121, 110 Stat. 857 (1996).

⁸ 5 U.S.C. 551.

Region. Regional Reliability Standard PRC-006-NPCC-1 is designed to ensure the development of an effective automatic underfrequency load shedding (UFLS) program to preserve the security and integrity of the Bulk-Power System during declining system frequency events, in coordination with the NERC continent-wide UFLS Reliability Standard PRC-006-1. The Commission approves the related violation risk factors, violation severity levels, implementation plan, and effective dates proposed by NERC.

DATES: *Effective Date:* This rule will become effective April 29, 2013.

FOR FURTHER INFORMATION CONTACT:

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Matthew Vlissides (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, Telephone: (202) 502-8408, Matthew.Vlissides@ferc.gov.

SUPPLEMENTARY INFORMATION:

Before Commissioners: Jon Wellinghoff, Chairman; Philip D. Moeller, John R. Norris, Cheryl A. LaFleur, and Tony T. Clark.

Final Rule

Issued February 21, 2013

1. Under section 215 of the Federal Power Act (FPA),¹ the Commission approves regional Reliability Standard PRC-006-NPCC-1 (Automatic Underfrequency Load Shedding). The Commission also approves the related violation risk factors (VRFs), violation severity levels (VSLs), implementation plan, and effective dates proposed by the North American Electric Reliability Corporation (NERC). NERC submitted regional Reliability Standard PRC-006-NPCC-1 to the Commission for approval. The regional Reliability Standard applies to generator owners, planning coordinators, distribution providers, and transmission owners in the Northeast Power Coordinating Council (NPCC) Region and is designed to ensure the development of an effective automatic underfrequency load shedding (UFLS) program to preserve the security and integrity of the Bulk-Power System during declining system frequency events, in coordination with

NERC's continent-wide UFLS Reliability Standard PRC-006-1.

I. Background

A. Mandatory Reliability Standards

2. Section 215 of the FPA requires a Commission-certified Electric Reliability Organization (ERO) to develop mandatory and enforceable Reliability Standards that are subject to Commission review and approval. Once approved, the Reliability Standards may be enforced by NERC (the Commission-certified ERO), subject to Commission oversight, or by the Commission independently.²

3. A Regional Entity may develop a Reliability Standard for Commission approval to be effective in that region only.³ In Order No. 672, the Commission stated that:

As a general matter, we will accept the following two types of regional differences, provided they are otherwise just, reasonable, not unduly discriminatory or preferential and in the public interest, as required under the statute: (1) a regional difference that is more stringent than the continent-wide Reliability Standard, including a regional difference that addresses matters that the continent-wide Reliability Standard does not; and (2) a regional Reliability Standard that is necessitated by a physical difference in the Bulk-Power System.⁴

4. On April 19, 2007, the Commission accepted delegation agreements between NERC and each of the eight Regional Entities.⁵ In the order, the Commission accepted NPCC as a Regional Entity.

5. NERC's Commission-approved and currently-effective Reliability Standard PRC-006-1 establishes continent-wide design and documentation requirements for UFLS programs that arrest declining frequency and assist recovery of frequency following system events leading to frequency degradation.

B. NERC Petition

6. On May 4, 2012, NERC petitioned the Commission to approve regional Reliability Standard PRC-006-NPCC-1 and the related violation risk factors, violation severity levels, effective dates, and implementation plan.⁶ On August

3, 2012, NERC filed an errata regarding the proposed implementation plan. NERC stated that regional Reliability Standard PRC-006-NPCC-1 is based on the program characteristics defined within NPCC Directory #12 Underfrequency Load Shedding Program Requirements (NPCC Directory #12), which contains the criteria that govern the NPCC Automatic UFLS program that have been in place since June 26, 2009.⁷ According to NERC, regional Reliability Standard PRC-006-NPCC-1 will achieve a coordinated, comprehensive UFLS region-wide consistent program within the NPCC Region and provides the regional requirements necessary to achieve and facilitate the broader program characteristics contained in the requirements of the NERC Reliability Standard PRC-006-1.⁸ NERC stated that the regional Reliability Standard adds specificity not contained in NERC Reliability Standard PRC-006-1 and is designed to work in conjunction with and augment Reliability Standard PRC-006-1 by mitigating the consequences of an underfrequency event, while accommodating differences in system transmission and distribution topology among NPCC planning coordinators due to historical design criteria, makeup of load demands, and generation resources.⁹ NERC further stated that regional Reliability Standard PRC-006-NPCC-1 facilitates uniformity and compliance, and clearly delineates what the applicable entities' requirements are within the NPCC Region to achieve a robust, reliable and effective UFLS program.¹⁰

7. In the petition, NERC proposed violation risk factors and violation severity levels for each requirement of the regional Reliability Standard, an implementation plan, and effective dates. NERC stated that these proposals were developed and reviewed for consistency with NERC and Commission guidelines. NERC proposed two effective dates for the regional Reliability Standard. NERC stated that Requirements R1 through R7 would become effective on the first day of the first calendar quarter following applicable regulatory approval but no earlier than January 1, 2016. For Requirements R8 through R23, NERC stated that they will become effective the first day of the first calendar quarter

document retrieval system in Docket No. RM12-12-000 and on the NERC Web site, www.nerc.com.

⁷ NERC Petition at 11.

⁸ *Id.* at 29-30.

⁹ *Id.*

¹⁰ *Id.* at 30.

² 16 U.S.C. 824o(e) (2006).

³ 16 U.S.C. 824o(e)(4). A Regional Entity is an entity approved by the Commission to enforce Reliability Standards under delegated authority from the ERO. See 16 U.S.C. 824o(a)(7) and (e)(4).

⁴ *Rules Concerning Certification of the Electric Reliability Organization; and Procedures for the Establishment, Approval, and Enforcement of Electric Reliability Standards*, Order No. 672, FERC Stats. & Regs. ¶ 31,204, at P 291 (2006), *order on reh'g*, Order No. 672-A, FERC Stats. & Regs. ¶ 31,212 (2006).

⁵ *North American Electric Reliability Corp.*, 119 FERC ¶ 61,060 (2007), *order on reh'g*, 120 FERC ¶ 61,260 (2007).

⁶ Regional Reliability Standard PRC-006-NPCC-1 is available on the Commission's eLibrary

¹ 16 U.S.C. 824o (2006).

two years following applicable regulatory approval.

C. Notice of Proposed Rulemaking

8. On September 20, 2012, the Commission issued a Notice of Proposed Rulemaking (NOPR) proposing to approve regional Reliability Standard PRC-006-NPCC-1 as just, reasonable, not unduly discriminatory or preferential, and in the public interest.¹¹ The Commission proposed to approve regional Reliability Standard PRC-006-NPCC-1 because it is designed to operate in conjunction with the NERC continent-wide UFLS Reliability Standard PRC-006-1 by mitigating the consequences of underfrequency events, while accommodating differences in system transmission and distribution topology among NPCC planning coordinators due to historical design criteria, makeup of load demands, and generation resources. The NOPR determined that the regional Reliability Standard includes requirements that are not found in the corresponding NERC Reliability Standard PRC-006-1 and that are more stringent than Reliability Standard PRC-006-1.

9. While proposing to approve regional Reliability Standard PRC-006-NPCC-1, the NOPR sought comment on two issues: (1) The technical basis for the 57.8 Hz maximum tripping limit for existing nuclear units established in Requirement R19; and (2) the time-frame for actions that result in changes to the NPCC UFLS program.

10. In response to the NOPR, initial comments were filed by NERC, NPCC, New York Independent System Operator (NYISO), PSEG Companies (PSEG),¹² and Dominion Resources Services, Inc. (Dominion).¹³ NERC and NPCC filed reply comments.

II. Discussion

11. Pursuant to FPA section 215(d)(2), we approve regional Reliability Standard PRC-006-NPCC-1 as just, reasonable, not unduly discriminatory or preferential, and in the public interest. Regional Reliability Standard PRC-006-NPCC-1 is designed to

operate in conjunction with the NERC continent-wide UFLS Reliability Standard PRC-006-1 by mitigating the consequences of underfrequency events, while accommodating differences in system transmission and distribution topology among NPCC planning coordinators. Regional Reliability Standard PRC-006-NPCC-1 includes requirements that are not found in the corresponding NERC Reliability Standard PRC-006-1 and that are more stringent than Reliability Standard PRC-006-1 while accommodating differences in system transmission and distribution topology among NPCC planning coordinators due to historical design criteria, makeup of load demands, and generation resources.

12. We address below the following issues raised in the NOPR and/or comments: (A) Requirement R19—nuclear generating plants; (B) Time-frame for completion of actions; (C) Compensatory load shedding requirements; and (D) violation risk factors and violations severity levels.

A. PRC-006-NPCC-1, Requirement R19

13. In the NOPR, the Commission sought comments on the technical basis for the 57.8 Hz maximum tripping limit for existing nuclear units established in Requirement R19. The NOPR observed that Requirement R19 provides that:

R19 Each Generator Owner of existing nuclear generating plants with units that have underfrequency relay threshold settings above the Eastern Interconnection generator tripping curve in Figure 1, based on their licensing design basis, shall: [Violation Risk Factor: High] [Time Horizon: Long Term Planning]

19.1 Set the underfrequency protection to operate at as low a frequency as possible in accordance with the plant design licensing limitations but not greater than 57.8 Hz.

19.2 Set the frequency trip setting upper tolerance to no greater than + 0.1 Hz.

19.3 Transmit the initial frequency trip setting and any changes to the setting and the technical basis for the settings to the Planning Coordinator.

14. The NOPR stated that the NERC petition did not explain the technical basis for establishing 57.8 Hz as the maximum frequency at which existing nuclear units may trip pursuant to Requirement R19.1, other than to state that the regional Reliability Standard was based on the work of an NPCC working group.¹⁴ The NOPR stated that

the NERC petition and its attachments did not provide any information as to how the 57.8 Hz limit was developed. The NOPR sought comment from NPCC, NERC, and other interested entities explaining the technical basis for the 57.8 Hz limit established in Requirement R19.1.

Comments

15. NPCC states that its UFLS program is designed to arrest frequency decline at or above 58.0 Hz while incorporating the performance characteristics of regional generation. In determining the 57.8 Hz limit for existing nuclear units within the NPCC Region, NPCC states that it “considered the minimum program frequency of 58.0 Hz, the existing maximum trip settings of the nuclear units (gathered through surveys) within NPCC’s footprint, system response, and credible islands as determined by the NPCC Planning Coordinators.”¹⁵ NPCC states that a maximum frequency threshold trip setting of 57.8 Hz for existing nuclear units provides a “margin of 0.2 Hz above the highest frequency at which [the nuclear units in NPCC’s footprint] are expected to be tripped by low coolant flow or under frequency protection and yields acceptable system performance with minimum changes required to the nuclear units.”¹⁶ NPCC adds that it considered 0.2 Hz to be a conservative margin and was developed in consideration of the typical relay drift tolerance of ± 0.1 Hz,¹⁷ which ensures the units do not trip above 58.0 Hz. NPCC states that if existing nuclear units adhere to the 57.8 Hz maximum tripping limit requirement, “islands with a 25% generation deficiency are able to survive, maintain automatic UFLS program requirements, and the program will achieve satisfactory system performance.”¹⁸

16. NERC states that it supports the comments submitted by NPCC regarding the technical basis for the 57.8 Hz limit. NERC also states that the requirements in regional Reliability Standard PRC-006-NPCC-1 are consistent with the continent-wide UFLS Reliability Standard PRC-006-1.¹⁹

¹⁵ NPCC Initial Comments at 4.

¹⁶ *Id.* at 5.

¹⁷ NPCC states that a relay setting of 57.8 Hz with a typical relay drift tolerance of ± 0.1 Hz would result in actual trip bandwidth of between 57.9 Hz and 57.7 Hz.

¹⁸ *Id.*

¹⁹ NYISO supports approval of regional Reliability Standard PRC-006-NPCC-1 without modification. NYISO Comments at 2.

¹¹ *Regional Reliability Standard PRC-006-NPCC-1—Automatic Underfrequency Load Shedding*, Notice of Proposed Rulemaking, 77 FR 59,151 (September 26, 2012), FERC Stats. & Regs. ¶ 32,691 (2012).

¹² PSEG is comprised of PSEG Power LLC and PSEG Energy Resources & Trade LLC.

¹³ Dominion filed comments on behalf of Virginia Electric and Power Company, Dominion Energy Kewaunee, Inc., Dominion Nuclear Connecticut, Inc., Dominion Energy Brayton Point, LLC, Dominion Energy Manchester Street, Inc., Elwood Energy, LLC, Kincaid Generation, LLC, and Fairless Energy, LLC.

¹⁴ NERC Petition at 11.

Commission Determination

17. The Commission finds that NPCC has provided an adequate technical basis for the 57.8 Hz maximum frequency threshold trip setting for existing nuclear units, as set forth in Requirement R19. As explained by NPCC, a maximum frequency threshold trip setting of 57.8 Hz for existing nuclear units provides a margin of 0.2 Hz above the highest frequency at which the nuclear units in NPCC's footprint are expected to trip by low coolant flow or underfrequency protection. Adherence to the 57.8 Hz limit should also result in islands with a 25% generation deficiency being able to survive and maintain automatic UFLS program requirements.

B. Time-Frame for Completion of Actions

18. In the NOPR, the Commission sought comments on the time-frames for actions that result in changes to the NPCC UFLS program. The NOPR observed that NERC's Reliability Standard PRC-006-1, Requirement R3, requires the planning coordinator to set the schedule for distribution providers and transmission owners to implement the UFLS program and that regional Reliability Standard PRC-006-NPCC-1, Requirements R5, R16.2, and R19.3, require distribution providers, transmission owners, and generator owners to provide, inform, and transmit exceptions to the UFLS program and justifications for the exceptions to the planning coordinator. The NOPR stated that these Requirements in regional Reliability Standard PRC-006-NPCC-1 do not specify a time-frame for the completion of these actions. The NOPR indicated that Requirements R5, R16.2, and R19.3 address actions that can result in changes to the UFLS program and should occur before the UFLS program is implemented, thus making it necessary for entities to provide the required information to the planning coordinator within a specified period of time. The NOPR further observed that other Requirements in regional Reliability Standard PRC-006-NPCC-1 require actions of distribution providers, transmission owners, and generator owners that should occur before the UFLS program is implemented and that those actions include specific time-frames for completion.²⁰ The NOPR sought comment on whether Requirements R5, R16.2, and R19.3 should also specify time-frames for completion of the required actions and,

if so, the appropriate time-frames for each.

Comments

19. NPCC states that Requirement R5 addresses a limited set of non-conforming circumstances and places the burden on entities to demonstrate that such non-conforming circumstances do not degrade the overall performance of the UFLS program. NPCC states that the absence of time-frames for completion of the required actions in Requirement R5 means that responsible entities are required to notify the NPCC planning coordinator "upon identification of any non-conformance with Requirement R5."²¹ NPCC states that this is the current practice with respect to applicable entities. NPCC states that providing a time-frame would "result in delays of the transmittal of critical information to the Planning Coordinator which could potentially impact UFLS system performance."²²

20. NPCC states that Requirement R16 addresses an existing class of non-nuclear units that "trip above the threshold curve for setting underfrequency trip protection for generators and which already provide compensatory load shedding in accordance with existing procedures."²³ NPCC states that "Planning Coordinators within NPCC have information for the class of existing units for R16, with underfrequency protection set to trip above the curve in Figure 1, [and thus] assigning time-frames is of no benefit to the program."²⁴ NPCC states, however, that Requirement R16.2 also requires changes to underfrequency settings, along with the technical basis for those settings from generators in this class of units, to be transmitted to the planning coordinator. NPCC maintains that "[i]t is the expectation that in the absence of a time-frame," in Requirement R16.2 those entities, "immediately upon identification of such a change," would notify the Planning Coordinator.²⁵

21. NPCC states that Requirement R19.3, similar to the requirements regarding non-nuclear units in Requirement R16.2, requires responsible entities to provide planning coordinators with the current operating parameters of an existing class of nuclear units that trip above the threshold curve for setting underfrequency trip protection for

generators units. NPCC further states that like Requirement R16.2, Requirement 19.3 requires responsible entities to transmit changes to the underfrequency settings to the planning coordinator. NPCC maintains that, in the absence of time-frames, responsible entities must notify the planning coordinator "immediately upon identification of such change."²⁶

22. NPCC also states that there is a limited number of existing nuclear and non-nuclear units that trip above the curve in Figure 1. NPCC notes that Requirement R15 requires that all new units conform to the curve in Figure 1. According to NPCC, the number of units that must comply with Requirement R16 and Requirement R19 is limited to the existing set of units described above and thus the inclusions of time-frames is unnecessary.

23. NERC states that it supports the comments submitted by NPCC on this issue.

Commission Determination

24. The Commission finds that NPCC has provided adequate justification for not including specific time-frames in Requirements R5, R16.2, and R19.3. NPCC states that these Requirements apply to a limited number of existing nuclear and non-nuclear units whose performance characteristics are already incorporated in the regional UFLS program, and that planning coordinators within NPCC have the existing technical parameters necessary to incorporate existing unit attributes and compensatory load shedding information into their assessment. NPCC further states that the absence of specific time-frames in these Requirements means that responsible entities must immediately notify planning coordinators upon identification of any non-conformance or changes to underfrequency settings pursuant to these Requirements. The Commission determines that this satisfies the concern raised in the NOPR.

C. Compensatory Load Shedding Requirements

25. Reliability Standard PRC-006-NPCC-1, Requirements R3, R16 and R18, address compensatory load shedding.²⁷ In particular, Requirement R16.3 requires generator owners of existing non-nuclear units that have non-conforming underfrequency

²⁶ *Id.*

²⁷ Compensatory load shedding is automatic shedding of load adequate to compensate for the loss of a generator due to the generator tripping early (i.e., because the generator has underfrequency protection set to trip above the curve in Figure 1).

²¹ NPCC Initial Comments at 7.

²² *Id.*

²³ *Id.*

²⁴ *Id.* at 7-8.

²⁵ *Id.* at 8.

²⁰ See, e.g., Requirements R11, R14, and R23 of proposed regional Reliability Standard PRC-006-NPCC-1.

protection set points to, among other things, “[h]ave compensatory load shedding, as provided by a Distribution Provider or Transmission Owner that is adequate to compensate for the loss of their generator due to early tripping.” Requirement R18 requires that “[e]ach Generator Owner, Distribution Provider or Transmission Owner within the Planning Coordinator area of ISO-NE or the New York ISO shall apply the criteria described in Attachment B to determine the compensatory load shedding that is required in Requirement R16.3 for generating units in its respective NPCC area.” Attachment B, Section 2.5, provides that the “amount of compensatory load shedding shall be equivalent ($\pm 5\%$) to the average net generator megawatt output for the prior two calendar years, as specified by the Planning Coordinator, plus expected station loads to be transferred to the system upon loss of the facility.”

Comments

26. Dominion states that there are technical difficulties associated with Requirements R16.3 and R18. Dominion states that shedding additional load equivalent to a non-conforming generator would be extremely difficult to design and coordinate and that the design would have to account for the real-time status and output of the generator. Dominion also states that Requirements R16.3 and R18 are unreasonable because they require non-conforming generators to procure compensatory load shedding service for which Dominion has found no willing provider. Dominion maintains that, as a result, the regional Reliability Standard cannot be practically implemented and may have an adverse impact on the Bulk-Power System. Dominion further states that NPCC’s assertion that generators in NPCC are already following these procedures as part of NPCC Directory #12 is misleading because only NPCC Full Members are required to follow the existing criteria. Dominion maintains that the regional Reliability Standard will impact a number of generators that are not NPCC Full Members. In addition, Dominion observes that several entities raised concerns with the compensatory load shedding provisions during the regional Reliability Standard drafting process. Dominion also maintains that Order No. 763,²⁸ in which the Commission approved the continent-wide NERC

UFLS Reliability Standard PRC-006-1, supports Dominion’s position that it is inappropriate for the regional Reliability Standard “to require a non-conforming generator to obtain compensating load shedding as it is ultimately the planning coordinators responsibility to design the UFLS system to account for such generator.”²⁹

27. PSEG states that it is inappropriate for planning coordinators to assign responsibility for compensatory load shedding, asserting that it is inconsistent with Order No. 763. PSEG also contends that the regional Reliability Standard contravenes the prohibition in FPA section 215 against setting standards for “adequacy or safety of electric facilities or services” because the regional Reliability Standard requires generator owners with existing non-conforming units to construct additional capacity or acquire off-setting UFLS at their expense.³⁰ PSEG also states that Requirement R16 imposes obligations upon generator owners that are absent from the NERC Reliability Functional Model.³¹ PSEG states that one of the tasks of a generator owner is to “[p]rovide verified generating facility performance characteristics/data,” but that there is no obligation for generators to compensate other entities for performance that does not meet a specific level. PSEG further states that distribution providers and transmission owners in NPCC do not have tariffs in place that would permit them to charge and/or provide generator owners with compensatory load shedding.

28. In reply to Dominion’s and PSEG’s comments, NPCC states that the regional Reliability Standard drafting team considered comments regarding the difficulty of designing and coordinating the shedding of load equivalent to a non-conforming generator, but that the overarching reliability objective of re-establishing a balance between load and generation during possible islanding events made shedding additional load necessary. NPCC states that it is impractical to expect an exact match between compensatory load shedding and unit output but maintains that

²⁹ Dominion Comments at 8.

³⁰ 16 U.S.C. 824o(i)(2). PSEG also contends that the regional Reliability Standard contravenes the definition of “Reliability Standard” in FPA section 215, which excludes “any requirement to enlarge [Bulk-Power System] facilities or to construct new transmission capacity or generation capacity.” 16 U.S.C. 824o(a)(3).

³¹ The NERC Reliability Functional Model provides the framework for the development and applicability of NERC’s Reliability Standards. NERC, Reliability Functional Model, Version 5 at 7 (approved May 2010), available at http://www.nerc.com/files/Functional_Model_V5_Final_2009Dec1.pdf.

compensatory load shedding based on an average megawatt output, as provided in Attachment B, aligns the amount of compensatory load shedding with the unit output most likely to be lost when the unit trips prematurely. NPCC further states that requiring compensatory load shedding based on a two year average net generator megawatt output is an effective approach to integrating small non-conforming generators into the design of a UFLS program. In addition, NPCC observes that that Regional Criteria requiring non-conforming generation to secure compensatory load shedding preexist the development of the regional Reliability Standard and that it is a cost effective alternative for generators. With respect to Order No. 763, NPCC states that the regional Reliability Standard is consistent with the Commission’s determination that it is appropriate for planning coordinators to consider generators that trip outside of the UFLS set points.

29. NPCC maintains that the regional Reliability Standard Requirements R1 and R3 are “only intended to communicate the results of locational assessments, and there is no obligation to obtain compensatory load shedding based solely on this information nor does the Planning Coordinator determine whether mitigation is necessary or who will be responsible for providing mitigation.”³² NPCC states that compensatory load shedding is merely an option to bring non-conforming generators into compliance. In response to comments regarding the absence of tariffs that permit for compensatory load shedding service, NPCC states that such concerns are tempered by the fact that all new generators, going forward, must conform with the underfrequency trip performance characteristics in the regional Reliability Standard and that compensatory load shedding only potentially impacts existing, non-conforming, non-nuclear units.

30. NPCC further notes that the existing compensatory load shedding requirements are presently contained in NPCC Directory #12 and “have been successfully implemented within the region * * * and non-conforming generators that are already interconnected either have existing contracts to provide compensatory load shedding or have mitigated the conditions that would trip the unit above the performance curve in order to comply with the Regional Criteria.”³³

³² NPCC Reply Comments at 5.

³³ *Id.* at 6-7.

²⁸ *Automatic Underfrequency Load Shedding and Load Shedding Plans Reliability Standards*, Order No. 763, 139 FERC ¶ 61,098, clarified, 140 FERC ¶ 61,164 (2012).

NPCC states that the regional Reliability Standard achieved an 83.5 percent overall approval “with a majority of registered Generator Owners in the region voting to approve the standard.”³⁴ With respect to FPA section 215, NPCC maintains that compensatory load shedding does not present a resource adequacy issue but, instead, addresses a generating unit’s ability to perform, with the generator having the option of meeting the performance curve, mitigating the operating condition, or obtaining compensatory load shedding. With respect to the NERC Reliability Functional Model, NPCC states that the absence of a task within the functional model does not preclude assigning a new or existing task based on a new or revised Reliability Standard. NPCC states that the functional model only defines the functions that must be performed to ensure the reliability of the bulk electric system and should not be used to restrict a reliability-related activity or Reliability Standard requirements.

31. In reply to Dominion’s and PSEG’s comments, NERC states it never intended to suggest that it is inappropriate for planning coordinators to determine whether mitigation is necessary and who will provide mitigation with respect to generators that trip outside the UFLS set points in UFLS programs. NERC states that “[o]n the contrary, the Planning Coordinator is one of the functional entities with responsibility for maintaining the reliability of the Bulk-Power System.”³⁵ NERC maintains that it has stated that it is inappropriate for a Reliability Standard to supplant the planning coordinator’s role in establishing UFLS program requirements. However, NERC states that regional Reliability Standard PRC-006-NPCC-1 “reflects the NPCC Planning Coordinators’ collective assessment of how to address this concern.”³⁶

32. Further, NERC claims that the technical concerns raised in the comments are overstated. NERC states that concerns “regarding potential overfrequency excursions due to overcompensating when a generating unit with non-conforming trip setting is off-line would be appropriate if compensatory loadshedding was applied to large generating units or if the provision was open-ended with applicability to future generating units not studied by the Planning

Coordinator.”³⁷ NERC observes that the compensatory load shedding provisions in the regional Reliability Standard, by contrast, are limited to a “defined amount of generating capacity that is included in Planning Coordinator assessments, [and] does not jeopardize reliability of the Bulk-Power System.”³⁸

Commission Determination

33. The Commission rejects the protests made by Dominion and PSEG regarding the compensatory load shedding provisions of regional Reliability Standard PRC-006-NPCC-1. Based on the record before us, we are not persuaded that the compensatory load shedding option for existing, non-conforming units in Requirement R16 presents a technical barrier to implementation of the regional Reliability Standard. NPCC states that generators already comply with the compensatory load shedding requirements in NPCC Directory #12, which is not disputed by Dominion and PSEG. While Dominion maintains that the regional Reliability Standard will require more generators (i.e., non-NPCC Full Members) to comply with the compensatory load shedding requirement, the fact that there are generators who do so now refutes the assertion that the requirement is technically or practically infeasible.³⁹ Moreover, we agree with NERC that the concerns regarding overfrequency excursions due to overcompensating for loss of off-line units might be valid if compensatory load shedding was applied to large generating units or to new generating units, but that is not the case here since compensatory load shedding only applies to existing, non-conforming, non-nuclear units. We also observe that, according to the implementation plan, compliance with Requirements R16.3 and R18 will become effective the first day of the first calendar quarter two years following applicable regulatory approval. Thus, the implementation plan provides existing, non-conforming generators a significant amount of time to prepare for compliance with the regional Reliability Standard.

34. We agree with NPCC that the NERC Reliability Functional Model does not preclude the assignment of a new or revised task in a Reliability Standard, such as to generator owners. The NERC

Reliability Functional Model provides that:

The Model is a guideline for the development of standards and their applicability. The Model it [sic] is not a Standard and does not have compliance requirements. Standards developers are not required to include all tasks envisioned in the model, nor are the developers precluded from developing Reliability Standards that address functions not described in the model. Where conflicts or inconsistency exist, the Reliability Standards requirements take precedence over the Model.⁴⁰

35. We disagree with Dominion and PSEG that the regional Reliability Standard is inconsistent with Order No. 763. In the context of the rulemaking addressing the continent-wide UFLS Reliability Standard PRC-006-1, Order No. 763 explained that it would be inappropriate to include in Reliability Standard PRC-006-1 specific requirements as to how to mitigate generators that tripped outside of the UFLS program (e.g., by procuring load to shed).⁴¹ We agree with NERC that, while it is inappropriate for a continent-wide Reliability Standard to supplant the planning coordinator’s role in establishing UFLS program requirements, the regional Reliability Standard PRC-006-NPCC-1 incorporates the NPCC’s planning coordinators’ views and experience.⁴² Accordingly, we see no inconsistency between Order No. 763 and our determination in this Final Rule.

36. Finally, we reject the claim that the compensatory load shedding provisions in regional Reliability Standard PRC-006-NPCC-1 contravene FPA section 215. As discussed above, the compensatory load shedding option for existing, non-conforming, non-nuclear units is one option for such generators. Generator owners may instead choose to bring their units into compliance rather than secure compensatory load shedding. We do not find that the regional Reliability Standard implicates the proscription in FPA section 215 against ordering the

⁴⁰ NERC Reliability Functional Model, Version 5 at 7.

⁴¹ Order No. 763, 139 FERC ¶ 61,098 at P 58.

⁴² We also note that the Commission granted clarification of Order No. 763, regarding NERC’s NOPR comments on compensatory load shedding, and found that NERC stated that “it is not appropriate for the Reliability Standards to prescribe how a planning coordinator determines whether mitigation is necessary or who is responsible for providing mitigation.” *Automatic Underfrequency Load Shedding and Load Shedding Plans Reliability Standards*, Order No. 763, 139 FERC ¶ 61,098, clarified, 140 FERC ¶ 61,164, at P 12 (2012).

³⁷ *Id.* at 4.

³⁸ *Id.*

³⁹ We also note NPCC’s statement that the regional Reliability Standard achieved an 83.5 percent overall approval “with a majority of registered Generator Owners in the region voting to approve the standard.” See NPCC Reply Comments at 9.

³⁴ *Id.* at 9.

³⁵ NERC Reply Comments at 2.

³⁶ *Id.* at 3.

“construction of additional generation or transmission capacity or to set and enforce compliance with standards for adequacy or safety of electric facilities or services.” The regional Reliability Standard does not require responsible entities to construct additional generation capacity or address the adequacy of electric facilities services. Instead, it merely requires generator owners, if they choose to, to secure compensatory load shedding to balance the performance characteristics of their existing, non-conforming units.

D. Violation Risk Factors, Violation Severity Levels, Implementation Plan, and Effective Dates

37. In the NOPR, the Commission proposed to approve NERC’s proposed violation risk factors and violation severity levels for regional Reliability Standard PRC-006-NPCC-1 as consistent with the Commission’s established guidelines.⁴³ In addition, the Commission proposed to accept the implementation plan and effective dates proposed by NERC for regional Reliability Standard PRC-006-NPCC-1.

Comments

38. No comments were received that specifically addressed the violation risk factors, violation severity levels, implementation plan, and effective dates proposed by NERC.⁴⁴

Commission Determination

39. The Commission approves the violation risk factors, violation severity levels, implementation plan, and effective dates proposed by NERC.

III. Information Collection Statement

40. The Office of Management and Budget (OMB) regulations require that OMB approve certain reporting and recordkeeping (collections of information) imposed by an agency.⁴⁵

Upon approval of a collection(s) of information, OMB will assign an OMB control number and expiration date. Respondents subject to the filing requirements of this rule will not be penalized for failing to respond to these collections of information unless the collections of information display a valid OMB control number.

41. The Commission is submitting these reporting and recordkeeping requirements to OMB for its review and approval under section 3507(d) of Paperwork Reduction Act of 1995. The Commission solicited comments on the need for and the purpose of the information contained in regional Reliability Standard PRC-006-NPCC-1 and the corresponding burden to implement the regional Reliability Standard. The Commission received comments on specific requirements in the regional Reliability Standard, which we address in this Final Rule. However, the Commission did not receive any comments on our reporting burden estimates. The Final Rule approves regional Reliability Standard PRC-006-NPCC-1. As noted previously, this is the first time NERC has requested Commission approval of regional Reliability Standard PRC-006-NPCC-1. Regional Reliability Standard PRC-006-NPCC-1 is designed to work with and augment the NERC continent-wide UFLS Reliability Standard PRC-006-1 by mitigating the consequences of underfrequency events, while accommodating differences in system transmission and distribution topology among NPCC planning coordinators due to historical design criteria, makeup of load demands, and generation resources. Regional Reliability Standard PRC-006-NPCC-1 is only applicable to generator owners, planning coordinators, distribution providers, and transmission owners in the NPCC

Region. To properly account for the burden on respondents, the Commission will treat the burden resulting from NERC-approved Reliability Standard PRC-006-NPCC-1 as pertaining to entities within the NPCC Region.

42. *Public Reporting Burden:* Our estimate below regarding the number of respondents is based on the NERC Compliance Registry as of July 24, 2012. According to the NERC Compliance Registry, there are 2 planning coordinators and 135 generator owners within the United States portion of the NPCC Region. The individual burden estimates are based on the time needed for planning coordinators to incrementally gather data, run studies, and analyze study results to design or update the UFLS programs that are required in the regional Reliability Standard in addition to the requirements of the NERC Reliability Standard PRC-006-1.⁴⁶ Additionally, generator owners must set each underfrequency trip relay below the appropriate generator underfrequency trip protection settings threshold curve in regional Reliability Standard PRC-006-NPCC-1, Figure 1 and provide the generator underfrequency trip setting and time delay to its planning coordinator within 45 days of the planning coordinator’s request. These burden estimates are consistent with estimates for similar tasks in other Commission-approved Reliability Standards. The following burden estimates relate to the requirements for this Final Rule in Docket No. RM12-12-000 (For Planning Coordinators) and are in addition to the burden estimates for the continent-wide Reliability Standard PRC-006-1, which was approved in Order No. 763 (approved by OMB Control No. 1902-0244 on 7/9/2012).

PRC-006-NPCC-1 (FERC-725L) (Automatic Underfrequency Load Shedding) ⁴⁷	Number of respondents annually	Number of responses per respondent	Average burden hours per response	Total annual burden hours
	(1)	(2)	(3)	(1)×(2)×(3)
PCs*: Design and document Automatic UFLS Program	2	1	8	16
PCs*: Update and Maintain UFLS Program Database			16	32
GOs*: Provide Documentation and Data to the Planning Coordinator	135	1	16	2160
GOs: Record Retention			4	540
Total				2748

*PC=planning coordinator; GO=generator owner.

⁴³ See *North American Electric Reliability Corp.*, 135 FERC ¶ 61,166 (2011).

⁴⁴ Dominion’s comments regarding the technical and practical feasibility of implementing regional Reliability Standard PRC-006-NPCC-1 were addressed in the previous section.

⁴⁵ 5 CFR 1320.11.

⁴⁶ The burden estimates for Reliability Standard PRC-006-1 are included in Order No. 763 and are not repeated here.

⁴⁷ Reliability Standard PRC-006-NPCC-1 applies to planning coordinators, transmission owners,

distribution providers and generator owners. However, the burden associated with the transmission owners and distribution providers is not included within this table because the Commission accounted for it under Commission-approved Reliability Standards PRC-006-1, PRC-007-0 and PRC-009-0.

Total Annual Hours for Collection: (Compliance/Documentation) = 2,748 hours.

Total Reporting Cost for planning coordinators: = 48 hours @ \$120/hour = \$5,760.

Total Reporting Cost for generator owners: = 2,160 hours @ \$120/hour = \$259,200.

Total Record Retention Cost for generator owners: 540 hours @ \$28/hour = \$15,120.

Total Annual Cost (Reporting + Record Retention)⁴⁸: = \$5,760 + \$259,200 + \$15,120 = \$280,080.

Title: Mandatory Reliability Standards for the NPCC Region.

Action: Proposed Collection FERC-725L.

OMB Control No.: 1902-0261.

Respondents: Businesses or other for-profit institutions; not-for-profit institutions.

Frequency of Responses: On Occasion.

Necessity of the Information: This Final Rule approves regional Reliability Standard PRC-006-NPCC-1 pertaining to automatic underfrequency load shedding. The regional Reliability Standard helps ensure the development of an effective UFLS program that preserves the security and integrity of the Bulk-Power System during declining system frequency events in coordination with the continent-wide Reliability Standard PRC-006-1 requirements.

Internal Review: The Commission has reviewed the regional Reliability Standard and made a determination that its action is necessary to implement section 215 of the FPA. These requirements, if accepted, should conform to the Commission's expectation for UFLS programs as well as procedures within the NPCC Region.

43. Interested persons may obtain information on the reporting requirements by contacting the following: Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426 [Attention: Ellen Brown, Office of the Executive Director, email: DataClearance@ferc.gov, phone: 202-502-8663, fax: 202-273-0873].

For submitting comments concerning the collection(s) of information and the associated burden estimate(s), please send your comments to the Commission and to the Office of Management and Budget, Office of Information and Regulatory Affairs, Washington, DC 20503 [Attention: Desk Officer for the Federal Energy Regulatory Commission,

phone: 202-395-4638, fax: 202-395-7285]. For security reasons, comments to OMB should be submitted by email to: oira_submission@omb.eop.gov. Comments submitted to OMB should include FERC-725L and Docket Number RM12-12-000.

IV. Environmental Analysis

44. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.⁴⁹ The Commission has categorically excluded certain actions from this requirement as not having a significant effect on the human environment. Included in the exclusion are rules that are clarifying, corrective, or procedural or that do not substantially change the effect of the regulations being amended.⁵⁰ The actions proposed here fall within this categorical exclusion in the Commission's regulations.

V. Regulatory Flexibility Act Certification

45. The Regulatory Flexibility Act of 1980 (RFA)⁵¹ generally requires a description and analysis of final rules that will have significant economic impact on a substantial number of small entities. The RFA mandates consideration of regulatory alternatives that accomplish the stated objectives of a proposed rule and that minimize any significant economic impact on a substantial number of small entities. The Small Business Administration's (SBA) Office of Size Standards develops the numerical definition of a small business.⁵² The SBA has established a size standard for electric utilities, stating that a firm is small if, including its affiliates, it is primarily engaged in the transmission, generation and/or distribution of electric energy for sale and its total electric output for the preceding twelve months did not exceed four million megawatt hours.⁵³

46. Regional Reliability Standard PRC-006-NPCC-1 establishes a coordinated, comprehensive UFLS region-wide consistent program with the NPCC region to achieve and facilitate the broader program characteristics contained in the requirements of the continent-wide PRC-006-1.⁵⁴ It will be

applicable to planning coordinators, generator owners, transmission owners and distribution providers. Comparison of the NERC Compliance Registry with data submitted to the Energy Information Administration on Form EIA-861 indicates that 5 small entities are registered as generator owners in the United States portion of the NPCC Region.⁵⁵ The Commission estimates that the small generator owners to whom the proposed regional Reliability Standard applies will incur compliance and record keeping costs of \$10,160 (\$2,032 per generator owner). Accordingly, regional Reliability Standard PRC-006-NPCC-1 should not impose a significant operating cost increase or decrease on the affected small entities.

47. Further, NERC explains that the cost for smaller entities to implement regional Reliability Standard PRC-006-NPCC-1 was considered during the development process. NERC states that regional Reliability Standard PRC-006-NPCC-1 provides an opportunity for smaller entities to aggregate their load with other such entities in the same electrical island. This allows each smaller entity's respective planning coordinator to achieve the desired aggregate outcome within that island according to program characteristics.⁵⁶

48. Based on this understanding, the Commission certifies that the regional Reliability Standard will not have a significant economic impact on a substantial number of small entities. Accordingly, no regulatory flexibility analysis is required.

VI. Document Availability

49. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through FERC's Home Page (<http://www.ferc.gov>) and in FERC's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street NE., Room 2A, Washington, DC 20426.

50. From FERC's Home Page on the Internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three

⁴⁸ The Commission bases the hourly reporting cost on the cost of an engineer to implement the requirements of the rule. The record retention cost comes from Commission staff research on record retention requirements.

⁴⁹ *Regulations Implementing National Environmental Policy Act of 1969*, Order No. 486, 52 FR 47897 (Dec. 17, 1987), FERC Stats. & Regs., Regulations Preambles 1986-1990 ¶ 30,783 (1987).

⁵⁰ 18 CFR 380.4(a)(2)(ii).

⁵¹ 5 U.S.C. 601-612.

⁵² 13 CFR 121.101.

⁵³ 13 CFR 121.201, Sector 22, Utilities & n.1.

⁵⁴ NERC Petition at 29-30.

⁵⁵ The two planning coordinators in the United States portion of the NPCC Region are not considered small entities.

⁵⁶ NERC Petition at 25.

digits of this document in the docket number field.

51. User assistance is available for eLibrary and the FERC's Web site during normal business hours from FERC Online Support at 202-502-6652 (toll free at 1-866-208-3676) or email at ferconlinesupport@ferc.gov, or the Public Reference Room at 202-502-8371, TTY 202-502-8659. Email the Public Reference Room at public.referenceroom@ferc.gov.

VII. Effective Date and Congressional Notification

52. These regulations are effective April 29, 2013. The Commission has determined, with the concurrence of the Administrator of the Office of Information and Regulatory Affairs of OMB, that this rule is not a "major rule" as defined in section 351 of the Small Business Regulatory Enforcement Fairness Act of 1996.

By the Commission.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013-04430 Filed 2-26-13; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9613]

RIN 1545-BI67

Reduced 2009 Estimated Income Tax Payments for Individuals With Small Business Income

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations and removal of temporary regulations.

SUMMARY: This document contains final regulations under section 6654 of the Internal Revenue Code (Code) relating to reduced estimated income tax payments for qualified individuals with small business income for any taxable year beginning in 2009 and does not apply to any taxable years beginning before or after 2009. The final regulations implement changes to section 6654 made by the American Recovery and Reinvestment Act of 2009. The final regulations provide guidance for qualified individuals with small business income to certify that they satisfy the statutory gross income requirement for purposes of the reduction in their required 2009 estimated income tax payments.

DATES: *Effective Date:* These regulations are effective on February 27, 2013.

Applicability Date: These regulations apply for any taxable year that begins in 2009.

FOR FURTHER INFORMATION CONTACT:

Janet Engel Kidd at (202) 622-4940 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains final amendments to the Income Tax Regulations (26 CFR part 1) under section 6654(d) of the Code relating to the addition to tax for failure by an individual to pay estimated income tax. Section 6654(d)(1)(D) was added by section 1212 of Division B of the American Recovery and Reinvestment Act of 2009, Public Law 111-5 (123 Stat. 336 (2009)), effective for taxable years beginning in 2009. It does not apply to any taxable years beginning before or after 2009.

Section 6654 imposes an addition to tax in the case of an individual taxpayer's underpayment of estimated tax. Estimated tax is payable in four installments throughout the taxable year, and the amount of each required installment is generally 25 percent of the required annual payment of estimated tax. Under section 6654(d)(1)(B), the required annual payment is the lesser of (i) 90 percent of the tax shown on the income tax return for the taxable year (or, if no return is filed, 90 percent of the tax for the year), or (ii) 100 percent of the tax shown on the taxpayer's return for the preceding taxable year (or 110 percent if the taxpayer's adjusted gross income for the preceding taxable year exceeded \$150,000). The provision allowing for the payment of 100 (or 110) percent of the tax shown on the taxpayer's return for the preceding taxable year does not apply if the preceding taxable year was less than 12 months or if the taxpayer did not file a return for that year.

Section 6654(d)(1)(D) provides a "[s]pecial rule for 2009." Under this provision, the applicable percentage of tax shown on the return for the preceding taxable year (either 100 or 110 percent) is reduced to 90 percent for qualified individuals for taxable years that begin in 2009. In other words, for taxable years that begin in 2009, a qualified individual's annual required payment of estimated tax is the lesser of (i) 90 percent of the tax shown on the return for the 2009 taxable year (or, if no return is filed, 90 percent of the tax for the year), or (ii) 90 percent of the tax shown on the individual's return for taxable year 2008.

To implement the special rule for 2009, the Treasury Department and the IRS published in the **Federal Register** (75 FR 9141) on March 1, 2010, a notice of proposed rulemaking (REG-117501-09) proposing amendments to § 1.6654-2, which provides exceptions to the addition to tax for an individual's failure to pay estimated income tax. The notice of proposed rulemaking cross-referenced temporary regulations (TD 9480) published in the **Federal Register** (75 FR 9101) on the same day.

The IRS received one written public comment responding to the proposed regulations. The comment is available for public inspection at <http://www.regulations.gov> or upon request. The commenter expressed appreciation for efforts to simplify tax reporting by small business owners. A public hearing was not requested or held.

Explanation of Provisions

The final regulations adopt the proposed regulations without change. The final regulations explain who is a qualified individual under section 6654(d)(1)(D) and how a taxpayer establishes that the taxpayer is a qualified individual. A qualified individual is any individual (1) whose adjusted gross income shown on the individual's return for the preceding taxable year (prior to the taxable year that begins in 2009) is less than \$500,000, and (2) who certifies that more than 50 percent of the gross income shown on that return was income from a small business. See section 6654(d)(1)(D)(ii). If an individual is married within the meaning of section 7703, and files a separate return for a taxable year that begins in 2009, then to qualify, the individual's adjusted gross income shown on the preceding year's return must be less than \$250,000, rather than \$500,000. See section 6654(d)(1)(D)(iv). Pursuant to section 6654(d)(1)(D)(ii)(II), the Secretary shall prescribe by regulation the form, manner, and time for filing a certification. Additionally, section 6654(m) authorizes the Secretary to prescribe regulations as necessary to carry out the purposes of section 6654.

Income from a small business is defined in general terms in section 6654(d)(1)(D)(iii) as income from a trade or business the average number of employees of which was less than 500 for calendar year 2008. The final regulations specify that the trade or business must be a bona fide trade or business of which the individual was an owner. The final regulations provide that a trade or business may be organized as, or take the legal form of, a corporation, partnership, limited

liability company, or sole proprietorship.

The final regulations also provide that a qualified individual shall file a certification with the IRS in the manner and at the time prescribed in forms, publications, or other guidance, such as Form 2210, "Underpayment of Estimated Tax by Individuals, Estates, and Trusts" (or any successor form and its instructions).

The final regulations will be applicable for taxable years that begin in 2009. The reduced percentage in section 6654(d)(1)(D) is limited to taxable years that begin in 2009 and does not apply to taxable years that begin before or after 2009.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866, as supplemented by Executive Order 13563. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because the regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking that preceded these final regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business and no comments were received.

Drafting Information

The principal author of these regulations is Janet Engel Kidd, Office of the Associate Chief Counsel, Procedure and Administration.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

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

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

Section 1.6654–2 also issued under 26 U.S.C. 6654(m).

■ **Par. 2.** Section 1.6654–2 is amended by revising paragraphs (a) introductory text, (a)(1)(ii), and (f) to read as follows:

§ 1.6654–2 Exceptions to imposition of the addition to the tax in the case of individuals.

(a) *In general.* The addition to the tax under section 6654 will not be imposed for any underpayment of any installment of estimated tax if, on or before the date prescribed for payment of the installment, the total amount of all payments of estimated tax made equals or exceeds the lesser of the amount in § 1.6654–2(a)(1) or the amount in § 1.6654–2(a)(2).

(1) * * *

(ii) *Special rule for taxable years beginning in 2009.* For any taxable year beginning in 2009, for a qualified individual, the amount described in paragraph (a)(1)(i) of this section is reduced to 90 percent of that amount.

(A) *Qualified individual* means any individual whose adjusted gross income shown on the individual's return for the preceding taxable year is less than \$500,000 and who certifies, as prescribed in paragraph (a)(1)(ii)(D) of this section, that more than 50 percent of the gross income shown on the return for the preceding taxable year was income from a small business.

(B) *Income from a small business* means income from the operation of a bona fide trade or business of which the individual was an owner during calendar year 2009, and that on average had fewer than 500 employees in calendar year 2008.

(C) The trade or business may be organized as, or take the legal form of, a corporation, partnership, limited liability company, or sole proprietorship.

(D) A qualified individual shall file a certification of the individual's qualification in the manner and at the time prescribed by the Internal Revenue Service in forms, publications, or other guidance.

* * * * *

(f) *Effective/applicability date.* Paragraph (a)(1)(ii) of this section applies to any taxable year beginning in 2009 and does not apply to any taxable years beginning before or after 2009.

§ 1.6654–2T [Removed]

■ **Par. 3.** Section 1.6654–2T is removed.

Steven T. Miller,

Deputy Commissioner for Services and Enforcement.

Approved: February 22, 2013.

Mark J. Mazur,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2013–04680 Filed 2–25–13; 4:15 pm]

BILLING CODE 4830–01–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1984

[Docket Number OSHA–2011–0193]

RIN 1218–AC79

Procedures for the Handling of Retaliation Complaints Under Section 1558 of the Affordable Care Act

AGENCY: Occupational Safety and Health Administration, Labor.

ACTION: Interim final rule; request for comments.

SUMMARY: This document provides the interim final regulations governing the employee protection (whistleblower) provision of section 1558 of the Affordable Care Act, which added section 18C of the Fair Labor Standards Act, to provide protections to employees of health insurance issuers or other employers who may have been subject to retaliation for reporting potential violations of the law's consumer protections (e.g., the prohibition on denials of insurance due to pre-existing conditions) or affordability assistance provisions (e.g., access to health insurance premium tax credits). This interim rule establishes procedures and time frames for the handling of retaliation complaints under section 18C, including procedures and time frames for employee complaints to the Occupational Safety and Health Administration (OSHA), investigations by OSHA, appeals of OSHA determinations to an administrative law judge (ALJ) for a hearing de novo, hearings by ALJs, review of ALJ decisions by the Administrative Review Board (ARB) (acting on behalf of the Secretary of Labor), and judicial review of the Secretary's final decision.

DATES: This interim final rule is effective on February 27, 2013. Comments and additional materials must be submitted (post-marked, sent or received) by April 29, 2013.

ADDRESSES: You may submit comments and attachments electronically at <http://www.regulations.gov>, which is the Federal eRulemaking Portal. Follow the instructions online for making electronic submissions.

Fax: If your submissions, 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 your comments and attachments to the OSHA Docket Office, Docket No. OSHA-2011-0193, U.S. Department of Labor, Room N-2625, 200 Constitution Avenue NW., Washington, DC 20210. Deliveries (hand, express mail, messenger and 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., ET.

Instructions: All submissions must include the Agency name and the OSHA docket number for this rulemaking (Docket No. OSHA-2011-0193). Submissions, including any personal information provided, are placed in the public docket without change and may be made available online at <http://www.regulations.gov>. Therefore, OSHA cautions against submitting personal information such as social security numbers and birth dates.

Docket: To read or download submissions or other material in the docket, go to <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 (e.g., 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.

FOR FURTHER INFORMATION CONTACT:

For Press inquiries: Frank Meilinger, Director, OSHA Office of Communications, Room N-3647, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone: (202) 693-1999. This is not a toll-free number. Email: meilinger.francis2@dol.gov.

For technical inquiries: Katelyn Wendell, Program Analyst, Directorate of Whistleblower Protection Programs, OSHA, U.S. Department of Labor, Room N-4624, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693-2199. This is not a toll-free number. Email: Wendell.katelyn.j@dol.gov. This **Federal Register** publication is available in alternative formats. The alternative formats available are: Large print, electronic file on computer disk (Word

Perfect, ASCII, Mates with Duxbury Braille System), and audiotape.

SUPPLEMENTARY INFORMATION:

I. Background

The Patient Protection and Affordable Care Act, Public Law 111-148, 124 Stat. 119, was signed into law on March 23, 2010 and was amended by the Health Care and Education Reconciliation Act of 2010, Public Law 111-152, 124 Stat. 1029, that was signed into law on March 30, 2010. The terms "Affordable Care Act" or "Act" are used in this rulemaking to refer to the final, amended version of the law. The Affordable Care Act contains various provisions designed to make health care more affordable and accountable.

Among the policies to achieve its goals, the Affordable Care Act's section 1558 amended the Fair Labor Standards Act (FLSA) to add section 18C, 29 U.S.C. 218C (section 18C), which provides protection to employees against retaliation by an employer for engaging in certain protected activities.

Under section 18C, an employer may not retaliate against an employee for receiving a credit under section 36B of the Internal Revenue Code of 1986 or a cost-sharing reduction (referred to as a "subsidy" in section 18C) under section 1402 of Affordable Care Act. These provisions allow employees to receive tax credits or cost-sharing reductions while enrolled in a qualified health plan through an exchange, if their employer does not offer a coverage option that is affordable and provides a basic level of value (i.e., "minimum value"). Certain large employers who fail to offer affordable plans that meet this minimum value may be assessed a tax penalty if any of their full-time employees receive a premium tax credit through the Exchange. Thus, the relationship between the employee's receipt of a credit and the potential tax penalty imposed on an employer could create an incentive for an employer to retaliate against an employee. Section 18C protects employees against such retaliation.

Section 18C also protects employees against retaliation because they provided or are about to provide to their employer, the Federal Government, or the attorney general of a State information relating to any violation of, or any act or omission the employee reasonably believes to be a violation of, any provision of or amendment made by title I of the Affordable Care Act; testified or are about to testify in a proceeding concerning such violation; assisted or participated, or are about to assist or participate, in such a proceeding; or objected to, or refused to

participate in, any activity, policy, practice, or assigned task that the employee reasonably believed to be in violation of any provision of title I of the Act (or amendment), or any order, rule, regulation, standard, or ban under title I of the Act (or amendment). Title I includes a range of insurance company accountability policies such as: The prohibition of lifetime dollar limits on coverage, the requirement for most plans to cover recommended preventive services with no cost sharing, and, starting in 2014, guaranteed availability (also known as guaranteed issue) protections so that individuals and employers will be able to obtain coverage that currently can be denied due to a pre-existing condition, and the prohibition on the use of factors such as health status, medical history, gender, and industry of employment to set premium rates.

Section 18C became effective on the date the health care law was enacted, March 23, 2010. On January 1, 2014, the scope of coverage of section 18C will be expanded by section 2706(b) of the Public Health Service Act (PHSA), 42 U.S.C. 300gg *et seq.*, as amended by section 1201 of the Affordable Care Act. Section 2706 of the PHSA is titled "Non-Discrimination in Health Care" and provides, in relevant part: "(b) INDIVIDUALS.—The provisions of section 1558 of the Patient Protection and Affordable Care Act (relating to non-discrimination) shall apply with respect to a group health plan or health insurance issuer offering group or individual health insurance coverage." Thus, the protections provided by section 18C will extend in 2014 to cover retaliation with respect to an employee's compensation, terms, conditions or other privileges of employment by health insurance issuers offering group or individual health insurance coverage regardless of whether those issuers are the employer of the person retaliated against. Since the enactment of the Affordable Care Act, a health insurance issuer is prohibited from retaliating against its own employees who engage in activity protected by section 18C. Beginning in 2014, those issuers will also be prohibited from retaliating against persons who are not their employees with respect to those persons' compensation, terms, conditions or other privileges of employment, including their employer-sponsored health insurance. An employee will be protected from retaliation (e.g., having that issuer limit or end health insurance coverage), not only by her employer, but also by the insurance issuer that provides

employer-sponsored health insurance coverage to the employee.

These interim rules establish procedures for the handling of whistleblower complaints under section 18C of the FLSA; these procedures are very similar to those used for whistleblower complaints in other industries.

II. Summary of Statutory Procedures

Section 18C(b)(1) adopts the procedures, notifications, burdens of proof, remedies, and statutes of limitation in the Consumer Product Safety Improvement Act of 2008 (CPSIA), 15 U.S.C. 2087(b). Accordingly, a covered employee may file a complaint with the Secretary of Labor (Secretary) within 180 days of the alleged retaliation. Upon receipt of the complaint, the Secretary must provide written notice to the person or persons named in the complaint alleged to have violated the Act (respondent) of the filing of the complaint, the allegations contained in the complaint, the substance of the evidence supporting the complaint, and the rights afforded the respondent throughout the investigation. The Secretary must then, within 60 days of receipt of the complaint, afford the complainant and respondent an opportunity to submit a response and meet with the investigator to present statements from witnesses, and conduct an investigation.

The Secretary may conduct an investigation only if the complainant has made a prima facie showing that the protected activity was a contributing factor in the adverse action alleged in the complaint and the respondent has not demonstrated, through clear and convincing evidence, that the respondent would have taken the same adverse action in the absence of that activity.

After investigating a complaint, the Secretary will issue written findings. If, as a result of the investigation, the Secretary finds there is reasonable cause to believe that retaliation has occurred, the Secretary must notify the respondent of those findings, along with a preliminary order that requires the respondent to, where appropriate: Take affirmative action to abate the violation; reinstate the complainant to his or her former position together with the compensation of that position (including back pay) and restore the terms, conditions, and privileges associated with his or her employment; and provide compensatory damages to the complainant, as well as all costs and expenses (including attorney fees and expert witness fees) reasonably incurred by the complainant for, or in connection

with, the bringing of the complaint upon which the order was issued.

The complainant and the respondent then have 30 days after the date of the Secretary's notification in which to file objections to the findings and/or preliminary order and request a hearing before an ALJ. The filing of objections under section 18C of the FLSA will stay any remedy in the preliminary order except for preliminary reinstatement. If a hearing before an ALJ is not requested within 30 days, the preliminary order becomes final and is not subject to judicial review.

If a hearing is held, the statute requires the hearing to be conducted "expeditiously." The Secretary then has 120 days after the conclusion of any hearing in which to issue a final order, which may provide appropriate relief or deny the complaint. Until the Secretary's final order is issued, the Secretary, the complainant, and the respondent may enter into a settlement agreement that terminates the proceeding. Where the Secretary has determined that a violation has occurred, the Secretary, where appropriate, will assess against the respondent a sum equal to the total amount of all costs and expenses, including attorney's and expert witness fees, reasonably incurred by the complainant for, or in connection with, the bringing of the complaint upon which the Secretary issued the order.

The Secretary also may award a prevailing respondent a reasonable attorney's fee, not exceeding \$1,000, if the Secretary finds that the complaint is frivolous or has been brought in bad faith. Within 60 days of the issuance of the final order, any person adversely affected or aggrieved by the Secretary's final order may file an appeal with the United States Court of Appeals for the circuit in which the violation occurred or the circuit where the complainant resided on the date of the violation.

The statute permits the employee to seek de novo review of the complaint by a United States district court in the event that the Secretary has not issued a final decision within 210 days after the filing of the complaint, or within 90 days after receiving a written determination. The court will have jurisdiction over the action without regard to the amount in controversy, and the case will be tried before a jury at the request of either party.

Finally, section 18C(b)(2) of the FLSA provides that nothing in section 18C shall be deemed to diminish the rights, privileges, or remedies of any employee under any Federal or State law or under any collective bargaining agreement, and the rights and remedies in section

18C may not be waived by any agreement, policy, form, or condition of employment.

III. Summary and Discussion of Regulatory Provisions

The regulatory provisions in this part have been written and organized to be consistent with other whistleblower regulations promulgated by OSHA to the extent possible within the bounds of the statutory language of section 18C of the FLSA and 15 U.S.C. 2087(b) of CPSIA. Responsibility for receiving and investigating complaints under section 18C has been delegated to the Assistant Secretary for Occupational Safety and Health. Secretary's Order 1-2012 (Jan. 18, 2012), 77 FR 3912 (Jan. 25, 2012). Hearings on determinations by the Assistant Secretary are conducted by the Office of Administrative Law Judges, and appeals from decisions by ALJs are decided by the ARB. Secretary's Order 1-2010 (Jan. 15, 2010), 75 FR 3924 (Jan. 25, 2010).

Subpart A—Complaints, Investigations, Findings and Preliminary Orders

Section 1984.100 Purpose and Scope

This section describes the purpose of the regulations implementing section 18C of the FLSA and provides an overview of the procedures covered by these regulations.

Section 1984.101 Definitions

This section includes general definitions for the Affordable Care Act whistleblower provision codified at section 18C of the FLSA. The definitions of the terms "employer," "employee," and "person" from section 3 of the FLSA, 29 U.S.C. 203, apply to these rules and are included here.

The FLSA defines "employer" as including "any person acting directly or indirectly in the interest of an employer in relation to an employee and includes a public agency, but does not include any labor organization (other than when acting as an employer) or anyone acting in the capacity of officer or agent of such labor organization." 29 U.S.C. 203(d). The FLSA defines "person" to mean "an individual, partnership, association, corporation, business trust, legal representative, or any organized group of persons." 29 U.S.C. 203(a).

The FLSA defines "employee" to mean "any individual employed by an employer." 29 U.S.C. 203(e)(1). In the case of an individual employed by a public agency, the term employee means any individual employed by the Government of the United States: As a civilian in the military departments (as defined in section 102 of the U.S. Code at title 5), in any executive agency (as

defined in section 105 of such title), in any unit of the judicial branch of the Government which has positions in the competitive service, in a nonappropriated fund instrumentality under the jurisdiction of the Armed Forces, in the Library of Congress, or in the Government Printing Office. 29 U.S.C. 203(e)(2)(A). An employee generally also includes any individual employed by the United States Postal Service or the Postal Regulatory Commission, 29 U.S.C. 203(e)(2)(b); and any individual employed by a State, political subdivision of a State, or an interstate governmental agency. The definition of “employee” under the FLSA does not include an individual who is not subject to the civil service laws of the State, political subdivision, or agency which employs him; and who holds a public elective office of that State, political subdivision, or agency, is selected by the holder of such an office to be a member of his personal staff, is appointed by such an officeholder to serve on a policymaking level, is an immediate adviser to such an officeholder with respect to the constitutional or legal powers of his office, or is an employee in the legislative branch or legislative body of that State, political subdivision, or agency and is not employed by the legislative library of such State, political subdivision, or agency. 29 U.S.C. 203(e)(2)(c).

Consistent with the Secretary’s interpretation of the term “employee” in the other whistleblower statutes administered by OSHA¹ and with the Secretary’s interpretation of the term “employee” under the anti-retaliation provision found at section 15(a)(3) of the FLSA, 29 U.S.C. 215(a)(3),² the

definition of the term “employee” in section 1984.101 also includes former employees and applicants for employment. This interpretation is supported by section 18C’s plain language which prohibits retaliation against “any employee” and provides that “[a]n employee who believes that he or she has been discharged or otherwise discriminated against by any employer in violation of this section” may file a complaint with the Secretary of Labor, (Emphasis added). Section 18C’s broad protection of “any employee” from discrimination and provision of a cause of action against “any employer” for retaliation makes clear that the parties need not have a current employment relationship. Section 18C’s broad protections, like the protections in section 15(a)(3), contrast with the narrower protections of sections 6 and 7 of the FLSA. Sections 6 and 7 provide respectively that an employer must pay at least the minimum wage to “each of his employees” and must pay overtime to “any of his employees,” and thus require a current employment relationship. See 29 U.S.C. 206(a) and (b), 29 U.S.C. 207(a)(1) and (2). Congress chose to use the broad term “any” to modify employee and employer in Sections 18C(a) and (b), rather than providing more restrictively that, for example, “no employer shall discharge or in any manner discriminate against any of his employees” or “an employee who believes that he or she has been discharged or otherwise discriminated against by his employer” may file a complaint with the Secretary of Labor. The Supreme Court has made clear that “any” has an expansive meaning that does not limit the word it modifies. See, e.g., *Kasten v. Saint-Gobain Performance Plastics Corp.*, 131 S. Ct. 1325, 1332 (2011) (noting that the use of “any” in the phrase “filed any complaint” in section 15(a)(3) of the FLSA “suggests a broad interpretation that would include an oral complaint”); *U.S. v. Gonzales*, 520 U.S. 1, 5 (1997) (“any” has an expansive meaning, that is, “one or some indiscriminately of whatever kind”) (internal citations omitted). In addition, the explicit inclusion of reinstatement and preliminary reinstatement (both of which can only be awarded to former employees) among the remedies available for whistleblowers under Section 18C confirms that the complainant and the respondent need not have a current employment relationship in order for the complainant to have a claim under section 18C. See *Dellinger v. Science*

Applications Int’l Corp., 649 F.3d at 230 n.2 (section 15(a)(3) of the FLSA protects former employees); cf. *Robinson v. Shell Oil Co.*, 519 U.S. 337 (1997) (term “employees” in anti-retaliation provision of Title VII of the Civil Rights Act of 1964 includes former employees).

Section 1984.102 Obligations and Prohibited Acts

This section describes the activities that are protected under section 18C of the FLSA, and the conduct that is prohibited in response to any protected activities. Section 18C(a)(1) protects any employee from retaliation “because the employee received a credit under section 36B of the Internal Revenue Code of 1986 or a subsidy under section 1402 of this Act.” The reference to “a subsidy under section 1402 this Act” in section 18C(a)(1) refers to receipt of a cost-sharing reduction under section 1402 of the Affordable Care Act. 42 U.S.C. 18071.

Under section 18C(a)(2), an employer may not retaliate against an employee because the employee “provided, caused to be provided, or is about to provide or cause to be provided to the employer, the Federal Government, or the attorney general of a State information relating to any violation of, or any act or omission the employee reasonably believes to be a violation of, any provision of this title (or an amendment made by this title).” Section 18C also protects employees who testify, assist or participate in proceedings concerning such violations. Sections 18C(a)(3) and (4), 29 U.S.C. 218C(a)(3) and (4). Finally, section 18C(a)(5) prohibits retaliation because an employee “objected to, or refused to participate in, any activity, policy, practice, or assigned task that the employee (or other such person) reasonably believed to be in violation of any provision of this title (or amendment), or any order, rule, regulation, standard, or ban under this title (or amendment).” References to “this title” in section 18C(a)(2) and (5) refer to Title I of the Affordable Care Act. This includes health insurance reforms such as providing guaranteed availability (also known as guaranteed issue) protections so that individuals and employers will be able to obtain coverage when it currently can be denied, continuing current guaranteed renewability protections, prohibiting the use of factors such as health status, medical history, gender, and industry of employment to set premium rates, limiting age rating, and prohibiting issuers from dividing up their insurance pools within markets.

¹ See, e.g., 29 CFR 1980.101(g) (defining employee to include former employees and applicants under the whistleblower provisions in the Sarbanes-Oxley Act); 29 CFR 1978.101 (Surface Transportation Assistance Act); 29 CFR 1981.101 (Pipeline Safety Improvement Act); 29 CFR 1982.101(d) (Federal Railroad Safety Act and the National Transit Systems Security Act); 29 CFR 1983.101(h) (Consumer Product Safety Improvement Act).

² See Brief for the Secretary of Labor and the Equal Employment Opportunity Commission as Amicus Curiae, *Dellinger v. Science Applications Int’l Corp.*, No. 10–1499 (4th Cir. Oct. 15, 2010) (explaining that the phrase “any employee” in section 15(a)(3) of the FLSA does not limit an individual’s retaliation claims to her current employer, but rather extends protection to prospective employees from retaliation for engaging in protected activity), and Brief of the Secretary of Labor and Equal Employment Opportunity Commission as Amicus Curiae, *Dellinger v. Science Applications Int’l Corp.*, No. 10–1499 (4th Cir. Sept. 9, 2011) (same); but see *Dellinger v. Science Applications Int’l Corp.*, 649 F.3d 226, 229–31 & n.2 (4th Cir. 2011) (accepting that former employees are protected from retaliation under section 15(a)(3) of the FLSA but holding that applicants for employment are not).

In order to have a “reasonable belief” under sections 18C(a)(2) and (5), a complainant must have both a subjective, good faith belief and an objectively reasonable belief that the complained-of conduct violates one of the listed categories of law. See *Sylvester v. Parexel Int’l LLC*, ARB No. 07–123, 2011 WL 2165854, at *11–12 (ARB May 25, 2011) (discussing the reasonable belief standard under analogous language in the Sarbanes-Oxley Act whistleblower provision, 18 U.S.C. 1514A). The requirement that the complainant have a subjective, good faith belief is satisfied so long as the complainant actually believed that the conduct complained of violated the relevant law. See *id.* The “reasonableness” of a complainant’s belief is typically determined “based on the knowledge available to a reasonable person in the same factual circumstances with the same training and experience as the aggrieved employee.” *Id.* at *12 (internal quotation marks and citation omitted). However, the complainant need not show that the conduct complained of constituted an actual violation of law. Pursuant to this standard, an employee’s whistleblower activity is protected where it is based on a reasonable, but mistaken, belief that a violation of the relevant law has occurred. *Id.* at *13.

Section 1984.103 Filing of Retaliation Complaint

This section explains the requirements for filing a retaliation complaint under section 18C. To be timely, a complaint must be filed within 180 days of when the alleged violation occurs. Under *Delaware State College v. Ricks*, 449 U.S. 250, 258 (1980), this is considered to be when the retaliatory decision has been both made and communicated to the complainant. In other words, the limitations period commences once the employee is aware or reasonably should be aware of the employer’s decision. *Equal Emp’t Opportunity Comm’n v. United Parcel Serv., Inc.*, 249 F.3d 557, 561–62 (6th Cir. 2001). However, the time for filing a complaint may be tolled for reasons warranted by applicable case law. Complaints filed under section 18C of the FLSA need not be in any particular form. They may be either oral or in writing. If the complainant is unable to file the complaint in English, OSHA will accept the complaint in any language. With the consent of the employee, complaints may be filed by any person on the employee’s behalf.

OSHA notes that a complaint of retaliation filed with OSHA under the Affordable Care Act is not a formal

document and need not conform to the pleading standards for complaints filed in federal district court articulated in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007) and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009). See *Sylvester v. Parexel Int’l, Inc.*, ARB No. 07–123, 2011 WL 2165854, at *9–10 (ARB May 26, 2011) (holding whistleblower complaints filed with OSHA under analogous provisions in the Sarbanes-Oxley Act need not conform to federal court pleading standards). Rather, the complaint filed with OSHA under this section simply alerts the Agency to the existence of the alleged retaliation and the complainant’s desire that the Agency investigate the complaint. Upon the filing of a complaint with OSHA, the Assistant Secretary is to determine whether “the complaint, supplemented as appropriate by interviews of the complainant” alleges “the existence of facts and evidence to make a prima facie showing.” 29 CFR 1984.104(e). As explained in section 1984.104(e), if the complaint, supplemented as appropriate, contains a prima facie allegation, and the respondent does not show clear and convincing evidence that it would have taken the same action in the absence of the alleged protected activity, OSHA conducts an investigation to determine whether there is reasonable cause to believe that retaliation has occurred. See 15 U.S.C. 2087(b)(2), 29 CFR 1984.104(e).

Section 1984.104 Investigation

This section describes the procedures that apply to the investigation of complaints under section 18C. Paragraph (a) of this section outlines the procedures for notifying the parties and appropriate Federal agencies of the complaint and notifying the respondent of its rights under these regulations. Paragraph (b) describes the procedures for the respondent to submit its response to the complaint. Paragraph (c) specifies that throughout the investigation the Agency will provide to the complainant (or the complainant’s legal counsel if the complainant is represented by counsel) a copy of respondent’s submissions to the Agency that are responsive to the complainant’s whistleblower complaint and the complainant will have an opportunity to respond to those submissions. Before providing such materials to the complainant, the Agency will redact them in accordance with the Privacy Act of 1974, 5 U.S.C. 552a, and other applicable confidentiality laws. Paragraph (d) of this section discusses confidentiality of information provided during investigations. Paragraph (e) of this section sets forth the applicable

burdens of proof. Paragraph (f) describes the procedures the Assistant Secretary will follow prior to the issuance of findings and a preliminary order when the Assistant Secretary has reasonable cause to believe that a violation has occurred.

Section 18C of the FLSA incorporates the burdens of proof set forth in CPSIA. 15 U.S.C. 2087(b). That statute requires that a complainant make an initial prima facie showing that protected activity was “a contributing factor” in the adverse action alleged in the complaint, *i.e.*, that the protected activity, alone or in combination with other factors, affected in some way the outcome of the employer’s decision. The complainant will be considered to have met the required burden if the complaint on its face, supplemented as appropriate through interviews of the complainant, alleges the existence of facts and either direct or circumstantial evidence to meet the required showing. The complainant’s burden may be satisfied, for example, if he or she shows that the adverse action took place shortly after protected activity, giving rise to the inference that it was a contributing factor in the adverse action.

If the complainant does not make the required prima facie showing, the investigation must be discontinued and the complaint dismissed. See *Trimmer v. U.S. Dep’t of Labor*, 174 F.3d 1098, 1101 (10th Cir. 1999) (noting that the burden-shifting framework of the Energy Reorganization Act of 1974 (ERA), which is the same framework now applicable to section 18C of the FLSA, serves a “gatekeeping function” that “stem[s] frivolous complaints”). Even in cases where the complainant successfully makes a prima facie showing, the investigation must be discontinued if the respondent demonstrates, by clear and convincing evidence, that it would have taken the same adverse action in the absence of the protected activity. Thus, OSHA must dismiss a complaint under section 18C of the FLSA and not investigate (or cease investigating) if either: (1) The complainant fails to meet the prima facie showing that protected activity was a contributing factor in the adverse action; or (2) the respondent rebuts that showing by clear and convincing evidence that it would have taken the same adverse action absent the protected activity.

Assuming that an investigation proceeds beyond the gatekeeping phase, the statutory burdens of proof require an employee to prove that the alleged protected activity was a “contributing factor” in the alleged adverse action. If the employee proves that the alleged

protected activity was a contributing factor in the adverse action, the respondent, to escape liability, must prove by “clear and convincing evidence” that it would have taken the same action in the absence of the protected activity. A contributing factor is “any factor which, alone or in connection with other factors, tends to affect in any way the outcome of the decision.” *Marano v. Dep’t of Justice*, 2 F.3d 1137, 1140 (Fed. Cir. 1993) (internal quotation marks, emphasis and citation omitted) (discussing the Whistleblower Protection Act, 5 U.S.C. 1221(e)(1)). In proving that protected activity was a contributing factor in the adverse action, “‘a complainant need not necessarily prove that the respondent’s articulated reason was a pretext in order to prevail,’” because a complainant alternatively can prevail by showing that the respondent’s “‘reason, while true, is only one of the reasons for its conduct,’” and that another reason was the complainant’s protected activity. See *Klopfenstein v. PCC Flow Techs. Holdings, Inc.*, ARB No. 04–149, 2006 WL 3246904, at *13 (ARB May 31, 2006) (quoting *Rachid v. Jack in the Box, Inc.*, 376 F.3d 305, 312 (5th Cir. 2004)) (discussing contributing factor test under the Sarbanes-Oxley whistleblower provision), *aff’d sub nom. Klopfenstein v. Admin. Review Bd., U.S. Dep’t of Labor*, 402 F. App’x 936, 2010 WL 4746668 (5th Cir. 2010).

The statutory burdens of proof do not address the evidentiary standard that applies to a complainant’s proof that protected activity was a contributing factor in an adverse action. Rather, they simply provide that the Secretary may find a violation only “if the complainant demonstrates” that protected activity was a contributing factor in the alleged adverse action. See 15 U.S.C. 2087(b)(2)(B)(iii). It is the Secretary’s position that the complainant must prove by a “preponderance of the evidence” that his or her protected activity contributed to the adverse action; otherwise the burden never shifts to the respondent to establish its defense by “clear and convincing evidence.” See, e.g., *Allen v. Admin. Review Bd.*, 514 F.3d 468, 475 n.1 (5th Cir. 2008) (“The term ‘demonstrates’ [under identical language in another whistleblower provision] means to prove by a preponderance of the evidence.”). Once the complainant establishes that the protected activity was a contributing factor in the adverse action, the respondent can escape liability only by proving by clear and convincing evidence that it would have taken the same action even in the

absence of the prohibited rationale. The “clear and convincing evidence” standard is a higher burden of proof than a “preponderance of the evidence” standard.

Section 18C also incorporates the authorities in the FLSA sections 9 and 11, 29 U.S.C. 209 and 211, to issue subpoenas and conduct investigations. Such authorities under section 18C are delegated and assigned to the Assistant Secretary for Occupational Safety and Health. See Secretary’s Order 1–2012 (Jan. 18, 2012), 77 FR 3912 (Jan. 25, 2012).

Section 1984.105 Issuance of Findings and Preliminary Orders

This section provides that, on the basis of information obtained in the investigation, the Assistant Secretary will issue, within 60 days of the filing of a complaint, written findings regarding whether or not there is reasonable cause to believe that the complaint has merit. If the findings are that there is reasonable cause to believe that the complaint has merit, the Assistant Secretary will order appropriate relief, including preliminary reinstatement, affirmative action to abate the violation, back pay with interest, and compensatory damages. The findings and, where appropriate, preliminary order, advise the parties of their right to file objections to the findings of the Assistant Secretary and to request a hearing. The findings and, where appropriate, preliminary order, also advise the respondent of the right to request an award of attorney’s fees not exceeding \$1,000 from the ALJ, regardless of whether the respondent has filed objections, if the respondent alleges that the complaint was frivolous or brought in bad faith. If no objections are filed within 30 days of receipt of the findings, the findings and any preliminary order of the Assistant Secretary become the final decision and order of the Secretary. If objections are timely filed, any order of preliminary reinstatement will take effect, but the remaining provisions of the order will not take effect until administrative proceedings are completed.

In ordering interest on back pay under section 18C, the Secretary has determined that interest due will be computed by compounding daily the Internal Revenue Service interest rate for the underpayment of taxes, which under 26 U.S.C. 6621 is generally the Federal short-term rate plus three percentage points. The Secretary believes that daily compounding of interest achieves the make-whole purpose of a back pay award. Daily

compounding of interest has become the norm in private lending and recently was found to be the most appropriate method of calculating interest on back pay by the National Labor Relations Board. See *Jackson Hosp. Corp. v. United Steel, Paper & Forestry, Rubber, Mfg., Energy, Allied Indus. & Serv. Workers Int’l Union*, 356 NLRB No. 8, 2010 WL 4318371, at *3–4 (NLRB Oct. 22, 2010). Additionally, interest on tax underpayments under the Internal Revenue Code, 26 U.S.C. 6621, is compounded daily pursuant to 26 U.S.C. 6622(a).

In appropriate circumstances, in lieu of preliminary reinstatement, OSHA may order that the complainant receive the same pay and benefits that he or she received prior to his termination, but not actually return to work. Such “economic reinstatement” is akin to an order for front pay and frequently is employed in cases arising under section 105(c) of the Federal Mine Safety and Health Act of 1977, 30 U.S.C. 815(c), which protects miners from retaliation. See, e.g., *Sec’y of Labor ex rel. York v. BR&D Enters., Inc.*, 23 FMSHRC 697, 2001 WL 1806020, at *1 (ALJ June 26, 2001). Front pay has been recognized as a possible remedy in cases under the whistleblower statutes enforced by OSHA in circumstances where reinstatement would not be appropriate. See, e.g., *Moder v. Vill. of Jackson*, ARB Nos. 01–095, 02–039, 2003 WL 21499864, at *10 (ARB June 30, 2003) (under environmental whistleblower statutes, “front pay may be an appropriate substitute when the parties prove the impossibility of a productive and amicable working relationship, or the company no longer has a position for which the complainant is qualified”); *Hobby v. Georgia Power Co.*, ARB No. 98–166, ALJ No. 1990–ERA–30 (ARB Feb. 9, 2001), *aff’d sub nom. Hobby v. U.S. Dep’t of Labor*, No. 01–10916 (11th Cir. Sept. 30, 2002) (unpublished) (noting circumstances where front pay may be available in lieu of reinstatement but ordering reinstatement); *Doyle v. Hydro Nuclear Servs.*, ARB Nos. 99–041, 99–042, 00–012, 1996 WL 518592, at *6 (ARB Sept. 6, 1996) (under ERA, front pay appropriate where employer had eliminated the employee’s position); *Michaud v. BSP Transport, Inc.*, ARB Nos. 97–113, 1997 WL 626849, at *4 (ARB Oct. 9, 1997) (under the Surface Transportation Assistance Act, 49 U.S.C. 31105, front pay appropriate where employee was unable to work due to major depression resulting from the retaliation); *Brown v. Lockheed Martin Corp.*, ALJ No. 2008–SOX–49,

2010 WL 2054426, at *55–56 (ALJ Jan. 15, 2010) (noting that while reinstatement is the “presumptive remedy” under Sarbanes-Oxley, front pay may be awarded as a substitute when reinstatement is inappropriate). Congress intended that employees be preliminarily reinstated to their positions if OSHA finds reasonable cause to believe that they were discharged in violation of section 18C of the FLSA. When a violation is found, the norm is for OSHA to order immediate preliminary reinstatement. Neither an employer nor an employee has a statutory right to choose economic reinstatement. Rather, economic reinstatement is designed to accommodate situations in which evidence establishes to OSHA’s satisfaction that reinstatement is inadvisable for some reason, notwithstanding the employer’s retaliatory discharge of the employee. In such situations, actual reinstatement might be delayed until after the administrative adjudication is completed as long as the employee continues to receive his or her pay and benefits and is not otherwise disadvantaged by a delay in reinstatement. There is no statutory basis for allowing the employer to recover the costs of economically reinstating an employee should the employer ultimately prevail in the whistleblower adjudication.

Subpart B—Litigation

Section 1984.106 Objections to the Findings and the Preliminary Order and Requests for a Hearing

To be effective, objections to the findings of the Assistant Secretary must be in writing and must be filed with the Chief Administrative Law Judge, U.S. Department of Labor, within 30 days of receipt of the findings. The date of the postmark, facsimile transmittal, or electronic communication transmittal is considered the date of the filing; if the objection is filed in person, by hand-delivery or other means, the objection is filed upon receipt. The filing of objections also is considered a request for a hearing before an ALJ. Although the parties are directed to serve a copy of their objections on the other parties of record, as well as the OSHA official who issued the findings and order, the Assistant Secretary, and the U.S. Department of Labor’s Associate Solicitor for Fair Labor Standards, the failure to serve copies of the objections on the other parties of record does not affect the ALJ’s jurisdiction to hear and decide the merits of the case. See *Shirani v. Calvert Cliffs Nuclear Power*

Plant, Inc., ARB No. 04–101, 2005 WL 2865915, at *7 (ARB Oct. 31, 2005).

The timely filing of objections stays all provisions of the preliminary order, except for the portion requiring reinstatement. A respondent may file a motion to stay OSHA’s preliminary order of reinstatement with the Office of Administrative Law Judges. However, such a motion will be granted only based on exceptional circumstances. The Secretary believes that a stay of the Assistant Secretary’s preliminary order of reinstatement under section 18C of the FLSA would be appropriate only where the respondent can establish the necessary criteria for equitable injunctive relief, *i.e.*, irreparable injury, likelihood of success on the merits, a balancing of possible harms to the parties, and the public interest favors a stay. If no timely objection to OSHA’s findings and/or preliminary order is filed, then OSHA’s findings and/or preliminary order become the final decision of the Secretary not subject to judicial review.

Section 1984.107 Hearings

This section adopts the rules of practice and procedure for administrative hearings before the Office of Administrative Law Judges at 29 CFR part 18 subpart A. It specifically provides for hearings to be consolidated if both the complainant and respondent object to the findings and/or order of the Assistant Secretary. This section provides that the hearing is to commence expeditiously, except upon a showing of good cause or unless otherwise agreed to by the parties. Hearings will be conducted *de novo* on the record. As noted in this section, formal rules of evidence will not apply, but rules or principles designed to assure production of the most probative evidence will be applied. The ALJ may exclude evidence that is immaterial, irrelevant, or unduly repetitious.

Section 1984.108 Role of Federal Agencies

The Assistant Secretary, at his or her discretion, may participate as a party or *amicus curiae* at any time in the administrative proceedings under section 18C of the FLSA. For example, the Assistant Secretary may exercise his or her discretion to prosecute the case in the administrative proceeding before an ALJ; petition for review of a decision of an ALJ, including a decision based on a settlement agreement between the complainant and the respondent, regardless of whether the Assistant Secretary participated before the ALJ; or participate as *amicus curiae* before the ALJ or in the ARB proceeding. Although

OSHA anticipates that ordinarily the Assistant Secretary will not participate, the Assistant Secretary may choose to do so in appropriate cases, such as cases involving important or novel legal issues, large numbers of employees, alleged violations that appear egregious, or where the interests of justice might require participation by the Assistant Secretary. The Internal Revenue Service of the United States Department of the Treasury, the United States Department of Health and Human Services, and the Employee Benefits Security Administration of the United States Department of Labor, if interested in a proceeding, also may participate as *amicus curiae* at any time in the proceedings.

Section 1984.109 Decision and Orders of the Administrative Law Judge

This section sets forth the requirements for the content of the decision and order of the ALJ, and includes the standard for finding a violation under section 18C. Paragraph (c) of this section further provides that the Assistant Secretary’s determination to dismiss the complaint without an investigation or without a complete investigation under section 1984.104 is not subject to review. Thus, section 1984.109(c) clarifies that the Assistant Secretary’s determinations on whether to proceed with an investigation under section 18C and whether to make particular investigative findings are discretionary decisions not subject to review by the ALJ. The ALJ hears cases *de novo* and, therefore, as a general matter, may not remand cases to the Assistant Secretary to conduct an investigation or make further factual findings. A full discussion of the burdens of proof used by the Department of Labor to resolve whistleblower cases under this part is described above in the discussion of section 1984.104. Paragraph (d) notes the remedies that the ALJ may order under section 18C and, as discussed under section 1984.105 above, provides that interest on back pay will be calculated using the interest rate applicable to underpayment of taxes under 26 U.S.C. 6621 and will be compounded daily. Paragraph (e) requires that the ALJ’s decision be served on all parties to the proceeding, the Assistant Secretary, and the U.S. Department of Labor’s Associate Solicitor for Fair Labor Standards. Paragraph (e) also provides that any ALJ decision requiring reinstatement or lifting an order of reinstatement by the Assistant Secretary will be effective immediately upon receipt of the decision by the respondent. All other

portions of the ALJ's order will be effective 14 days after the date of the decision unless a timely petition for review has been filed with the ARB. If no timely petition for review is filed with the ARB, the decision of the ALJ becomes the final decision of the Secretary and is not subject to judicial review.

Section 1984.110 Decision and Orders of the Administrative Review Board

Upon the issuance of the ALJ's decision, the parties have 14 days within which to petition the ARB for review of that decision. The date of the postmark, facsimile transmittal, or electronic communication transmittal is considered the date of filing of the petition; if the petition is filed in person, by hand delivery or other means, the petition is considered filed upon receipt.

The appeal provisions in this part provide that an appeal to the ARB is not a matter of right but is accepted at the discretion of the ARB. The parties should identify in their petitions for review the legal conclusions or orders to which they object, or the objections may be deemed waived. The ARB has 30 days to decide whether to grant the petition for review. If the ARB does not grant the petition, the decision of the ALJ becomes the final decision of the Secretary. If a timely petition for review is filed with the ARB, any relief ordered by the ALJ, except for that portion ordering reinstatement, is inoperative while the matter is pending before the ARB. When the ARB accepts a petition for review, the ALJ's factual determinations will be reviewed under the substantial evidence standard.

This section also provides that, based on exceptional circumstances, the ARB may grant a motion to stay an ALJ's preliminary order of reinstatement under section 18C, which otherwise would be effective, while review is conducted by the ARB. The Secretary believes that a stay of an ALJ's preliminary order of reinstatement under section 18C would be appropriate only where the respondent can establish the necessary criteria for equitable injunctive relief, *i.e.*, irreparable injury, likelihood of success on the merits, a balancing of possible harms to the parties, and the public interest favors a stay.

If the ARB concludes that the respondent has violated the law, it will issue a final order providing relief to the complainant. The final order will require, where appropriate: Affirmative action to abate the violation; reinstatement of the complainant to his or her former position, together with the

compensation (including back pay and interest), terms, conditions, and privileges of the complainant's employment; and payment of compensatory damages, including, at the request of the complainant, the aggregate amount of all costs and expenses (including attorney's and expert witness fees) reasonably incurred. Interest on back pay will be calculated using the interest rate applicable to underpayment of taxes under 26 U.S.C. 6621 and will be compounded daily. If the ARB determines that the respondent has not violated the law, an order will be issued denying the complaint. If, upon the request of the respondent, the ARB determines that a complaint was frivolous or was brought in bad faith, the ARB may award to the respondent a reasonable attorney's fee, not exceeding \$1,000.

Subpart C—Miscellaneous Provisions.

Section 1984.111 Withdrawal of Complaints, Findings, Objections, and Petitions for Review; Settlement

This section provides the procedures and time periods for withdrawal of complaints, the withdrawal of findings and/or preliminary orders by the Assistant Secretary, and the withdrawal of objections to findings and/or orders. It permits complainants to withdraw their complaints orally and provides that, in such circumstances, OSHA will confirm a complainant's desire to withdraw in writing. It also provides for approval of settlements at the investigative and adjudicative stages of the case.

Section 1984.112 Judicial Review

This section describes the statutory provisions of CPSIA, incorporated into section 18C of the FLSA, for judicial review of decisions of the Secretary and requires, in cases where judicial review is sought, the ARB to submit the record of proceedings to the appropriate court pursuant to the rules of such court.

Section 1984.113 Judicial Enforcement

This section describes the Secretary's authority under section 18C to obtain judicial enforcement of orders and the terms of settlement agreements. Section 18C incorporates the procedures, notifications, burdens of proof, remedies, and statutes of limitations set forth in CPSIA, 15 U.S.C. 2087(b), which expressly authorizes district courts to enforce orders, including preliminary orders of reinstatement, issued by the Secretary. See 15 U.S.C. 2087(b)(6) ("Whenever any person has failed to comply with an order issued under paragraph (3), the Secretary may

file a civil action in the United States district court for the district in which the violation was found to occur, or in the United States district court for the District of Columbia, to enforce such order."'). Specifically, reinstatement orders issued at the close of OSHA's investigation are immediately enforceable in district court pursuant to 15 U.S.C. 2087(b)(6) and (7). Section 18C of the FLSA provides, through CPSIA, that the Secretary shall order the person who has committed a violation to reinstate the complainant to his or her former position. See 15 U.S.C. 2087(b)(3)(B)(ii). Section 18C of the FLSA also provides, through CPSIA, that the Secretary shall accompany any reasonable cause finding that a violation occurred with a preliminary order containing the relief prescribed by subsection (b)(3)(B) of CPSIA, which includes reinstatement where appropriate, and that any preliminary order of reinstatement shall not be stayed upon the filing of objections. See 15 U.S.C. 2087(b)(2)(A) ("The filing of such objections shall not operate to stay any reinstatement remedy contained in the preliminary order."'). Thus, under section 18C of the FLSA enforceable orders include preliminary orders that contain the relief of reinstatement prescribed by 15 U.S.C. 2087(b)(3)(B). This statutory interpretation is consistent with the Secretary's interpretation of similar language in the Wendell H. Ford Aviation Investment and Reform Act for the 21st Century and Sarbanes-Oxley. See Brief for the Intervenor/Plaintiff-Appellee Secretary of Labor, *Solis v. Tenn. Commerce Bancorp, Inc.*, No. 10–5602 (6th Cir. 2010); *Solis v. Tenn. Commerce Bancorp, Inc.*, 713 F. Supp. 2d 701 (M.D. Tenn. 2010); *but see Bechtel v. Competitive Techs., Inc.*, 448 F.3d 469 (2d Cir. 2006); *Welch v. Cardinal Bankshares Corp.*, 454 F. Supp. 2d 552 (W.D. Va. 2006) (*decision vacated, appeal dismissed*, No. 06–2295 (4th Cir. Feb. 20, 2008)). Also through application of CPSIA, section 18C of the FLSA permits the person on whose behalf the order was issued to obtain judicial enforcement of the order. See 15 U.S.C. 2087(b)(7).

Section 1984.114 District Court Jurisdiction of Retaliation Complaints

This section sets forth provisions that allow a complainant to bring an original *de novo* action in district court, alleging the same allegations contained in the complaint filed with OSHA, under certain circumstances. By incorporating the procedures, notifications, burdens of proof, remedies, and statutes of limitations set forth in CPSIA, 15 U.S.C.

2087(b), section 18C permits a complainant to file an action for de novo review in the appropriate district court if there has been no final decision of the Secretary within 210 days of the filing of the complaint, or within 90 days after receiving a written determination. "Written determination" refers to the Assistant Secretary's written findings issued at the close of OSHA's investigation under section 1984.105(a). 15 U.S.C. 2087(b)(4). The Secretary's final decision is generally the decision of the ARB issued under section 1984.110. In other words, a complainant may file an action for de novo review in the appropriate district court in either of the following two circumstances: (1) A complainant may file a de novo action in district court within 90 days of receiving the Assistant Secretary's written findings issued under section 1984.105(a), or (2) a complainant may file a de novo action in district court if more than 210 days have passed since the filing of the complaint and the Secretary has not issued a final decision. The plain language of 15 U.S.C. 2087(b)(4), by distinguishing between actions that can be brought if the Secretary has not issued a "final decision" within 210 days and actions that can be brought within 90 days after a "written determination," supports allowing de novo actions in district court under either of the circumstances described above. However, it is the Secretary's position that complainants may not initiate an action in federal court after the Secretary issues a final decision, even if the date of the final decision is more than 210 days after the filing of the complaint or within 90 days of the complainant's receipt of the Assistant Secretary's written findings. The purpose of the "kick-out" provision is to aid the complainant in receiving a prompt decision. That goal is not implicated in a situation where the complainant already has received a final decision from the Secretary. In addition, permitting the complainant to file a new case in district court in such circumstances could conflict with the parties' rights to seek judicial review of the Secretary's final decision in the court of appeals. See 15 U.S.C. 2087(b)(5)(B) (providing that an order with respect to which review could have been obtained in [the court of appeals] shall not be subject to judicial review in any criminal or other civil proceeding).

Under section 18C of the FLSA, the Assistant Secretary's written findings become the final order of the Secretary, not subject to judicial review, if no

objection is filed within 30 days. See 15 U.S.C. 2087(b)(2). Thus, a complainant may need to file timely objections to the Assistant Secretary's findings in order to preserve the right to file an action in district court.

This section also requires that, within seven days after filing a complaint in district court, a complainant must provide a file-stamped copy of the complaint to the Assistant Secretary, the ALJ, or the ARB, depending on where the proceeding is pending. A copy of the complaint also must be provided to the OSHA official who issued the findings and/or preliminary order, the Assistant Secretary, and the U.S. Department of Labor's Associate Solicitor for Fair Labor Standards. This provision is necessary to notify the Agency that the complainant has opted to file a complaint in district court. This provision is not a substitute for the requirements for service of process of the district court complaint contained in the Federal Rules of Civil Procedure and the local rules of the district court where the complaint is filed. The section also incorporates the statutory provisions which allow for a jury trial at the request of either party in a district court action, and which specify the remedies and burdens of proof in a district court action.

Section 1984.115 Special Circumstances; Waiver of Rules

This section provides that in circumstances not contemplated by these rules or for good cause the ALJ or the ARB may, upon application and notice to the parties, waive any rule as justice or the administration of section 18C of the FLSA requires.

IV. Paperwork Reduction Act

This rule contains a reporting provision (filing a retaliation complaint, section 1984.103) which was previously reviewed as a statutory requirement of section 18C of the FLSA, 29 U.S.C. 218C, and approved for use by the Office of Management and Budget ("OMB"), and was assigned OMB control number 1218-0236 under the provisions of the Paperwork Reduction Act of 1995, Public Law 104-13, 109 Stat. 163 (1995). A non-material change has been submitted to OMB to include the regulatory citation.

V. Administrative Procedure Act

The notice and comment rulemaking procedures of section 553 of the Administrative Procedure Act (APA) do not apply "to interpretative rules, general statements of policy, or rules of agency organization, procedure, or

practice." 5 U.S.C. 553(b)(A). This is a rule of agency procedure, practice and interpretation within the meaning of that section. Therefore, publication in the **Federal Register** of a notice of proposed rulemaking and request for comments are not required for these regulations, which provide the procedures for the handling of retaliation complaints. Although this is a procedural rule not subject to the notice and comment procedures of the APA, the Agency is providing persons interested in this interim final rule 60 days to submit comments. A final rule will be published after the Agency receives and reviews the public's comments.

Furthermore, because this rule is procedural and interpretative rather than substantive, the normal requirement of 5 U.S.C. 553(d) that a rule be effective 30 days after publication in the **Federal Register** is inapplicable. The Assistant Secretary also finds good cause to provide an immediate effective date for this interim final rule. It is in the public interest that the rule be effective immediately so that parties may know what procedures are applicable to pending cases.

VI. Executive Orders 12866 and 13563; Unfunded Mandates Reform Act of 1995; Executive Order 13132

The Office of Management and Budget has concluded that this rule is a "significant regulatory action" within the meaning of section 3(f)(4) of Executive Order 12866. Executive Order 12866, reaffirmed by Executive Order 13563, requires a full economic impact analysis only for "economically significant" rules, which are defined in section 3(f)(1) of Executive Order 12866 as rules that may "[h]ave an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities." Because the rule is procedural and interpretative in nature, it is expected to have a negligible economic impact. Therefore, no economic impact analysis has been prepared. For the same reason, the rule does not require a section 202 statement under the Unfunded Mandates Reform Act of 1995. 2 U.S.C. 1531 *et seq.* Finally, this rule does not have "federalism implications." The rule does not have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government" and

therefore is not subject to Executive Order 13132 (Federalism).

VII. Regulatory Flexibility Analysis

The Department has determined that the regulation will not have a significant economic impact on a substantial number of small entities. The regulation simply implements procedures necessitated by enactment of section 18C of the FLSA. Furthermore, no certification to this effect is required and no regulatory flexibility analysis is required because no proposed rule has been issued.

List of Subjects in 29 CFR Part 1984

Administrative practice and procedure, Employment, Health care, Investigations, Reporting and recordkeeping requirements, Whistleblower.

Authority and Signature

This document was prepared under the direction and control of David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health.

Signed at Washington, DC, on February 13, 2013.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

Accordingly, for the reasons set out in the preamble, 29 CFR part 1984 is added to read as follows:

PART 1984—PROCEDURES FOR THE HANDLING OF RETALIATION COMPLAINTS UNDER SECTION 1558 OF THE AFFORDABLE CARE ACT

Subpart A—Complaints, Investigations, Findings and Preliminary Orders

Sec.

- 1984.100 Purpose and scope.
- 1984.101 Definitions.
- 1984.102 Obligations and prohibited acts.
- 1984.103 Filing of retaliation complaint.
- 1984.104 Investigation.
- 1984.105 Issuance of findings and preliminary orders.

Subpart B—Litigation

- 1984.106 Objections to the findings and the preliminary order and requests for a hearing.
- 1984.107 Hearings.
- 1984.108 Role of Federal agencies.
- 1984.109 Decision and orders of the administrative law judge.
- 1984.110 Decision and orders of the Administrative Review Board.

Subpart C—Miscellaneous Provisions

- 1984.111 Withdrawal of complaints, findings, objections, and petitions for review; settlement.
- 1984.112 Judicial review.
- 1984.113 Judicial enforcement.

1984.114 District court jurisdiction of retaliation complaints.

1984.115 Special circumstances; waiver of rules.

Authority: 29 U.S.C. 218C; Secretary's Order 1–2012 (Jan. 18, 2012), 77 FR 3912 (Jan. 25, 2012); Secretary's Order 1–2010 (Jan. 15, 2010), 75 FR 3924 (Jan. 25, 2010).

Subpart A—Complaints, Investigations, Findings and Preliminary Orders

§ 1984.100 Purpose and scope.

(a) This part implements procedures under section 1558 of the Patient Protection and Affordable Care Act, Public Law 111–148, 124 Stat. 119, which was signed into law on March 23, 2010 and was amended by the Health Care and Education Reconciliation Act of 2010, Public Law 111–152, 124 Stat. 1029, signed into law on March 30, 2010. The terms “Affordable Care Act” or “the Act” are used in this part to refer to the final, amended version of the law. Section 1558 of the Act amended the Fair Labor Standards Act, 29 U.S.C. 201 *et seq.* (FLSA) by adding new section 18C. 29 U.S.C. 218C. Section 18C of the FLSA provides protection for an employee from retaliation because the employee has received a credit under section 36B of the Internal Revenue Code of 1986, 26 U.S.C. 36B, or a cost-sharing reduction (referred to as a “subsidy” in section 18C) under the Affordable Care Act section 1402, 42 U.S.C. 18071, or because the employee has engaged in protected activity pertaining to title I of the Affordable Care Act or any amendment made by title I of the Affordable Care Act.

(b) This part establishes procedures under section 18C of the FLSA for the expeditious handling of retaliation complaints filed by employees, or by persons acting on their behalf. These rules, together with those codified at 29 CFR part 18, set forth the procedures under section 18C of the FLSA for submission of complaints, investigations, issuance of findings and preliminary orders, objections to findings and orders, litigation before administrative law judges (ALJs), post-hearing administrative review, and withdrawals and settlements.

§ 1984.101 Definitions.

As used in this part:

(a) *Affordable Care Act* or “the Act” means The Patient Protection and Affordable Care Act, Public Law 111–148, 124 Stat. 119 (Mar. 23, 2010), as amended by the Health Care and Education Reconciliation Act of 2010, Public Law 111–152.

(b) *Assistant Secretary* means the Assistant Secretary of Labor for

Occupational Safety and Health or the person or persons to whom he or she delegates authority under section 18C of the FLSA.

(c) *Business days* means days other than Saturdays, Sundays, and Federal holidays.

(d) *Complainant* means the employee who filed an FLSA section 18C complaint or on whose behalf a complaint was filed.

(e)(1) *Employee* means any individual employed by an employer. In the case of an individual employed by a public agency, the term employee means any individual employed by the Government of the United States: As a civilian in the military departments (as defined in 5 U.S.C. 102), in any executive agency (as defined in 5 U.S.C. 105), in any unit of the judicial branch of the Government which has positions in the competitive service, in a nonappropriated fund instrumentality under the jurisdiction of the Armed Forces, in the Library of Congress, or in the Government Printing Office. The term employee also means any individual employed by the United States Postal Service or the Postal Regulatory Commission; and any individual employed by a State, political subdivision of a State, or an interstate governmental agency, other than an individual who is not subject to the civil service laws of the State, political subdivision, or agency which employs him; and who holds a public elective office of that State, political subdivision, or agency, is selected by the holder of such an office to be a member of his personal staff, is appointed by such an officeholder to serve on a policymaking level, is an immediate adviser to such an officeholder with respect to the constitutional or legal powers of his office, or is an employee in the legislative branch or legislative body of that State, political subdivision, or agency and is not employed by the legislative library of such State, political subdivision, or agency.

(2) The term *employee* does not include:

(i) Any individual who volunteers to perform services for a public agency which is a State, a political subdivision of a State, or an interstate governmental agency, if the individual receives no compensation or is paid expenses, reasonable benefits, or a nominal fee to perform the services for which the individual volunteered—and such services are not the same type of services which the individual is employed to perform for such public agency;

(ii) Any employee of a public agency which is a State, political subdivision of a State, or an interstate governmental agency that volunteers to perform services for any other State, political subdivision, or interstate governmental agency, including a State, political subdivision or agency with which the employing State, political subdivision, or agency has a mutual aid agreement; or

(iii) Any individual who volunteers their services solely for humanitarian purposes to private non-profit food banks and who receive groceries from the food banks.

(3) The term employee includes former employees and applicants for employment.

(f) *Employer* includes any person acting directly or indirectly in the interest of an employer in relation to an employee and includes a public agency, but does not include any labor organization (other than when acting as an employer) or anyone acting in the capacity of officer or agent of such labor organization.

(g) *OSHA* means the Occupational Safety and Health Administration of the United States Department of Labor.

(h) *Person* means an individual, partnership, association, corporation, business trust, legal representative, or any organized group of persons.

(i) *Respondent* means the employer named in the complaint who is alleged to have violated the Act.

(j) *Secretary* means the Secretary of Labor or person to whom authority under the Affordable Care Act has been delegated.

(k) Any future statutory amendments that affect the definition of a term or terms listed in this section will apply in lieu of the definition stated herein.

§ 1984.102 Obligations and prohibited acts.

(a) No employer may discharge or otherwise retaliate against, including, but not limited to, intimidating, threatening, restraining, coercing, blacklisting or disciplining, any employee with respect to the employee's compensation, terms, conditions, or privileges of employment because the employee (or an individual acting at the request of the employee), has engaged in any of the activities specified in paragraphs (b)(1) through (5) of this section.

(b) An employee is protected against retaliation because the employee (or an individual acting at the request of the employee) has:

(1) Received a credit under section 36B of the Internal Revenue Code of 1986, 26 U.S.C. 36B, or a subsidy under

section 1402 of the Affordable Care Act, 42 U.S.C. 18071;

(2) Provided, caused to be provided, or is about to provide or cause to be provided to the employer, the Federal Government, or the attorney general of a State information relating to any violation of, or any act or omission the employee reasonably believes to be a violation of, any provision of title I of the Affordable Care Act (or an amendment made by title I of the Affordable Care Act);

(3) Testified or is about to testify in a proceeding concerning such violation;

(4) Assisted or participated, or is about to assist or participate, in such a proceeding; or

(5) Objected to, or refused to participate in, any activity, policy, practice, or assigned task that the employee (or other such person) reasonably believed to be in violation of any provision of title I of the Affordable Care Act (or amendment), or any order, rule, regulation, standard, or ban under title I of the Affordable Care Act (or amendment).

§ 1984.103 Filing of retaliation complaint.

(a) *Who may file.* An employee who believes that he or she has been retaliated against in violation of section 18C of the FLSA may file, or have filed by any person on the employee's behalf, a complaint alleging such retaliation.

(b) *Nature of filing.* No particular form of complaint is required. A complaint may be filed orally or in writing. Oral complaints will be reduced to writing by OSHA. If the complainant is unable to file the complaint in English, OSHA will accept the complaint in any language.

(c) *Place of filing.* The complaint should be filed with the OSHA office responsible for enforcement activities in the geographical area where the employee resides or was employed, but may be filed with any OSHA officer or employee. Addresses and telephone numbers for these officials are set forth in local directories and at the following Internet address: <http://www.osha.gov>.

(d) *Time for filing.* Within 180 days after an alleged violation of section 18C of the FLSA occurs, any employee who believes that he or she has been retaliated against in violation of that section may file, or have filed by any person on the employee's behalf, a complaint alleging such retaliation. The date of the postmark, facsimile transmittal, electronic communication transmittal, telephone call, hand-delivery, delivery to a third-party commercial carrier, or in-person filing at an OSHA office will be considered the date of filing. The time for filing a

complaint may be tolled for reasons warranted by applicable case law.

§ 1984.104 Investigation.

(a) Upon receipt of a complaint in the investigating office, the Assistant Secretary will notify the respondent of the filing of the complaint, of the allegations contained in the complaint, and of the substance of the evidence supporting the complaint. Such materials will be redacted, if necessary, in accordance with the Privacy Act of 1974, 5 U.S.C. 552a, and other applicable confidentiality laws. The Assistant Secretary will also notify the respondent of its rights under paragraphs (b) and (f) of this section and paragraph (e) of § 1984.110. The Assistant Secretary will provide an unredacted copy of these same materials to the complainant (or complainant's legal counsel if complainant is represented by counsel) and to the appropriate office of the Federal agency charged with the administration of the general provisions of the Affordable Care Act under which the complaint is filed: Either the Internal Revenue Service of the United States Department of the Treasury (IRS), the United States Department of Health and Human Services (HHS), or the Employee Benefits Security Administration of the United States Department of Labor (EBSA).

(b) Within 20 days of receipt of the notice of the filing of the complaint provided under paragraph (a) of this section, the respondent and the complainant each may submit to the Assistant Secretary a written statement and any affidavits or documents substantiating its position. Within the same 20 days, the respondent and the complainant each may request a meeting with the Assistant Secretary to present its position.

(c) Throughout the investigation, the Agency will provide to the complainant (or the complainant's legal counsel if complainant is represented by counsel) a copy of all of respondent's submissions to the Agency that are responsive to the complainant's whistleblower complaint. Before providing such materials to the complainant, the Agency will redact them, if necessary, in accordance with the Privacy Act of 1974, 5 U.S.C. 552a, and other applicable confidentiality laws. The Agency will also provide the complainant with an opportunity to respond to such submissions.

(d) Investigations will be conducted in a manner that protects the confidentiality of any person who provides information on a confidential

basis, other than the complainant, in accordance with part 70 of this title.

(e)(1) A complaint will be dismissed unless the complainant has made a prima facie showing that protected activity was a contributing factor in the adverse action alleged in the complaint.

(2) The complaint, supplemented as appropriate by interviews of the complainant, must allege the existence of facts and evidence to make a prima facie showing as follows:

(i) The employee engaged in a protected activity;

(ii) The respondent knew or suspected that the employee engaged in the protected activity;

(iii) The employee suffered an adverse action; and

(iv) The circumstances were sufficient to raise the inference that the protected activity was a contributing factor in the adverse action.

(3) For purposes of determining whether to investigate, the complainant will be considered to have met the required burden if the complaint on its face, supplemented as appropriate through interviews of the complainant, alleges the existence of facts and either direct or circumstantial evidence to meet the required showing, i.e., to give rise to an inference that the respondent knew or suspected that the employee engaged in protected activity and that the protected activity was a contributing factor in the adverse action. The burden may be satisfied, for example, if the complaint shows that the adverse action took place shortly after the protected activity, giving rise to the inference that it was a contributing factor in the adverse action. If the required showing has not been made, the complainant (or the complainant's legal counsel, if complainant is represented by counsel) will be so notified and the investigation will not commence.

(4) Notwithstanding a finding that a complainant has made a prima facie showing, as required by this section, an investigation of the complaint will not be conducted or will be discontinued if the respondent demonstrates by clear and convincing evidence that it would have taken the same adverse action in the absence of the complainant's protected activity.

(5) If the respondent fails to make a timely response or fails to satisfy the burden set forth in the prior paragraph, the Assistant Secretary will proceed with the investigation. The investigation will proceed whenever it is necessary or appropriate to confirm or verify the information provided by the respondent.

(f) Prior to the issuance of findings and a preliminary order as provided for

in § 1984.105, if the Assistant Secretary has reasonable cause, on the basis of information gathered under the procedures of this part, to believe that the respondent has violated section 18C of the FLSA and that preliminary reinstatement is warranted, the Assistant Secretary will again contact the respondent (or the respondent's legal counsel if respondent is represented by counsel) to give notice of the substance of the relevant evidence supporting the complainant's allegations as developed during the course of the investigation. This evidence includes any witness statements, which will be redacted to protect the identity of confidential informants where statements were given in confidence; if the statements cannot be redacted without revealing the identity of confidential informants, summaries of their contents will be provided. The complainant will also receive a copy of the materials that must be provided to the respondent under this paragraph. Before providing such materials to the complainant, the Agency will redact them, if necessary, in accordance with the Privacy Act of 1974, 5 U.S.C. 552a, and other applicable confidentiality laws. The respondent will be given the opportunity to submit a written response, to meet with the investigators, to present statements from witnesses in support of its position, and to present legal and factual arguments. The respondent must present this evidence within 10 business days of the Assistant Secretary's notification pursuant to this paragraph, or as soon thereafter as the Assistant Secretary and the respondent can agree, if the interests of justice so require.

§ 1984.105 Issuance of findings and preliminary orders.

(a) After considering all the relevant information collected during the investigation, the Assistant Secretary will issue, within 60 days of the filing of the complaint, written findings as to whether or not there is reasonable cause to believe that the respondent has retaliated against the complainant in violation of section 18C of the FLSA.

(1) If the Assistant Secretary concludes that there is reasonable cause to believe that a violation has occurred, the Assistant Secretary will accompany the findings with a preliminary order providing relief to the complainant. The preliminary order will require, where appropriate: Affirmative action to abate the violation; reinstatement of the complainant to his or her former position, together with the compensation (including back pay and

interest), terms, conditions and privileges of the complainant's employment; and payment of compensatory damages, including, at the request of the complainant, the aggregate amount of all costs and expenses (including attorney's and expert witness fees) reasonably incurred. Interest on back pay will be calculated using the interest rate applicable to underpayment of taxes under 26 U.S.C. 6621 and will be compounded daily.

(2) If the Assistant Secretary concludes that a violation has not occurred, the Assistant Secretary will notify the parties of that finding.

(b) The findings and, where appropriate, the preliminary order will be sent by certified mail, return receipt requested, to all parties of record (and each party's legal counsel if the party is represented by counsel). The findings and, where appropriate, the preliminary order will inform the parties of the right to object to the findings and/or order and to request a hearing, and of the right of the respondent to request an award of attorney's fees not exceeding \$1,000 from the ALJ, regardless of whether the respondent has filed objections, if respondent alleges that the complaint was frivolous or brought in bad faith. The findings and, where appropriate, the preliminary order also will give the address of the Chief Administrative Law Judge, U.S. Department of Labor. At the same time, the Assistant Secretary will file with the Chief Administrative Law Judge a copy of the original complaint and a copy of the findings and/or order.

(c) The findings and any preliminary order will be effective 30 days after receipt by the respondent (or the respondent's legal counsel if the respondent is represented by counsel), or on the compliance date set forth in the preliminary order, whichever is later, unless an objection and/or a request for hearing has been timely filed as provided at § 1984.106. However, the portion of any preliminary order requiring reinstatement will be effective immediately upon the respondent's receipt of the findings and the preliminary order, regardless of any objections to the findings and/or the order.

Subpart B—Litigation

§ 1984.106 Objections to the findings and the preliminary order and requests for a hearing.

(a) Any party who desires review, including judicial review, of the findings and/or preliminary order, or a respondent alleging that the complaint was frivolous or brought in bad faith

who seeks an award of attorney's fees under section 18C of the FLSA, must file any objections and/or a request for a hearing on the record within 30 days of receipt of the findings and preliminary order pursuant to § 1984.105. The objections, request for a hearing, and/or request for attorney's fees must be in writing and state whether the objections are to the findings, the preliminary order, and/or whether there should be an award of attorney's fees. The date of the postmark, facsimile transmittal, or electronic communication transmittal is considered the date of filing; if the objection is filed in person, by hand delivery or other means, the objection is filed upon receipt. Objections must be filed with the Chief Administrative Law Judge, U.S. Department of Labor, and copies of the objections must be mailed at the same time to the other parties of record, the OSHA official who issued the findings and order, the Assistant Secretary, and the Associate Solicitor, Division of Fair Labor Standards, U.S. Department of Labor.

(b) If a timely objection is filed, all provisions of the preliminary order will be stayed, except for the portion requiring preliminary reinstatement, which will not be automatically stayed. The portion of the preliminary order requiring reinstatement will be effective immediately upon the respondent's receipt of the findings and preliminary order, regardless of any objections to the order. The respondent may file a motion with the Office of Administrative Law Judges for a stay of the Assistant Secretary's preliminary order of reinstatement, which shall be granted only based on exceptional circumstances. If no timely objection is filed with respect to either the findings or the preliminary order, the findings and/or the preliminary order will become the final decision of the Secretary, not subject to judicial review.

§ 1984.107 Hearings.

(a) Except as provided in this part, proceedings will be conducted in accordance with the rules of practice and procedure for administrative hearings before the Office of Administrative Law Judges, codified at subpart A of part 18 of this title.

(b) Upon receipt of an objection and request for hearing, the Chief Administrative Law Judge will promptly assign the case to an ALJ who will notify the parties, by certified mail, of the day, time, and place of hearing. The hearing is to commence expeditiously, except upon a showing of good cause or unless otherwise agreed to by the parties. Hearings will be conducted de

novo on the record. ALJs have broad discretion to limit discovery in order to expedite the hearing.

(c) If both the complainant and the respondent object to the findings and/or order, the objections will be consolidated and a single hearing will be conducted.

(d) Formal rules of evidence will not apply, but rules or principles designed to assure production of the most probative evidence will be applied. The ALJ may exclude evidence that is immaterial, irrelevant, or unduly repetitious.

§ 1984.108 Role of Federal agencies.

(a)(1) The complainant and the respondent will be parties in every proceeding and must be served with copies of all documents in the case. At the Assistant Secretary's discretion, the Assistant Secretary may participate as a party or as *amicus curiae* at any time at any stage of the proceeding. This right to participate includes, but is not limited to, the right to petition for review of a decision of an ALJ, including a decision approving or rejecting a settlement agreement between the complainant and the respondent.

(2) Copies of documents must be sent to the Assistant Secretary, and to the Associate Solicitor, Division of Fair Labor Standards, U.S. Department of Labor, only upon request of the Assistant Secretary, or where the Assistant Secretary is participating in the proceeding, or where service on the Assistant Secretary and the Associate Solicitor is otherwise required by these rules.

(b) The IRS, HHS, and EBSA, if interested in a proceeding, may participate as *amicus curiae* at any time in the proceeding, at those agencies' discretion. At the request of the interested Federal agency, copies of all documents in a case must be sent to the Federal agency, whether or not the agency is participating in the proceeding.

§ 1984.109 Decision and orders of the administrative law judge.

(a) The decision of the ALJ will contain appropriate findings, conclusions, and an order pertaining to the remedies provided in paragraph (d) of this section, as appropriate. A determination that a violation has occurred may be made only if the complainant has demonstrated by a preponderance of the evidence that protected activity was a contributing factor in the adverse action alleged in the complaint.

(b) If the complainant has satisfied the burden set forth in the prior paragraph, relief may not be ordered if the respondent demonstrates by clear and convincing evidence that it would have taken the same adverse action in the absence of any protected activity.

(c) Neither the Assistant Secretary's determination to dismiss a complaint without completing an investigation pursuant to § 1984.104(e) nor the Assistant Secretary's determination to proceed with an investigation is subject to review by the ALJ, and a complaint may not be remanded for the completion of an investigation or for additional findings on the basis that a determination to dismiss was made in error. Rather, if there otherwise is jurisdiction, the ALJ will hear the case on the merits or dispose of the matter without a hearing if the facts and circumstances warrant.

(d)(1) If the ALJ concludes that the respondent has violated the law, the ALJ will issue an order that will require, where appropriate: Affirmative action to abate the violation; reinstatement of the complainant to his or her former position, together with the compensation (including back pay and interest), terms, conditions, and privileges of the complainant's employment; and payment of compensatory damages, including, at the request of the complainant, the aggregate amount of all costs and expenses (including attorney's and expert witness fees) reasonably incurred. Interest on back pay will be calculated using the interest rate applicable to underpayment of taxes under 26 U.S.C. 6621 and will be compounded daily.

(2) If the ALJ determines that the respondent has not violated the law, an order will be issued denying the complaint. If, upon the request of the respondent, the ALJ determines that a complaint was frivolous or was brought in bad faith, the ALJ may award to the respondent a reasonable attorney's fee, not exceeding \$1,000.

(e) The decision will be served upon all parties to the proceeding, the Assistant Secretary, and the Associate Solicitor, Division of Fair Labor Standards, U.S. Department of Labor. Any ALJ's decision requiring reinstatement or lifting an order of reinstatement by the Assistant Secretary will be effective immediately upon receipt of the decision by the respondent. All other portions of the ALJ's order will be effective 14 days after the date of the decision unless a timely petition for review has been filed with the Administrative Review Board (ARB), U.S. Department of Labor. The

decision of the ALJ will become the final order of the Secretary unless a petition for review is timely filed with the ARB and the ARB accepts the petition for review.

§ 1984.110 Decision and orders of the Administrative Review Board.

(a) Any party desiring to seek review, including judicial review, of a decision of the ALJ, or a respondent alleging that the complaint was frivolous or brought in bad faith who seeks an award of attorney's fees, must file a written petition for review with the ARB, which has been delegated the authority to act for the Secretary and issue final decisions under this part. The parties should identify in their petitions for review the legal conclusions or orders to which they object, or the objections may be deemed waived. A petition must be filed within 14 days of the date of the decision of the ALJ. The date of the postmark, facsimile transmittal, or electronic communication transmittal will be considered to be the date of filing; if the petition is filed in person, by hand delivery or other means, the petition is considered filed upon receipt. The petition must be served on all parties and on the Chief Administrative Law Judge at the time it is filed with the ARB. Copies of the petition for review must be served on the Assistant Secretary, and on the Associate Solicitor, Division of Fair Labor Standards, U.S. Department of Labor.

(b) If a timely petition for review is filed pursuant to paragraph (a) of this section, the decision of the ALJ will become the final order of the Secretary unless the ARB, within 30 days of the filing of the petition, issues an order notifying the parties that the case has been accepted for review. If a case is accepted for review, the decision of the ALJ will be inoperative unless and until the ARB issues an order adopting the decision, except that any order of reinstatement will be effective while review is conducted by the ARB, unless the ARB grants a motion by the respondent to stay that order based on exceptional circumstances. The ARB will specify the terms under which any briefs are to be filed. The ARB will review the factual determinations of the ALJ under the substantial evidence standard. If no timely petition for review is filed, or the ARB denies review, the decision of the ALJ will become the final order of the Secretary. If no timely petition for review is filed, the resulting final order is not subject to judicial review.

(c) The final decision of the ARB will be issued within 120 days of the

conclusion of the hearing, which will be deemed to be 14 days after the date of the decision of the ALJ, unless a motion for reconsideration has been filed with the ALJ in the interim. In such case, the conclusion of the hearing is the date the motion for reconsideration is ruled upon or 14 days after a new decision is issued. The ARB's final decision will be served upon all parties and the Chief Administrative Law Judge by mail. The final decision will also be served on the Assistant Secretary, and on the Associate Solicitor, Division of Fair Labor Standards, U.S. Department of Labor, even if the Assistant Secretary is not a party.

(d) If the ARB concludes that the respondent has violated the law, the ARB will issue a final order providing relief to the complainant. The final order will require, where appropriate: Affirmative action to abate the violation; reinstatement of the complainant to the complainant's former position, together with the compensation (including back pay and interest), terms, conditions, and privileges of the complainant's employment; and payment of compensatory damages, including, at the request of the complainant, the aggregate amount of all costs and expenses (including attorney's and expert witness fees) reasonably incurred. Interest on back pay will be calculated using the interest rate applicable to underpayment of taxes under 26 U.S.C. 6621 and will be compounded daily.

(e) If the ARB determines that the respondent has not violated the law, an order will be issued denying the complaint. If, upon the request of the respondent, the ARB determines that a complaint was frivolous or was brought in bad faith, the ARB may award to the respondent a reasonable attorney's fee, not exceeding \$1,000.

Subpart C—Miscellaneous Provisions

§ 1984.111 Withdrawal of complaints, findings, objections, and petitions for review; settlement.

(a) At any time prior to the filing of objections to the Assistant Secretary's findings and/or preliminary order, a complainant may withdraw his or her complaint by notifying the Assistant Secretary, orally or in writing, of his or her withdrawal. The Assistant Secretary then will confirm in writing the complainant's desire to withdraw and determine whether to approve the withdrawal. The Assistant Secretary will notify the parties (and each party's legal counsel if the party is represented by counsel) of the approval of any withdrawal. If the complaint is

withdrawn because of settlement, the settlement must be submitted for approval in accordance with paragraph (d) of this section. A complainant may not withdraw his or her complaint after the filing of objections to the Assistant Secretary's findings and/or preliminary order.

(b) The Assistant Secretary may withdraw the findings and/or preliminary order at any time before the expiration of the 30-day objection period described in § 1984.106, provided that no objection has been filed yet, and substitute new findings and/or a new preliminary order. The date of the receipt of the substituted findings or order will begin a new 30-day objection period.

(c) At any time before the Assistant Secretary's findings and/or order become final, a party may withdraw objections to the Assistant Secretary's findings and/or order by filing a written withdrawal with the ALJ. If the case is on review with the ARB, a party may withdraw a petition for review of an ALJ's decision at any time before that decision becomes final by filing a written withdrawal with the ARB. The ALJ or the ARB, as the case may be, will determine whether to approve the withdrawal of the objections or the petition for review. If the ALJ approves a request to withdraw objections to the Assistant Secretary's findings and/or order, and there are no other pending objections, the Assistant Secretary's findings and/or order will become the final order of the Secretary. If the ARB approves a request to withdraw a petition for review of an ALJ decision, and there are no other pending petitions for review of that decision, the ALJ's decision will become the final order of the Secretary. If objections or a petition for review are withdrawn because of settlement, the settlement must be submitted for approval in accordance with paragraph (d) of this section.

(d)(1) *Investigative settlements.* At any time after the filing of a complaint, and before the findings and/or order are objected to or become a final order by operation of law, the case may be settled if the Assistant Secretary, the complainant, and the respondent agree to a settlement. The Assistant Secretary's approval of a settlement reached by the respondent and the complainant demonstrates the Assistant Secretary's consent and achieves the consent of all three parties.

(2) *Adjudicatory settlements.* At any time after the filing of objections to the Assistant Secretary's findings and/or order, the case may be settled if the participating parties agree to a settlement and the settlement is

approved by the ALJ if the case is before the ALJ, or by the ARB if the ARB has accepted the case for review. A copy of the settlement will be filed with the ALJ or the ARB, as the case may be.

(e) Any settlement approved by the Assistant Secretary, the ALJ, or the ARB will constitute the final order of the Secretary and may be enforced in United States district court pursuant to § 1984.113.

§ 1984.112 Judicial review.

(a) Within 60 days after the issuance of a final order under §§ 1984.109 and 1984.110, any person adversely affected or aggrieved by the order may file a petition for review of the order in the United States Court of Appeals for the circuit in which the violation allegedly occurred or the circuit in which the complainant resided on the date of the violation.

(b) A final order is not subject to judicial review in any criminal or other civil proceeding.

(c) If a timely petition for review is filed, the record of a case, including the record of proceedings before the ALJ, will be transmitted by the ARB or the ALJ, as the case may be, to the appropriate court pursuant to the Federal Rules of Appellate Procedure and the local rules of such court.

§ 1984.113 Judicial enforcement.

Whenever any person has failed to comply with a preliminary order of reinstatement, or a final order, including one approving a settlement agreement, issued under section 18C of the FLSA, the Secretary or a person on whose behalf the order was issued may file a civil action seeking enforcement of the order in the United States district court for the district in which the violation was found to have occurred. The Secretary also may file a civil action seeking enforcement of the order in the United States district court for the District of Columbia.

§ 1984.114 District court jurisdiction of retaliation complaints.

(a) The complainant may bring an action at law or equity for de novo review in the appropriate district court of the United States, which will have jurisdiction over such an action without regard to the amount in controversy, either:

(1) Within 90 days after receiving a written determination under § 1984.105(a) provided that there has been no final decision of the Secretary; or

(2) If there has been no final decision of the Secretary within 210 days of the filing of the complaint.

(3) At the request of either party, the action shall be tried by the court with a jury.

(b) A proceeding under paragraph (a) of this section shall be governed by the same legal burdens of proof specified in section 1984.109. The court shall have jurisdiction to grant all relief necessary to make the employee whole, including injunctive relief and compensatory damages, including:

(1) Reinstatement with the same seniority status that the employee would have had, but for the discharge or discrimination;

(2) The amount of back pay, with interest; and

(3) Compensation for any special damages sustained as a result of the discharge or discrimination, including litigation costs, expert witness fees, and reasonable attorney fees.

(c) Within seven days after filing a complaint in federal court, a complainant must file with the Assistant Secretary, the ALJ, or the ARB, depending on where the proceeding is pending, a copy of the file-stamped complaint. A copy of the complaint also must be served on the OSHA official who issued the findings and/or preliminary order, the Assistant Secretary, and the Associate Solicitor, Division of Fair Labor Standards, U.S. Department of Labor.

§ 1984.115 Special circumstances; waiver of rules.

In special circumstances not contemplated by the provisions of these rules, or for good cause shown, the ALJ or the ARB on review may, upon application, after three- days notice to all parties, waive any rule or issue such orders that justice or the administration of section 18C of the FLSA requires.

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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[DOD-2009-HA-0038]

RIN 0720-AB50

TRICARE: Smoking Cessation Program

AGENCY: Office of the Secretary, Department of Defense.

ACTION: Final rule.

SUMMARY: This final rule implements Section 713 of the Duncan Hunter National Defense Authorization Act

(NDAA) for Fiscal Year 2009. Section 713 states the Secretary shall establish a smoking cessation program under the TRICARE program. The smoking cessation program under TRICARE shall, at a minimum, include the following: The availability, at no cost to the beneficiary, of pharmaceuticals used for smoking cessation, with the limitation on the availability of such pharmaceuticals to the mail-order pharmacy program under the TRICARE program; smoking cessation counseling; access to a toll-free quit line 24 hours a day, 7 days a week; access to print and Internet web-based tobacco cessation material. Per the statute, Medicare-eligible beneficiaries are excluded from the TRICARE smoking cessation program.

DATES: *Effective Date:* This final rule is effective March 29, 2013.

FOR FURTHER INFORMATION CONTACT: Ms. Ginnean Quisenberry, Population Health, Medical Management, and Patient Centered Medical Home Division, Office of the Chief Medical Officer, TRICARE Management Activity, telephone (703) 681-6717.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose of the Final Rule

The purpose of this final rule is to implement the provisions of the Duncan Hunter NDAA for FY 2009 (Pub. L. 110-417) that establishes a smoking cessation program under the TRICARE program. Establishment of the TRICARE smoking cessation program attempts to reduce the number of TRICARE beneficiaries who are nicotine dependent, thereby improving the health of the TRICARE beneficiary population and reducing Department of Defense costs, in particular those related to the adverse effects of smoking. The legal authority for the Final Rule is Section 713 of the Duncan Hunter NDAA FY09 (Pub. L. 110-417).

B. Summary of the Major Provisions of the Final Rule

Section 713 of the Duncan Hunter NDAA for FY 2009 stipulates the following key features for inclusion in the TRICARE smoking cessation program:

1. *The availability, at no cost to the beneficiary, of pharmaceuticals used for smoking cessation, with a limitation on the availability of such pharmaceuticals to the national mail-order pharmacy program under the TRICARE program if appropriate.*

Smoking cessation medications will be covered by TRICARE through the Mail Order Pharmacy program, as well

as at Military Treatment Facilities at no cost, including no co-pay. The type of smoking cessation medications available, which may include over-the-counter medications, will be determined by the TRICARE Pharmacy and Therapeutics Committee based on clinical and cost effectiveness considerations.

2. Counseling.

In person smoking cessation counseling from a TRICARE authorized provider as detailed in the TRICARE Policy Manual for is a covered TRICARE benefit for those beneficiaries that are not eligible for Medicare.

3. Access to a toll-free quit line that is available 24 hours a day, 7 days a week.

Beneficiaries will have access to a toll-free smoking cessation quit line that will be available 24 hours a day, 7 days a week.

4. Access to print and Internet web-based tobacco cessation material.

TRICARE will provide access to both print and web-based tobacco cessation materials for any beneficiary who is interested in quitting using tobacco products.

5. Chain of command involvement by officers in the chain of command of participants in the program who are on active duty.

All of those in the chain of command are expected to provide their support to the program and to any member who wishes to quit smoking. There is no intent for any reporting requirements to the chain of command related to any member's participation.

C. Costs and Benefits of this Regulatory Action

The cost for these changes is estimated to be 24 million dollars for a one year period. The benefits are that TRICARE will be in compliance with its statutory provisions and health of beneficiaries who quit smoking will be improved.

II. Background

The Duncan Hunter NDAA for FY 2009 (Pub. L. 110-417) provides authority for establishment of a smoking cessation program under the TRICARE program. Prior to enactment of Section 713 of the Duncan Hunter NDAA FY09 (Pub. L. 110-417), all supplies and services related to "stop smoking" programs were excluded from TRICARE coverage per the regulation, 32 CFR 199.4(g)(65).

Smoking is the number one cause of preventable illness and disease in the United States and yet, the prevalence of smoking among TRICARE beneficiaries exceeds that of the general population.

According to the Centers for Disease Control and Prevention (CDC), adverse health effects from smoking account for an estimated 443,000 deaths in the United States each year.

Smoking causes respiratory diseases such as emphysema, bronchitis, and chronic airway obstruction. It also causes several types of cancers including, but not limited to, esophageal, oral cavity, uterine, and lung cancer. In fact, the CDC estimates that 90 percent of lung cancer deaths in men and 80 percent in women are caused by smoking.

Smoking also puts individuals at increased risk for several other types of diseases and adverse health outcomes such as coronary artery disease, chronic obstructive lung diseases, peripheral vascular disease, heart attack, and stroke. In addition, it increases the risk of infertility, preterm delivery, stillbirth, low birth weight, and sudden infant death syndrome.

Smoking and its related adverse effects pose a significant challenge for many TRICARE beneficiaries. Establishment of the TRICARE smoking cessation program attempts to reduce the number of TRICARE beneficiaries who are nicotine dependent, thereby improving the health of the TRICARE beneficiary population and reducing Department of Defense costs, in particular those related to the adverse effects of smoking. For further information on TRICARE and the benefits provided under the TRICARE program, please visit www.tricare.mil.

III. Section 713 of the Duncan Hunter NDAA for FY 2009

This final rule implements Section 713 of the Duncan Hunter NDAA for FY 2009. Section 713 stipulates the following key features for inclusion in the TRICARE smoking cessation program:

(1) The availability, at no cost to the beneficiary, of pharmaceuticals used for smoking cessation, with a limitation on the availability of such pharmaceuticals to the national mail-order pharmacy program under the TRICARE program if appropriate.

(2) Counseling.

(3) Access to a toll-free quit line that is available 24 hours a day, 7 days a week.

(4) Access to print and Internet web-based tobacco cessation material.

(5) Chain of command involvement by officers in the chain of command of participants in the program who are on active duty.

Additionally, Section 713 of NDAA FY 2009 stated the TRICARE smoking cessation program shall not be made

available to Medicare-eligible beneficiaries. The statutory language further stated that refunds of copayments paid by Medicare-eligible beneficiaries are available during fiscal year 2009, subject to the specific availability of appropriations for this purpose. However, this authority was not extended beyond FY 2009; consequently, no action is required by TRICARE regarding this provision.

IV. Final Rule

This final rule establishes a smoking cessation program under the TRICARE program. The TRICARE smoking cessation program will be available to all TRICARE beneficiaries who reside in one of the 50 United States or the District of Columbia who are not eligible for Medicare benefits authorized under Title XVIII of the Social Security Act. In general, the TRICARE smoking cessation program will not be available to TRICARE beneficiaries who reside overseas except that under authority of 32 CFR 199.17, active duty service members and active duty dependents residing overseas including the U.S. territories of Guam, Puerto Rico, and the Virgin Islands who are enrolled in TRICARE Prime at a military treatment facility may have access to those services that the ASD(HA) has determined may be reasonably provided overseas.

It is the intent of the Department to provide access to smoking cessation pharmaceuticals and web based smoking cessation materials overseas where feasible. However, beneficiaries residing in certain areas overseas may not have easy access to the mail services, equipment or technology needed to receive these smoking cessation benefits and in those areas there is no requirement to make them available. For example, there is no intent by the Department to make the web based services available in areas where there are no web based carriers to provide such a service. Additionally, the laws and our treaties with various countries restrict the mailing of pharmaceuticals into the country. If such laws or treaties do not allow the delivery of the pharmaceuticals through the TRICARE Mail Order Pharmacy (TMOP), it is not the intent of the Secretary to provide the pharmaceutical benefit in those areas through this mechanism.

At this time, it is not the intent of the Department to provide access to the toll free quit line overseas due to the technological barriers and cost involved in providing this service. In addition, it is not the intent of the Department at this time to make face-to-face smoking

cessation counseling available overseas through the local economy. However, in accordance with 32 CFR 199.17 should the ASD(HA) determine that it is technologically, economically, or otherwise feasible to provide additional benefits or it becomes impractical to continue the benefits and services overseas, the ASD(HA) may use this authority to add or modify any benefit or service. Notice of the use of this authority shall be published in the **Federal Register**.

There will be no requirement for an eligible beneficiary to be diagnosed with a smoking related illness in order to access benefits under the TRICARE smoking cessation program. Benefits under this program will include, at no cost to the beneficiary, pharmaceuticals used for smoking cessation available through the TRICARE mail-order pharmacy program and at Military Treatment Facilities. The program will include smoking cessation counseling; access to a toll-free quit line 24 hours a day, 7 days a week; and access to printed and Internet web-based tobacco cessation material. Like other pharmaceuticals, smoking cessation pharmaceuticals may also be available at no cost to the beneficiary at an MTF; however, smoking cessation pharmaceuticals are not a covered benefit under the TRICARE Retail Pharmacy program.

V. Public Comments

The proposed rule was published in the **Federal Register** (76 FR 58199) dated September 20, 2011, for a 60-day public comment period. We received sixteen comments from different respondents on the proposed rule.

All but one of the public comments was positive and supported the provisions of the proposed rule. Fifteen of the respondents approved of the new coverage of smoking cessation medications with no copay, however there were two comments questioning the limitation of availability to the Mail Order Pharmacy Program. There was concern that TRICARE had not explained the reasoning for this decision and some were concerned that this limitation would be a barrier to those seeking treatment. We appreciate the comments and acknowledge the concern. However, we do not believe that limiting availability of smoking cessation pharmaceuticals to the mail order pharmacy will be a barrier to seeking care by the majority of beneficiaries. Mail order is a more cost effective venue than retail pharmacy and this limitation is a way of controlling the cost of providing these pharmaceuticals at no cost to the

beneficiary. We believe that providing these pharmaceuticals at no cost has a greater influence on a beneficiary's decision to seek care than the fact that the care is limited to a specific venue. We believe this to be a prudent, fair, and reasonable approach to providing the pharmaceutical component of the benefit.

Additionally, one respondent, representing the National Community Pharmacists Association felt that since some retail pharmacists provide smoking cessation counseling, it would be more convenient for beneficiaries to be able to get their medications at the retail pharmacy where they might possibly be going for smoking cessation counseling, so that both activities could occur in one location. We appreciate the respondent's comment and the suggestion that would seemingly offer greater convenience to TRICARE beneficiaries; however, consistent with Center for Medicare and Medicaid Services (CMS), pharmacists are not recognized as authorized TRICARE independent providers. Although TRICARE currently recognizes pharmacies as providers for purposes of the pharmacy benefits program under 32 CFR 199.21, which includes providing immunizations to our beneficiaries, the individual pharmacist is not recognized as an independent provider. Therefore, pharmacist counseling services are not currently a covered benefit under TRICARE and pharmacists cannot be reimbursed for this service. Therefore, beneficiaries who obtain smoking cessation products in a retail pharmacy may not receive counseling from the pharmacist as a covered benefit. In addition, as mentioned above, providing these products in the retail venue would significantly increase the cost of this program. The respondents were also concerned that if medications for smoking cessation are mailed to a patient's home, they will not have the opportunity to ask questions of a pharmacist before taking them. Unlike the majority of retail pharmacies, the mail order pharmacy program provides access to pharmacists 24/7 via a toll free number. Consistent with most pharmacy services, the mail order program provides complete written information including instructions for use, side effects, adverse effects, doses, warnings, and telephone numbers for questions.

Five respondents expressed concern that these new benefits were only available CONUS and not OCONUS. One respondent suggested a change to the language that deals with OCONUS availability. The commentor would prefer that it say that TRICARE is required to make the smoking cessation

program available overseas unless the ASD(HA) determines it is not possible to provide the program in specific overseas locations or situations, instead of stating that the benefits are not available overseas unless the Assistant Secretary of Defense for Health Affairs [ASD(HA)] determines they can be reasonably provided. We appreciate the respondent's comments and acknowledge the respondent's suggestion, however during the implementation of this benefit the ability to provide the benefit overseas was extensively explored. The Department found significant barriers and elected not to implement at this time. The language gives the Assistant Secretary the ability to expand the benefit as technology and other innovations make the delivery of these benefits feasible. Additionally the current federal regulations relating to the implementation of TRICARE overseas states that the program is not implemented overseas without affirmative action by the Department, thus the language used is consistent with our current regulatory framework.

One person commented that the smoking cessation program should include provisions to assist with tobacco cessation as well. We appreciate the comment; however, the language in section 713 of the NDAA 2009 limits us to providing a smoking cessation program with one exception. That exception allows the Department to provide printed and Internet web-based tobacco cessation materials.

One respondent was concerned that the language in the summary statement that says that there is a "limitation on the availability of such pharmaceuticals to the mail-order pharmacy" will cause the beneficiaries to believe that they cannot get these medications at the MTF pharmacies. We appreciate the respondent's comment and concern, and would like to assure the respondent that this was unintentional. To correct this and assure clarity, the language in Section III, the Summary, concerning the availability of smoking cessation pharmaceuticals has been revised to include a reference to the availability of pharmaceuticals at the MTFs. The language in the regulation itself reflects the correct availability of these pharmaceutical agents.

The statement in the proposed rule that says, "the Secretary of Defense shall provide for involvement by officers in the chain of command of participants in the program who are on active duty" caused concern for one responder. This commentor took this statement to mean that those active duty members who took advantage of the program would

have to report on their progress to their supervisor, which they felt would be very intimidating for those trying to quit, especially if they were having difficulties. We appreciate the comment, and want to clarify that the intent is not to have supervising officers be directly involved in individual active duty service members quit attempts, but to have them provide their support to the program. That is, it is the intent of the Department for all parts of the chain of command to support any member who wishes to quit smoking. There is no intent for any reporting requirements by a member to his or her command or for any member within the chain of command to report to their superiors relating to any member's participation in a smoking cessation program.

There were several comments related to the number of quit attempts available to participants in the program. One respondent did not think that a beneficiary should get more than three attempts total. The commenter was opposed to having three possible attempts per year and felt it would be a waste of TRICARE resources to continue to pay for additional attempts for someone who was not successful within a year of trying. We acknowledge the respondent's comments and appreciate the concerns. TRICARE is dedicated to the appropriate and judicious use of taxpayers' money and the decision to allow more than three quit attempts in total was the result of extensive research concerning smoking cessation. This research revealed that, on average, it takes smokers seven attempts to quit. Allowing more than three total attempts will give TRICARE beneficiaries who want to quit smoking the best opportunity to do so. This will result in a healthier beneficiary population; and as this population becomes healthier and more individuals choose to quit, TRICARE health care costs associated with treating diseases that are either caused by or exacerbated by smoking will be reduced.

Another respondent had the opposite view, believing that since "tobacco dependence is a chronic disease that often requires repeated intervention and multiple attempts to quit", patients should not be limited in their attempts and should have access to tobacco cessation services throughout the year. We acknowledge and respect this respondent's point of view; however, believe it would be fiscally irresponsible not to impose a limit on quit attempts. Furthermore, while our research revealed that the average person requires multiple attempts at quitting before they are successful, our research did not support a conclusion that

allowing unlimited quit attempts results in improved success rates.

This respondent also requested that the DoD Pharmacy and Therapeutics Committee, when deciding which specific smoking cessation medications TRICARE will cover, will choose to include all FDA-approved tobacco cessation medications. We appreciate this respondent's comment and suggestion. The Pharmacy and Therapeutics Committee has a mandate to review and recommend drugs based on their clinical and cost effectiveness. After this formal process, these recommendations will then go to the TMA Director, who will make the final decision. At this point, we do not know which of the smoking cessation medications will, or will not be on the formulary.

Another comment requested that TRICARE providers be made aware of the available cessation benefits and be trained in smoking cessation counseling. We appreciate the respondent's comments and suggestions and want to assure this respondent that once the final rule is published and this becomes a TRICARE benefit, information concerning it will be well publicized. This publicity will include information for TRICARE providers and our beneficiaries. Information concerning this new benefit will also be available on the TRICARE Web site (www.TRICARE.mil), which is accessible to beneficiaries, providers and the general public. In addition, the Managed Care Support Contractors are required to disseminate information to providers affected by implementation of new TRICARE benefits.

Another comment recommended an expansion of the TRICARE smoking cessation program to include a reduction of tobacco advertising in military literature and increasing the cost of tobacco products on military bases. We appreciate this respondent's comment and suggestions; however, the authority to take the actions suggested is beyond the scope of the requirements of the law that TRICARE was tasked to implement.

Unrelated to the Proposed Rule on Smoking Cessation, one comment was received from a retiree who was upset that he might be forced to pay more for TRICARE Prime as a part of DoD cutbacks. We appreciate this respondent's comments; however, we cannot address these here as they are outside the scope of the law that implements the TRICARE smoking cessation benefits.

VI. Regulatory Procedures

Executive Order 12866, "Regulatory Planning and Review" and Executive Order 13563, "Improving Regulation and Regulatory Review"

Section 801 of title 5, United States Code, and Executive Orders 12866 and 13563 require certain regulatory assessments and procedures for any major rule or significant regulatory action, defined as one that would result in an annual effect of \$100 million or more on the national economy or which would have other substantial impacts. This final rule is not a significant regulatory action.

Public Law 96-354, "Regulatory Flexibility Act" (RFA) (5 U.S.C. 601)

Public Law 96-354, "Regulatory Flexibility Act" (RFA) (5 U.S.C. 601), requires that each Federal agency prepare a regulatory flexibility analysis when the agency issues a regulation which would have a significant impact on a substantial number of small entities. This final rule will not have a significant impact on a substantial number of small entities. Therefore, this final rule is not subject to the requirements of the RFA.

Public Law 96-511, "Paperwork Reduction Act" (44 U.S.C. Chapter 35)

This rule does not contain a "collection of information" requirement, and will not impose additional information collection requirements on the public under Public Law 96-511, "Paperwork Reduction Act" (44 U.S.C. Chapter 35).

Public Law 104-4, Section 202, "Unfunded Mandates Reform Act"

Section 202 of Public Law 104-4, "Unfunded Mandates Reform Act," requires that an analysis be performed to determine whether any federal mandate may result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector of \$100 million in any one year. This final rule does not contain a Federal mandate that may result in the expenditure by State, local and tribal governments, in aggregate, or by the private sector, of \$100 million or more in any one year, and thus this final rule is not subject to this requirement.

Executive Order 13132, "Federalism"

Executive Order 13132, "Federalism," requires that an impact analysis be performed to determine whether the rule has federalism implications that would have substantial direct effects on the States, on the relationship between the national government and the States,

or on the distribution of power and responsibilities among the various levels of government. This final rule does not have federalism implications, as set forth in Executive Order 13132.

List of Subjects in 32 CFR Part 199

Claims, Dental health, Health care, Health insurance, Individuals with disabilities, Military personnel.

Accordingly, 32 CFR Part 199 is amended as follows:

PART 199—[AMENDED]

■ 1. The authority citation for Part 199 continues to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. Chapter 55.

■ 2. Section 199.4 is amended by:

- a. Revising paragraph (d)(3)(vi) introductory text.
- b. Adding new paragraph (d)(3)(vi)(C).
- c. Adding new paragraph (e)(30).
- d. Revising paragraph (g)(39).
- e. Removing and reserving paragraph (g)(65).

The revisions and additions read as follows:

§ 199.4 Basic program benefits.

* * * * *

(d) * * *

(3) * * *

(vi) *Drugs and medicines.* Drugs and medicines that by United States law require a prescription are also referred to as “legend drugs.” Legend drugs are covered when prescribed by a physician or other authorized individual professional provider acting within the scope of the provider’s license and ordered or prescribed in connection with an otherwise covered condition or treatment, and not otherwise excluded by TRICARE. This includes Rh immune globulin.

* * * * *

(C) Over-the-counter (OTC) drugs (drugs that by United States law do not require a prescription), in general, are not covered. However, insulin is covered for a known diabetic even in states that do not require a prescription for its purchase. In addition, OTC drugs used for smoking cessation are covered when all requirements under the TRICARE smoking cessation program are met as provided in paragraph (e)(30) of this section.

* * * * *

(e) * * *

(30) *Smoking cessation program.* The TRICARE smoking cessation program is a behavioral modification program to assist eligible beneficiaries who desire to quit smoking. The program consists of a pharmaceutical benefit; smoking

cessation counseling; access to a toll-free quit line for non-medical assistance; and, access to print and internet web-based tobacco cessation materials.

(i) *Availability.* The TRICARE smoking cessation program is available to all TRICARE beneficiaries who reside in one of the 50 United States or the District of Columbia who are not eligible for Medicare benefits authorized under Title XVIII of the Social Security Act. In addition, pursuant to § 199.17, if authorized by the Assistant Secretary of Defense (Health Affairs), the TRICARE smoking cessation program may be implemented in whole or in part in areas outside the 50 states and the District of Columbia for active duty members and their dependents who are enrolled in TRICARE Prime (overseas Prime beneficiaries). In such cases, the Assistant Secretary of Defense (Health Affairs) may also authorize modifications to the TRICARE smoking cessation program rules and procedures as may be appropriate to the overseas area involved. Notice of the use of this authority, not otherwise mentioned in this paragraph (e)(30), shall be published in the **Federal Register**.

(ii) *Benefits.* There is no requirement for an eligible beneficiary to be diagnosed with a smoking related illness to access benefits under this program. The specific benefits available under the TRICARE smoking cessation program are:

(A) *Pharmaceutical agents.* Products available under this program are identified through the DoD Pharmacy and Therapeutics Committee, consistent with the DoD Uniform Formulary in § 199.21. Smoking cessation pharmaceutical agents, including FDA-approved over-the-counter (OTC) pharmaceutical agents, are available through the TRICARE Mail Order Pharmacy (TMOP) or the MTF at no cost to the beneficiary. Smoking cessation pharmaceuticals through the TRICARE program will not be available at any retail pharmacies. A prescription from a TRICARE-authorized provider is required to obtain any pharmaceutical agent used for smoking cessation, including OTC agents. For overseas Prime beneficiaries, pharmaceutical agents may be provided either in the MTF or through the TMOP where such facility or service is available.

(B) *Face-to-face smoking cessation counseling.* Both individual and group smoking cessation counseling are covered. The number and mix of face-to-face counseling sessions covered under this program shall be determined by the Director, TMA; however, shall not exceed the limits established in paragraph (e)(30)(iii) of this section. A

TRICARE-authorized provider listed in § 199.6 must render all counseling sessions.

(C) *Toll-free quit line.* Access to a non-medical toll-free quit line 7 days a week, 24 hours a day will be available. The quit line will be staffed with smoking cessation counselors trained to assess a beneficiary’s readiness to quit, identify barriers to quitting, and provide specific suggested actions and motivational counseling to enhance the chances of a successful quit attempt. When appropriate, quit line counselors will refer beneficiaries to a TRICARE-authorized provider for medical intervention. The quit line may, at the discretion of the Director, TMA, include the opportunity for the beneficiary to request individual follow-up contact initiated by quit line personnel; however, the beneficiary is not required to participate in the quit line initiated follow-up. Printed educational materials on the effects of tobacco use will be provided to the beneficiary upon request. This benefit may be made available to overseas Prime beneficiaries should the ASD(HA) exercise his authority to do so and provide appropriate notice in the **Federal Register**.

(D) *Web-based resources.* Downloadable educational materials on the effects of tobacco use will be available through the internet or other electronic media. This service may be made available to overseas Prime beneficiaries in all locations where web based resources are available. There shall be no requirement to create web based resources in any geographic area in order to make this service available.

(iii) *Limitations of smoking cessation program.* Eligible beneficiaries are entitled to two quit attempts per year (consecutive 12 month period). A third quit attempt may be covered per year with physician justification and pre-authorization. A quit attempt is defined as up to eighteen face-to-face counseling sessions over a 120 consecutive day period and/or 120 days of pharmacologic intervention for the purpose of smoking cessation. Counseling and pharmacological treatment periods that overlap by at least 60-days are considered a single quit attempt.

* * * * *

(g) * * *

(39) *Counseling.* Educational, vocational, and nutritional counseling and counseling for socioeconomic purposes, stress management, and/or lifestyle modification purposes, except that the following are not excluded:

(i) Services provided by a certified marriage and family therapist, pastoral

or mental health counselor in the treatment of a mental disorder as specifically provided in paragraph (c)(3)(ix) of this section and in § 199.6.

(ii) Diabetes self-management training (DSMT) as specifically provided in paragraph (d)(3)(ix) of this section.

(iii) Smoking cessation counseling and education as specifically provided in paragraph (e)(30) of this section.

(iv) Services provided by alcoholism rehabilitation counselors only when rendered in a CHAMPUS-authorized treatment setting and only when the cost of those services is included in the facility's CHAMPUS-determined allowable cost rate.

* * * * *

(65) [Reserved]

* * * * *

■ 3. Section 199.21 is amended by:

■ a. Revising paragraph (a)(2);

■ b. Revising paragraph (h)(2)(i);

■ c. Adding a new paragraph (h)(2)(iii); and

■ d. Adding a new (i)(2)(v)(D).

The additions and revisions read as follows:

§ 199.21 Pharmacy benefits program.

(a) * * *

(2) *Pharmacy benefits program.* (i) *Applicability.* The pharmacy benefits program, which includes the uniform formulary and its associated tiered co-payment structure, is applicable to all of the uniformed services. Geographically, except as specifically provided in paragraph (a)(2)(ii) of this section, this program is applicable to all 50 states and the District of Columbia, Guam, Puerto Rico, and the Virgin Islands. In addition, if authorized by the Assistant Secretary of Defense (Health Affairs) (ASD(HA)), the TRICARE pharmacy benefits program may be implemented in areas outside the 50 states and the District of Columbia, Guam, Puerto Rico, and the Virgin Islands. In such case, the ASD (HA) may also authorize modifications to the pharmacy benefits program rules and procedures as may be appropriate to the area involved.

(ii) *Applicability exception.* The pharmaceutical benefit under the TRICARE smoking cessation program under § 199.4(e)(30) is available to TRICARE beneficiaries who are not entitled to Medicare benefits authorized under Title XVIII of the Social Security Act. Except as noted in § 199.4(e)(30), the smoking cessation program, including the pharmaceutical benefit, is not applicable or available to beneficiaries who reside overseas, including the U. S. territories of Guam, Puerto Rico, and the Virgin Islands, except that under the authority of

§ 199.17 active duty service members and active duty dependents enrolled in TRICARE Prime residing overseas, including the U. S. territories of Guam, Puerto Rico, and the Virgin Islands, shall have access to smoking cessation pharmaceuticals through either an MTF or the TMOP program where available.

* * * * *

(h) * * *

(2) *Availability of formulary pharmaceutical agents.* (i) *General.* Subject to paragraphs (h)(2)(ii) and (h)(2)(iii) of this section, formulary pharmaceutical agents are available under the Pharmacy Benefits Program from all points of service identified in paragraph (h)(1) of this section.

* * * * *

(iii) Pharmaceutical agents prescribed for smoking cessation are not available for coverage when obtained through a retail pharmacy. This includes network and non-network retail pharmacies.

* * * * *

(i) * * *

(2) * * *

(v) * * *

(D) \$0.00 co-payment for smoking cessation pharmaceutical agents covered under the smoking cessation program.

* * * * *

Dated: February 1, 2013.

Patricia L. Toppings,

*OSD Federal Register Liaison Officer,
Department of Defense.*

[FR Doc. 2013-03417 Filed 2-26-13; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG-2012-1065]

RIN 1625-AA09

Drawbridge Operation Regulation; Sabine River, Near Ruliff, LA

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is removing the existing drawbridge operation regulation for the Kansas City Southern (KCS) Railroad drawbridge across Sabine River, mile 36.2, between Newton County, TX and Calcasieu Parish, LA. The drawbridge was converted to a fixed bridge in 2012 and the operating regulation is no longer applicable or necessary.

DATES: This rule is effective February 27, 2013.

ADDRESSES: Documents mentioned in this preamble are part of docket USCG-2012-1065. To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type the docket number in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12-140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mr. Jim Wetherington, Bridge Administration Branch, Coast Guard; telephone 504-671-2128, email james.r.wetherington@uscg.mil. If you have questions on viewing the docket, call Barbara Hairston, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

A. Regulatory History and Information

The Coast Guard is issuing this final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the Kansas City Southern Railroad Bridge over the Sabine River, mile 36.2, that once required draw operations in 33 CFR 117.493(b), was converted to a fixed bridge in 2012. Therefore, the regulation is no longer applicable and shall be removed from publication. It is unnecessary to publish an NPRM because this regulatory action does not purport to place any restrictions on mariners but rather removes a restriction that has no further use or value.

Under 5 U.S.C. 553(d)(1), a rule that relieves a restriction is not required to provide the 30 day notice period before its effective date. This rule removes the Kansas City Southern (KCS) Railroad Bridge over the Sabine River, mile 36.2, draw operation requirements under 33 CFR 117.493(b), thus removing a regulatory restriction on the public.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective in less than 30 days after publication in the **Federal Register**. The bridge has had an operation regulation that states the bridge “need not open” since 1992. At that time, the bridge was rendered effectively fixed with the removal of all operations equipment associated with that bridge by KCS. The bridge has been a fixed bridge for one year and this rule merely requires an administrative change to the **Federal Register**, in order to omit a regulatory requirement that is no longer applicable or necessary.

B. Basis and Purpose

The KCS Railroad Bridge across the Sabine River, mile 36.2, was converted to a fixed bridge in 2012 after 20 years of not being required to open, by regulation, and being effectively fixed with the removal of all operations equipment by the owner. It has come to the attention of the Coast Guard that the governing regulation for this drawbridge was never removed subsequent to the conversion of the existing bridge to a fixed bridge. The conversion of this drawbridge necessitates the removal of the parts of the drawbridge operation regulation, 33 CFR 117.493(b), that are pertaining to the former drawbridge.

The purpose of this rule is to remove the parts of the paragraph of 33 CFR 117.493(b) that refer to the KCS Railroad Drawbridge at mile 36.2, from the Code of Federal Regulations since it governs a bridge that is no longer able to be opened.

C. Discussion of Rule

The Coast Guard is changing the regulation in 33 CFR 117.493(b) by removing restrictions and the regulatory burden related to the draw operations for this bridge that is no longer a drawbridge. The change removes the part of the paragraph of the regulation governing the KCS Railroad Bridge, mile 36.2, since the bridge has been converted to a fixed bridge. This Final Rule seeks to update the Code of Federal Regulations by removing language that governs the operation of the KCS Railroad Bridge, mile 36.2, which in fact is no longer a drawbridge. This change does not affect waterway or land traffic. This change does not affect nor does it alter the operating schedules in 33 CFR 117.493(a), the remainder of 33 CFR 117.493(b) that governs the remaining active drawbridge listed in this paragraph nor the remaining active drawbridges on the Sabine River.

D. Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on these statutes or executive orders.

1. Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders.

The Coast Guard does not consider this rule to be “significant” under that Order because it is an administrative change and does not affect the way vessels operate on the waterway.

2. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule will have no effect on small entities since this drawbridge has been converted to a fixed bridge and the regulation governing draw operations for this bridge is no longer applicable. There is no new restriction or regulation being imposed by this rule; therefore, the Coast Guard certifies under 5 U.S.C. 605(b) that this final rule will not have a significant economic impact on a substantial number of small entities.

3. Collection of Information

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

4. Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has 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. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

5. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

6. Unfunded Mandates Reform Act

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

7. Taking of Private Property

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

8. Civil Justice Reform

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

9. Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that might disproportionately affect children.

10. Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

11. Energy Effects

This action is not a “significant energy action” under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.

12. Technical Standards

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

13. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023-01 and Commandant Instruction M16475.ID, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321-4370f), and have concluded that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves the removal of the parts of the paragraph of 33 CFR 117.493 (b) that refer to the KCS Railroad Drawbridge at mile 36.2, from the Code of Federal Regulations since it governs a bridge that has been converted to a fixed bridge. This rule is categorically excluded, under figure 2-1, paragraph (32) (e), of the Instruction.

Under figure 2-1, paragraph (32)(e), of the Instruction, an environmental analysis checklist and a categorical exclusion determination are not required for this rule.

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

- 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05-1; Department of Homeland Security Delegation No. 0170.1.

- 2. Revise § 117.493(b) to read as follows:

§ 117.493 Sabine River.

* * * * *

(b) The draw of the S12 Bridge, mile 40.8, at Starks, need not be opened for the passage of vessels.

Dated: January 31, 2013.

Roy A. Nash,
Rear Admiral, U.S. Coast Guard, Commander,
Eighth Coast Guard District.

[FR Doc. 2013-04492 Filed 2-26-13; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Parts 126, 127, 154, and 155

46 CFR Parts 32, 34, 39, 54, 56, 76, 95, 108, 153, 160, 162, and 193

[Docket No. USCG-2012-0866]

RIN 1625-AB98

Updates to Standards Incorporated by Reference; Reapproved ASTM Standards; Technical Amendment

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: Many of the Coast Guard’s regulations incorporate by reference consensus standards that are developed by organizations other than the Coast Guard. This final rule updates references to standards developed by ASTM International, that have been reapproved, without change, since their incorporation into Coast Guard regulation. This rule does not address standards that have changed substantively, and it will not have any substantive impact on the regulated public.

DATES: This rule is effective March 29, 2013. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register on March 29, 2013.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket USCG-2012-0866 and are available for inspection or copying at 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. You may also find this docket on the Internet by going to <http://www.regulations.gov>, inserting USCG-2012-0866 in the “Keyword” box, and then clicking “Search.”

Viewing incorporation by reference material. You may inspect the material incorporated by reference at the U.S. Coast Guard Headquarters, Room 1304, 2100 2nd Street SW., Washington, DC 20593 between 9 a.m. and 2 p.m.,

Monday through Friday, except Federal holidays. The telephone number is 202-372-1494. Copies of the material are available as indicated in the “Incorporation by Reference” section of this preamble.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mr. Roger K. Butturini, PE, U.S. Coast Guard Office of Standards Evaluation and Development; telephone 202-372-1494, email

Roger.K.Butturini@uscg.mil. If you have questions on viewing the docket, call Ms. Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

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I. Abbreviations

ASTM ASTM International
 CFR Code of Federal Regulations
 NTTAA National Technology Transfer and Advancement Act
 U.S.C. United States Code

II. Regulatory History

The Coast Guard is issuing this final rule without prior notice and opportunity to comment, pursuant to section 4(a) of the Administrative Procedure Act (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency, for good cause, finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” As discussed in more detail in this final rule, the industry standards adopted in this rule are merely reapproved editions of the previously incorporated standards. Reapproving a

standard is a maintenance activity that confirms to the reader that the standard in question is not outdated or superseded as of the year of reapproval. This rule does not change any substantive regulatory requirements or pose any anticipated costs to the public, and will have no substantive effect on the public. Because the revisions implemented by this rule are all non-substantive changes without effect on the public, the Coast Guard finds that notice and public comment on the changes is unnecessary, and that good cause therefore exists under 5 U.S.C. 553(b)(B) for forgoing notice and comment procedures.

III. Basis and Purpose

The purpose of this rule is to update references to incorporated industry standards that have been reapproved, without change, by the standards organization that developed them. In this rule, we focus on standards developed by ASTM International (ASTM). We also are standardizing usage of ASTM’s name, which was formerly the American Society for Testing and Materials, updating the listed contact information for publishers, and reformatting certain sections for ease of use.

In updating our references, we ensure that the publications we have incorporated by reference are reasonably available to the public as required by 1 CFR part 51. The Coast Guard’s authority to revise its regulations is outlined in 33 CFR 1.05–1, as well as in the authority citations for each part of the Code of Federal Regulations (CFR) amended by this rule. Incorporation by reference is governed by 5 U.S.C. 552(a), 15 U.S.C. 272 note, and 1 CFR part 51.

IV. Background

A. History of Incorporation by Reference

Voluntary consensus standards are technical standards that are developed or adopted by voluntary consensus standards bodies. They may include specifications for materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices. The Coast Guard has actively

participated in the development of industry standards for the safety of marine equipment at the International Maritime Organization, the International Organization for Standardization, ASTM, the American Society of Mechanical Engineers, and other standards development bodies. The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or would otherwise be impractical.

When appropriate, the Coast Guard incorporates industry standards, and particularly voluntary consensus standards, into its regulations. This process, known as incorporation by reference, gives the content of incorporated standards the same force as regulations published in the CFR. Incorporation by reference occurs as part of a rulemaking and is governed by specific rules, which are available at 1 CFR part 51. Under these rules the Coast Guard may only incorporate a specific edition of a standard, and that standard must be reasonably available to the class of persons affected by it. Because standards organizations revise and replace standards over time, the specific edition incorporated by the Coast Guard eventually may become outdated, unavailable, or both. This can lead to conflicts between domestic and international requirements, or between regulatory requirements and modern best practices. Therefore, the Coast Guard reviews its incorporations by reference and updates them if necessary.

B. Reapproved Standards

Standards organizations sometimes “reapprove” standards without modifying them. Reapproving a standard is a maintenance activity that confirms to the reader that the standard in question is not outdated or superseded as of the year of reapproval. For example, the standard known as ASTM A 575–96, “Standard

Specification for Steel Bars, Carbon, Merchant Quality, M-Grades,” was originally published in 1996; when it was reapproved in 2002, it became known as ASTM A 575–96 (Reapproved 2002). It was reapproved again in 2007 as ASTM A 575–96 (Reapproved 2007). The substantive content remains the same as in the 1996 edition.

Because the Coast Guard must incorporate a specific edition, however, reapproval can cause the Coast Guard’s incorporation to become outdated or confusing even if the substance of the incorporated standard is unchanged. For example, the Coast Guard incorporated ASTM A 575–96. Although the content of the standard has not changed since the Coast Guard incorporated it, the current version is ASTM A 575–96 (Reapproved 2007) and the incorporated ASTM A 575–96 has been superseded. In some cases, superseded standards are no longer readily available.

This rule updates regulatory references to certain incorporated ASTM standards that have been reapproved without change. We chose to focus on ASTM standards in this rule because we had recently verified that several such standards had been reapproved without change. The Coast Guard is aware that standards developed by other organizations may also have been reapproved and may also require updating, and that some of the Coast Guard’s other incorporations may require updating for other reasons. The Coast Guard intends to address those incorporations in future publications in the **Federal Register**. To that end, we published a request for comments on November 30, 2012, (77 FR 71369) to solicit public input as to which incorporations by reference require updating.

V. Discussion of Changes

A. Incorporation of Reapproved Standards

The following table lists the title of each standard affected by this rule, the version previously incorporated, the more recent version to be incorporated, and the locations in the CFR where these references occur.

TABLE 1—LIST OF ASTM STANDARDS AFFECTED BY THE FINAL RULE

Title of standard	Standard previously incorporated	Standard to be incorporated	Where incorporated	
			CFR title	CFR section(s)
Standard Specification for Welded Joints for Shipboard Piping Systems.	F722–82 (1993)	F722–82 (Reapproved 2008).	33	154.106

TABLE 1—LIST OF ASTM STANDARDS AFFECTED BY THE FINAL RULE—Continued

Title of standard	Standard previously incorporated	Standard to be incorporated	Where incorporated	
			CFR title	CFR section(s)
Standard Specification for International Shore Connections for Marine Fire Applications.	F1121–87 (1993)	F1121–87 (Reapproved 2010).	33 46	126.5, 127.003 34.01–15, 76.01–2, 95.01–2, 108.101, 193.01–3
Standard Specification for Pipe, Steel, Electric-Fusion (Arc)—Welded (Sizes NPS 16 and Over).	A134–96	A134–96 (Reapproved 2012).	46	56.01–2
Standard Specification for Seamless Cold-Drawn Low-Carbon Steel Heat-Exchanger and Condenser Tubes.	A179/A179M–90a (1996).	A179/A179M–90a (Reapproved 2012).	46	56.01–2
Standard Specification for Pressure Vessel Plates, Alloy Steel, Nickel.	A203/A203M–97	A203/A203M–97 (Reapproved 2007) ^{e1} .	46	54.01–1
Standard Specification for Electric-Resistance-Welded Carbon Steel Heat-Exchanger and Condenser Tubes.	A214/A214M–96	A214/A214M–96 (Reapproved 2012).	46	56.01–2
Standard Specification for Ductile Iron Castings	A536–84 (1993)	A536–84 (Reapproved 2009).	46	56.01–2
Standard Specification for Steel Bars, Carbon, Merchant Quality, M-Grades.	A575–96	A575–96 (Reapproved 2007).	46	56.01–2
Standard Specification for Steel Bars, Carbon, Hot-Wrought, Special Quality.	A576–90b (1995)	A576–90b (Reapproved 2012).	46	56.01–2
Standard Test Method for Determining Gas Permeability Characteristics of Plastic Film and Sheeting.	D1434–82 (1988)	D1434–82 (Reapproved 2009) ^{e1} .	46	160.077–5, 160.176–4
Standard Specification for Wrought Carbon Steel Sleeve-Type Pipe Couplings.	F682–82a	F682–82a (Reapproved 2008).	46	56.01–2
Standard Specification for Entrapment Separators for Use in Marine Piping Applications.	F1006–86 (1992)	F1006–86 (Reapproved 2008).	46	56.01–2
Standard Specification for Pipeline Expansion Joints of the Packed Slip Type for Marine Application.	F1007–86 (1996)	F1007–86 (Reapproved 2007).	46	56.01–2
Standard Specification for Line-Blind Valves for Marine Applications.	F1020–86 (1996)	F1020–86 (Reapproved 2011).	46	56.01–2
Standard Specification for Circular Metallic Bellows Type Expansion Joints for Piping Applications.	F1120–87 (1993)	F1120–87 (Reapproved 2010).	46	56.01–2
Standard Specification for Non-Metallic Expansion Joints.	F1123–87 (1993)	F1123–87 (Reapproved 2010).	46	56.01–2
Standard Specification for Steam Traps and Drains.	F1139–88 (1993)	F1139–88 (Reapproved 2010).	46	56.01–2
Standard Specification for Fuel Oil Meters of the Volumetric Positive Displacement Type.	F1172–88 (1993)	F1172–88 (Reapproved 2010).	46	56.01–2
Standard Specification for Cast (All Temperatures and Pressures) and Welded Pipe Line Strainers (150 psig and 150 °F Maximum).	F1199–88 (1993)	F1199–88 (Reapproved 2010).	46	56.01–2
Standard Specification for Fabricated (Welded) Pipe Line Strainers (Above 150 psig and 150 °F).	F1200–88 (1993)	F1200–88 (Reapproved 2010).	46	56.01–2
Standard Specification for Fluid Conditioner Fittings in Piping Applications Above 0 °F.	F1201–88 (1993)	F1201–88 (Reapproved 2010).	46	56.01–2
Standard Specification for Spill Valves for Use in Marine Tank Liquid Overpressure Protections Applications.	F1271–90 (1995)	F1271–90 (Reapproved 2012).	46	39.10–5, 153.4
Standard Specification for Tank Vent Flame Arresters.	F1273–91 (1997)	F1273–91 (Reapproved 2007).	46	32.01–1
Standard Specification for Fire Hose Nozzles	F1546/F1546 M–96	F1546/F1546M–96 (Reapproved 2012).	46	162.027–1

All of the incorporated standards in Table 1 have been reapproved without change. For that reason, incorporating the most recent versions does not change the substantive regulatory requirements and will have no substantive impact on the regulated public.

The Coast Guard is also standardizing usage of the name “ASTM International,” formerly known as the American Society for Testing and Materials, as well as reformatting the reapproved document titles to match the capitalization and punctuation used in the most current publications. These

changes are administrative in nature, and will not affect the regulated public in a substantive manner.

B. Reformatting Involving Standards Other Than Reapproved ASTM Standards

Some of the reapproved ASTM standards appear in older sections of the CFR that did not include paragraph designations. The lack of paragraph designations makes reading and cross-referencing these sections more difficult. This rule reformats those sections using the Office of the Federal Register's preferred paragraph designation format. The reformatted sections are 46 CFR 32.01–1, 76.01–2, 153.4, 160.077–5, 160.176–4, and 162.027–1. This rule also updates publisher contact information in these sections when appropriate.

Although these reformatted sections contain incorporated standards other than reapproved ASTM standards, this rule does not update those references, incorporate newer versions, or make any other substantive change to those references. With the exception of the reapproved ASTM standards discussed above, the content of the reformatted sections remains the same as it was prior to this rule. Suggestions for updates to these sections may be submitted to the Coast Guard using the contact information in **ADDRESSES**.

C. Removal of 33 CFR 155.140(c)(3)

In developing this rule, the Coast Guard became aware that 33 CFR 155.140(c)(3) indicated standard ASTM F 722–82 was incorporated by reference in Appendices A and B of 33 CFR part 155. Appendices A and B do not contain any reference to ASTM F 722–82, however, and subsequent research determined this reference to be a typographical error. This rule removes the reference to ASTM F 722–82 from § 155.140. As there is no regulatory requirement in Part 155 associated with the standard, the removal can have no substantive impact on the public.

VI. Incorporation by Reference

The Director of the **Federal Register** has approved the material in 33 CFR 126.5, 127.003, and 154.106; and 46 CFR 32.01–1, 34.01–15, 39.10–5, 54.01–1, 56.01–2, 76.01–2, 95.01–2, 108.101, 153.4, 160.077–5, 160.176–4, 162.027–1, and 193.01–3 for incorporation by reference under 5 U.S.C. 552 and 1 CFR part 51. Copies of the material are available from the sources listed in these sections.

VII. Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses

based on these statutes or executive orders.

A. Regulatory Planning and Review

Executive Orders 12866 (“Regulatory Planning and Review”) and 13563 (“Improving Regulation and Regulatory Review”) direct agencies to assess the 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). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule has not been designated a “significant regulatory action” under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

This final rule makes non-substantive changes throughout Titles 33 and 46 of the CFR. As discussed in more detail in Section V (Discussion of Changes) of this preamble, the industry standards adopted in this rule are merely reapproved editions of the previously incorporated standards. Reapproving a standard is a maintenance activity that confirms to the reader that the standard in question is not outdated or superseded as of the year of reapproval. Therefore, this rule does not change any substantive regulatory requirements and will have no substantive effect on the public. As a result, we expect no additional cost to the industry. No additional labor or resources would be required by the regulated public.

We expect this final rule to be beneficial to the public and to the maritime industry because it will make the Coast Guard's references to these standards consistent with the current standards available for use by industry and will ensure that the publications we have incorporated by reference are reasonably available to the public.

B. Small Entities

This rule is not preceded by a notice of proposed rulemaking and, therefore, is exempt from the requirements of the Regulatory Flexibility Act (5 U.S.C. 601–612). The Regulatory Flexibility Act does not apply when the agency for good cause finds that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

C. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we want to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking. The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

D. Collection of Information

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

E. Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if the rule has 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. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

F. Unfunded Mandates Reform Act

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

G. Taking of Private Property

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

H. Civil Justice Reform

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

I. Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

J. Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial

direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

K. Energy Effects

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

require a Statement of Energy Effects under Executive Order 13211.

L. Technical Standards

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

This rule uses the following voluntary consensus standards:

TABLE 2—LIST OF ASTM VOLUNTARY CONSENSUS STANDARDS

ID No. of standard	Title of standard
A134–96 (Reapproved 2012)	Standard Specification for Pipe, Steel, Electric-Fusion (Arc)-Welded (Sizes NPS 16 and Over).
A179/A179M–90a (Reapproved 2012)	Standard Specification for Seamless Cold-Drawn Low-Carbon Steel Heat-Exchanger and Condenser Tubes.
A 203/A 203M–97 (Reapproved 2007) ^{e1}	Standard Specification for Pressure Vessel Plates, Alloy Steel, Nickel.
A214/A214M–96 (Reapproved 2012)	Standard Specification for Electric-Resistance-Welded Carbon Steel Heat-Exchanger and Condenser Tubes.
A 536–84 (Reapproved 2009)	Standard Specification for Ductile Iron Castings.
A 575–96 (Reapproved 2007)	Standard Specification for Steel Bars, Carbon, Merchant Quality, M-Grades.
A576–90b (Reapproved 2012)	Standard Specification for Steel Bars, Carbon, Hot-Wrought, Special Quality.
D1434–82 (Reapproved 2009) ^{e1}	Standard Test Method for Determining Gas Permeability Characteristics of Plastic Film and Sheeting.
F682–82a (Reapproved 2008)	Standard Specification for Wrought Carbon Steel Sleeve-Type Pipe Couplings.
F722–82 (Reapproved 2008)	Standard Specification for Welded Joints for Shipboard Piping Systems.
F1006–86 (Reapproved 2008)	Standard Specification for Entrainment Separators for Use in Marine Piping Applications.
F1007–86 (Reapproved 2007)	Standard Specification for Pipeline Expansion Joints of the Packed Slip Type for Marine Application.
F1020–86 (Reapproved 2011)	Standard Specification for Line-Blind Valves for Marine Applications.
F1120–87 (Reapproved 2010)	Standard Specification for Circular Metallic Bellows Type Expansion Joints for Piping Applications.
F1121–87 (Reapproved 2010)	Standard Specification for International Shore Connections for Marine Fire Applications.
F1123–87 (Reapproved 2010)	Standard Specification for Non-Metallic Expansion Joints.
F1139–88 (Reapproved 2010)	Standard Specification for Steam Traps and Drains.
F1172–88 (Reapproved 2010)	Standard Specification for Fuel Oil Meters of the Volumetric Positive Displacement Type.
F1199–88 (Reapproved 2010)	Standard Specification for Cast (All Temperatures and Pressures) and Welded Pipe Line Strainers (150 psig and 150° F Maximum).
F1200–88 (Reapproved 2010)	Standard Specification for Fabricated (Welded) Pipe Line Strainers (Above 150 psig and 150° F).
F1201–88 (Reapproved 2010)	Standard Specification for Fluid Conditioner Fittings in Piping Applications Above 0° F.
F1271–90 (Reapproved 2012)	Standard Specification for Spill Valves for Use in Marine Tank Liquid Overpressure Protections Applications.
F1273–91 (Reapproved 2007)	Standard Specification for Tank Vent Flame Arresters.
F1546/F1546M–96 (Reapproved 2012)	Standard Specification for Fire Hose Nozzles.

M. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.ID, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321–4370f), and

have concluded that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded under section 2.B.2, figure 2–1, paragraph (34)(a) of the Instruction. This rule falls under the category of editorial or procedural regulations since

it involves the adoption of voluntary consensus standards already in effect. An environmental analysis checklist and a categorical exclusion determination are available in the docket where indicated under **ADDRESSES**.

List of Subjects

33 CFR Part 126

Explosives, Harbors, Hazardous substances, Incorporation by reference, Reporting and recordkeeping requirements.

33 CFR Part 127

Fire prevention, Harbors, Hazardous substances, Incorporation by reference, Natural gas, Reporting and recordkeeping requirements, Security measures.

33 CFR Part 154

Alaska, Fire prevention, Hazardous substances, Incorporation by reference, Oil pollution, Reporting and recordkeeping requirements.

33 CFR Part 155

Alaska, Hazardous substances, Incorporation by reference, Oil pollution, Reporting and recordkeeping requirements.

46 CFR Part 32

Cargo vessels, Fire prevention, Incorporation by reference, Marine safety, Navigation (water), Occupational safety and health, Reporting and recordkeeping requirements, Seamen.

46 CFR Part 34

Cargo vessels, Fire prevention, Incorporation by reference, Marine safety.

46 CFR Part 39

Cargo vessels, Fire prevention, Hazardous materials transportation, Incorporation by reference, Marine safety, Occupational safety and health, Reporting and recordkeeping requirements.

46 CFR Parts 54 and 56

Incorporation by reference, Reporting and recordkeeping requirements, Vessels.

46 CFR Part 76

Fire prevention, Incorporation by reference, Marine safety, Passenger vessels.

46 CFR Part 95

Cargo vessels, Fire prevention, Incorporation by reference, Marine safety.

46 CFR Part 108

Fire prevention, Incorporation by reference, Marine safety, Occupational safety and health, Oil and gas exploration, Vessels.

46 CFR Part 153

Administrative practice and procedure, Cargo vessels, Hazardous materials transportation, Incorporation by reference, Marine safety, Reporting and recordkeeping requirements, Water pollution control.

46 CFR Part 160

Incorporation by reference, Marine safety, Reporting and recordkeeping requirements.

46 CFR Part 162

Fire prevention, Incorporation by reference, Marine safety, Oil pollution, Reporting and recordkeeping requirements.

46 CFR Part 193

Fire prevention, Incorporation by reference, Marine safety, Oceanographic research vessels.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR parts 126, 127, 154, and 155, and 46 CFR parts 32, 34, 39, 54, 56, 76, 95, 108, 153, 160, 162, and 193 as follows:

Title 33

PART 126—HANDLING OF DANGEROUS CARGO AT WATERFRONT FACILITIES

■ 1. The authority citation for part 126 continues to read as follows:

Authority: 33 U.S.C. 1231; 49 CFR 1.46.

■ 2. In § 126.5, in the table in paragraph (b), revise the first two entries to read as follows:

§ 126.5 Incorporation by reference: Where can I get a copy of the publications mentioned in this part?

* * * * *
(b) * * *

ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428-2959, 877-909-2786, <http://www.astm.org>.

ASTM F1121-87 (Reapproved 2010), Standard Specification for International Shore Connections for Marine Fire Applications, (approved March 1, 2010) 126.15

* * * * *

PART 127—WATERFRONT FACILITIES HANDLING LIQUEFIED NATURAL GAS AND LIQUEFIED HAZARDOUS GAS

■ 3. The authority citation for part 127 continues to read as follows:

Authority: 33 U.S.C. 1231; 46 U.S.C. Chapter 701; Department of Homeland Security Delegation No. 0170.1.

■ 4. In § 127.003, in the table in paragraph (b), revise the entries for the

“American Society for Testing and Materials (ASTM)” to read as follows:

§ 127.003 Incorporation by reference.

* * * * *
(b) * * *

* * * * *

ASTM International

100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428-2959, 877-909-2786, <http://www.astm.org>.

ASTM F1121-87 (Reapproved 2010), Standard Specification for International Shore Connections for Marine Fire Applications, (approved March 1, 2010) 127.611; 127.1511

* * * * *

**PART 154—FACILITIES
TRANSFERRING OIL OR HAZARDOUS
MATERIAL IN BULK**

■ 5. The authority citation for part 154 continues to read as follows:

Authority: 33 U.S.C. 1231, 1321(j)(1)(C), (j)(5), (j)(6), and (m)(2); sec. 2, E.O. 12777, 56 FR 54757; Department of Homeland Security Delegation No. 0170.1. Subpart F is also issued under 33 U.S.C. 2735.

■ 6. In § 154.106, revise paragraph (d) introductory text and paragraph (d)(3) to read as follows:

**§ 154.106 Incorporation by reference:
Where can I get a copy of the publications
incorporated by reference in this part?**

* * * * *

(d) ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959, 877–909–2786, <http://www.astm.org>;

* * * * *

(3) ASTM F722–82 (Reapproved 2008), Standard Specification for Welded Joints for Shipboard Piping Systems, (approved November 1, 2008), incorporation by reference approved for Appendix A and Appendix B.

* * * * *

**PART 155—OIL OR HAZARDOUS
MATERIAL POLLUTION PREVENTION
REGULATIONS FOR VESSELS**

■ 7. The authority citation for part 155 continues to read as follows:

Authority: 33 U.S.C. 1231, 1321(j); 46 U.S.C. 3703; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; Department of Homeland Security Delegation No. 0170.1. Sections 155.100 through 155.130, 150.350 through 155.400, 155.430, 155.440, 155.470, 155.1030(j) and (k), and 155.1065(g) are also issued under 33 U.S.C. 1903(b). Section 155.490 also issued under section 4110(b) of Pub. L. 101–380. Sections 155.1110 through 155.1150 also issued under 33 U.S.C. 2735.

■ 8. In § 155.140, revise paragraph (c) introductory text and remove and

reserve paragraph (c)(3) to read as follows:

§ 155.140 Incorporation by reference.

* * * * *

(c) *ASTM International*, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959, 877–909–2786, <http://www.astm.org>;

* * * * *

(3) [Reserved].

* * * * *

Title 46

**PART 32—SPECIAL EQUIPMENT,
MACHINERY, AND HULL
REQUIREMENTS**

■ 9. The authority citation for part 32 continues to read as follows:

Authority: 46 U.S.C. 2103, 3306, 3703, 3719; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1; Subpart 32.59 also issued under the authority of Sec. 4109, Pub. L. 101–380, 104 Stat. 515.

■ 10. Amend § 32.01–1 by revising paragraph (b) and adding paragraph (c) to read as follows:

§ 32.01–1 Incorporation by reference.

* * * * *

(b) American Bureau of Shipping (ABS), ABS Plaza, 16855 Northchase Drive, Houston, TX 77060, 281–877–5800, <http://www.eagle.org>.

(1) Rules for Building and Classing Steel Vessels, 1989, incorporation by reference approved for §§ 32.15–15; 32.60–10; 32.65–40.

(2) [Reserved]

(c) ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959, 877–909–2786, <http://www.astm.org>.

(1) ASTM D4986–98, Standard Test Method for Horizontal Burning Characteristics of Cellular Polymeric Materials, incorporation by reference approved for § 32.57–10.

(2) ASTM F1273–91 (Reapproved 2007), Standard Specification for Tank Vent Flame Arresters (approved December 1, 2007), incorporation by reference approved for § 32.20–10.

PART 34—FIREFIGHTING EQUIPMENT

■ 11. The authority citation for part 34 continues to read as follows:

Authority: 46 U.S.C. 3306, 3703; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

■ 12. In § 34.01–15, revise paragraph (b) introductory text and paragraph (b)(1) to read as follows:

§ 34.01–15 Incorporation by reference.

* * * * *

(b) ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959, 877–909–2786, <http://www.astm.org>.

(1) ASTM F1121–87 (Reapproved 2010), Standard Specification for International Shore Connections for Marine Fire Applications, (approved March 1, 2010), incorporation by reference approved for § 34.10–15 (“ASTM F 1121”).

* * * * *

**PART 39—VAPOR CONTROL
SYSTEMS**

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

Authority: 33 U.S.C. 1231; 46 U.S.C. 3306, 3703, 3715(b); 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

■ 14. In § 39.10–5, revise the fifth and sixth entries in the table, in paragraph (b) to read as follows:

**§ 39.10–5 Incorporation by reference—TB/
ALL.**

* * * * *

(b) * * *

*	*	*	*	*	*	*	*
<i>ASTM International</i> , 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959, 877–909–2786, http://www.astm.org .							
ASTM F1271–90 (Reapproved 2012), Standard Specification for Spill Valves for Use in Marine Tank Liquid Overpressure Protections Applications, (approved May 1, 2012) 39.20–9							
*	*	*	*	*	*	*	*

PART 54—PRESSURE VESSELS

■ 15. The authority citation for part 54 continues to read as follows:

Authority: 33 U.S.C. 1509; 43 U.S.C. 1333; 46 U.S.C. 3306, 3703; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277;

Department of Homeland Security Delegation No. 0170.1.

■ 16. In § 54.01–1, revise paragraph (c) introductory text and paragraph (c)(2) to read as follows:

§ 54.01–1 Incorporation by reference.

* * * * *

(c) *ASTM International*, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959, 877–909–2786, <http://www.astm.org>;

* * * * *

(2) ASTM A 203/A 203M–97 (Reapproved 2007)ε¹, Standard

Specification for Pressure Vessel Plates, Alloy Steel, Nickel (“ASTM A 203”), (approved November 1, 2007), incorporation by reference approved for § 54.05–20;

* * * * *

PART 56—PIPING SYSTEMS AND APPURTENANCES

■ 17. The authority citation for part 56 continues to read as follows:

Authority: 33 U.S.C. 1321(j), 1509; 43 U.S.C. 1333; 46 U.S.C. 3306, 3703; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; Department of Homeland Security Delegation No. 0170.1.

■ 18. Amend § 56.01–2 as follows:

- a. Redesignate paragraphs (e)(9) through (e)(82) as paragraphs (e)(10) through (e)(83), respectively;
- b. Redesignate the second paragraph (e)(8) as paragraph (e)(9); and
- c. Revise paragraph (e) introductory text, paragraph (e)(6), and newly redesignated paragraphs (e)(10), (e)(17), (e)(40) through (e)(42), (e)(69) through (e)(76), and (e)(78) through (e)(80) to read as follows:

§ 56.01–2 Incorporation by reference.

* * * * *

(e) *ASTM International*, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959, 877–909–2786, <http://www.astm.org>;

* * * * *

(6) ASTM A134–96 (Reapproved 2012), Standard Specification for Pipe, Steel, Electric-Fusion (Arc)-Welded (Sizes NPS 16 and Over) (“ASTM A 134”), (approved March 1, 2012), incorporation by reference approved for § 56.60–1;

* * * * *

(10) ASTM A179/A179M–90a (Reapproved 2012), Standard Specification for Seamless Cold-Drawn Low-Carbon Steel Heat-Exchanger and Condenser Tubes (“ASTM A 179”), (approved March 1, 2012), incorporation by reference approved for § 56.60–1;

* * * * *

(17) ASTM A214/A214M–96 (Reapproved 2012), Standard Specification for Electric-Resistance-Welded Carbon Steel Heat-Exchanger and Condenser Tubes (“ASTM A 214”), (approved March 1, 2012), incorporation by reference approved for § 56.60–1;

* * * * *

(40) ASTM A 536–84 (Reapproved 2009), Standard Specification for Ductile Iron Castings (“ASTM A 536”), (approved May 1, 2009), incorporation by reference approved for § 56.60–1;

(41) ASTM A 575–96 (Reapproved 2007), Standard Specification for Steel

Bars, Carbon, Merchant Quality, M-Grades (“ASTM A 575”), (approved September 1, 2005), incorporation by reference approved for § 56.60–2;

(42) ASTM A576–90b (Reapproved 2012), Standard Specification for Steel Bars, Carbon, Hot-Wrought, Special Quality (“ASTM A576”), (approved March 1, 2012), incorporation by reference approved for § 56.60–2;

* * * * *

(69) ASTM F682–82a (Reapproved 2008), Standard Specification for Wrought Carbon Steel Sleeve-Type Pipe Couplings (“ASTM F 682”), (approved November 1, 2008), incorporation by reference approved for § 56.60–1;

(70) ASTM F1006–86 (Reapproved 2008), Standard Specification for Entrainment Separators for Use in Marine Piping Applications (“ASTM F 1006”), (approved November 1, 2008), incorporation by reference approved for § 56.60–1;

(71) ASTM F1007–86 (Reapproved 2007), Standard Specification for Pipeline Expansion Joints of the Packed Slip Type for Marine Application (“ASTM F 1007”), (approved December 1, 2007), incorporation by reference approved for § 56.60–1;

(72) ASTM F1020–86 (Reapproved 2011), Standard Specification for Line-Blind Valves for Marine Applications (“ASTM F 1020”), (approved April 1, 2011), incorporation by reference approved for § 56.60–1;

(73) ASTM F1120–87 (Reapproved 2010), Standard Specification for Circular Metallic Bellows Type Expansion Joints for Piping Applications (“ASTM F 1120”), (approved May 1, 2010), incorporation by reference approved for § 56.60–1;

(74) ASTM F1123–87 (Reapproved 2010), Standard Specification for Non-Metallic Expansion Joints (“ASTM F 1123”), (approved March 1, 2010), incorporation by reference approved for § 56.60–1;

(75) ASTM F1139–88 (Reapproved 2010), Standard Specification for Steam Traps and Drains (“ASTM F 1139”), (approved March 1, 2010), incorporation by reference approved for § 56.60–1;

(76) ASTM F1172–88 (Reapproved 2010), Standard Specification for Fuel Oil Meters of the Volumetric Positive Displacement Type (“ASTM F 1172”), (approved March 1, 2010), incorporation by reference approved for § 56.60–1;

* * * * *

(78) ASTM F1199–88 (Reapproved 2010), Standard Specification for Cast (All Temperatures and Pressures) and Welded Pipe Line Strainers (150 psig and 150 °F Maximum) (“ASTM F 1199”), (approved March 1, 2010),

incorporation by reference approved for § 56.60–1;

(79) ASTM F1200–88 (Reapproved 2010), Standard Specification for Fabricated (Welded) Pipe Line Strainers (Above 150 psig and 150 °F) (“ASTM F 1200”), (approved March 1, 2010), incorporation by reference approved for § 56.60–1;

(80) ASTM F1201–88 (Reapproved 2010), Standard Specification for Fluid Conditioner Fittings in Piping Applications above 0 °F (“ASTM F 1201”), (approved May 1, 2010), incorporation by reference approved for § 56.60–1;

* * * * *

PART 76—FIRE PROTECTION EQUIPMENT

■ 19. The authority citation for part 76 continues to read as follows:

Authority: 46 U.S.C. 3306; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

■ 20. In § 76.01–2, revise paragraphs (b), (c), and (d) to read as follows:

§ 76.01–2 Incorporation by reference.

* * * * *

(b) *ASTM International*, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959, 877–909–2786, <http://www.astm.org>.

(1) *ASTM F1121–87* (Reapproved 2010), Standard Specification for International Shore Connections for Marine Fire Applications (“ASTM F 1121”), (approved March 1, 2010), incorporation by reference approved for § 76.10–10.

(2) [Reserved]

(c) *National Fire Protection Association (NFPA)*, 1 Batterymarch Park, Quincy, MA 02169–7471, 617–770–3000, <http://nfp.org>.

(1) *NFPA 13–1996*, Standard for the Installation of Sprinkler Systems (“NFPA 13”), incorporation by reference approved for §§ 76.25–1; 76.25–90.

(2) [Reserved]

(d) *Underwriters Laboratories Inc. (UL)*, 12 Laboratory Drive, Research Triangle Park, NC 27709–3995, 919–549–1400, <http://www.ul.com>.

(1) *UL 19 Standard for Safety, Lined Fire Hose and Hose Assemblies* (“UL 19”) (2001), incorporation by reference approved for § 76.10–10.

(2) [Reserved]

PART 95—FIRE PROTECTION EQUIPMENT

■ 21. The authority citation for part 95 continues to read as follows:

Authority: 46 U.S.C. 3306; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277;

Department of Homeland Security Delegation No. 0170.1.

■ 22. In § 95.01–2, revise paragraph (b) introductory text and paragraph (b)(1) to read as follows:

§ 95.01–2 Incorporation by reference.

* * * * *

(b) ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959, 877–909–2786, <http://www.astm.org>.

(1) ASTM F1121–87 (Reapproved 2010), Standard Specification for International Shore Connections for Marine Fire Applications, (approved March 1, 2010), incorporation by reference approved for § 95.10–10.

* * * * *

PART 108—DESIGN AND EQUIPMENT

■ 23. The authority citation for part 108 continues to read as follows:

Authority: 43 U.S.C. 1333; 46 U.S.C. 3102, 3306; Department of Homeland Security Delegation No. 0170.1.

24. In § 108.101, in the table in paragraph (b), revise the first, second, and fifth entry to read as follows:

§ 108.101 Incorporation by reference.

* * * * *

(b) * * *

ASTM International

100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959, 877–909–2786, <http://www.astm.org>.

*	*	*	*	*	*	*
ASTM F1121–87 (Reapproved 2010), Standard Specification for International Shore Connections for Marine Fire Applications, (approved March 1, 2010)						108.427
*	*	*	*	*	*	*

PART 153—SHIPS CARRYING BULK LIQUID, LIQUEFIED GAS, OR COMPRESSED GAS HAZARDOUS MATERIALS

■ 25. The authority citation for part 153 continues to read as follows:

Authority: 46 U.S.C. 3703; Department of Homeland Security Delegation No. 0170.1. Section 153.40 issued under 49 U.S.C. 5103. Sections 153.470 through 153.491, 153.1100 through 153.1132, and 153.1600 through 153.1608 also issued under 33 U.S.C. 1903 (b).

■ 26. Amend § 153.4 by revising paragraph (b) and adding paragraph (c) as follows:

(b) American National Standards Institute (ANSI), 25 West 43rd Street, 4th Floor, New York, NY 10036, <http://www.ansi.org>.

(1) ANSI B16.5, Pipe Flanges and Flanged Fittings, 1988, incorporation by reference approved for § 153.940.

(2) ANSI B16.24, Bronze Pipe Flanges and Flanged Fittings, 1979, incorporation by reference approved for § 153.940.

(3) ANSI B16.31, Non-Ferrous Flanges, 1971, incorporation by reference approved for § 153.940.

(c) American Society for Testing and Materials (ASTM), 100 Barr Harbor Drive, West Conshohocken, PA 19428–2959, 877–909–2786, <http://www.astm.org>.

(1) ASTM F 1122–87 (1992), Standard Specification for Quick Disconnect Couplings, incorporation by reference approved for § 153.940.

(2) ASTM F1271–90 (Reapproved 2012), Standard Specification for Spill Valves for Use in Marine Tank Liquid Overpressure Protections Applications (approved May 1, 2012), incorporation by reference approved for § 153.365.

PART 160—LIFESAVING EQUIPMENT

■ 27. The authority citation for part 160 continues to read as follows:

Authority: 46 U.S.C. 2103, 3306, 3703 and 4302; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; 49 CFR 1.46.

■ 28. Revise § 160.077–5 to read as follows:

§ 160.077–5 Incorporation by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the **Federal Register** in accordance with 5 U.S.C. 552(a). To enforce any edition other than that specified in paragraph (b) of this section, the Coast Guard must publish a notice of change in the **Federal Register** and make the material available to the public. All approved material is on file at the U.S. Coast Guard, Office of Design and Engineering Standards (CG–ENG), 2100 2nd Street SW., Stop 7126, Washington, DC 20593–7126 or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. All material is available from the sources listed below.

(b) ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959, 877–909–2786, <http://www.astm.org>.

(1) ASTM B 117–97, Standard Practice for Operating Salt Spray (Fog) Apparatus, into § 160.077–11.

(2) ASTM D 751–95, Standard Test Methods for Coated Fabrics, incorporation by reference approved for § 160.077–19.

(3) ASTM D1434–82 (Reapproved 2009) ε¹, Standard Test Method for Determining Gas Permeability Characteristics of Plastic Film and Sheeting (approved May 1, 2009), incorporation by reference approved for § 160.077–19.

(c) DLA Document Services, 700 Robbins Avenue, Building 4/D, Philadelphia, PA 19111–5094, 215–697–6396, <http://assistdocs.com>.

(1) In Federal Test Method Standard No. 191 the following test methods:

(i) Method 5100, Strength and Elongation, Breaking of Woven Cloth; Grab Method.

(ii) Method 5132, Strength of Cloth, Tearing; Falling-Pendulum Method.

(iii) Method 5134, Strength of Cloth, Tearing; Tongue Method.

(iv) Method 5804.1, Weathering Resistance of Cloth; Accelerated Weathering Method.

(v) Method 5762, Mildew Resistance of Textile Materials; Soil Burial Method.

(2) Federal Standard No. 751, Stitches, Seams, and Stitching.

(3) MIL–L–24611(SH), Life Preserver Support Package for Life Preserver, MK 4.

(d) National Institute of Standards and Technology (NIST) (formerly National Bureau of Standards), 100 Bureau Drive, Stop 1070, Gaithersburg, MD 20899–1070, 301–975–6478, <http://www.nist.gov>.

(1) “The Universal Color Language” and “The Color Names Dictionary” in *Color: Universal Language and Dictionary of Names*, National Institute of Standards Special Publication 440.

(2) [Reserved.]

(e) Underwriters Laboratories Inc. (UL), 12 Laboratory Drive, Research Triangle Park, NC 27709–3995, 919–549–1400, <http://www.ul.com>.

(1) UL 1191, Components for Personal Flotation Devices.

(2) UL 1517, Standard for Hybrid Personal Flotation Devices (November 12, 1984), incorporation by reference approved for 46 CFR 160.077–5(e)(2); 160.077–11(a)(5)(ii) and (g)(1); 160.077–15(b)(12); 160.077–17(b)(9); 160.077–19(a)(5) and (b)(1) through (18); 160.077–21(c)(1) through (5); 160.077–23(h)(4) through (7); 160.077–27(e)(1) and (4); and 160.077–29(c)(5), (7), and (9), and (d)(1) and (5).

■ 29. Revise § 160.176–4 to read as follows:

§ 160.176–4 Incorporation by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a). To enforce any edition other than that specified in paragraph (b) of this section, the Coast Guard must publish a notice of change in the **Federal Register** and make the material available to the public. All approved material is on file at the U.S. Coast Guard, Office of Design and Engineering Standards (CG–ENG), 2100 2nd Street SW., Stop 7126, Washington, DC 20593–7126 or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. All material is available from the sources listed below.

(b) ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959, 877–909–2786, <http://www.astm.org>.

(1) ASTM B 117–97, Standard Practice for Operating Salt Spray (Fog) Apparatus, incorporation by reference approved for §§ 160.176–8; 160.176–13.

(2) ASTM D 751–95, Standard Test Methods for Coated Fabrics, incorporation by reference approved for § 160.176–13.

(3) ASTM D 975–98, Standard Specification for Diesel Fuel Oils, incorporation by reference approved for § 160.176–13.

(4) ASTM D1434–82 (Reapproved 2009)e¹, Standard Test Method for Determining Gas Permeability Characteristics of Plastic Film and Sheeting—(approved May 1, 2009), incorporation by reference approved for § 160.176–13.

(c) Federal Aviation Administration, Aircraft Certification Service, 800 Independence Avenue SW., Washington, DC 20591, 202–385–6346, http://www.faa.gov/aircraft/air_cert/design_approvals/tso.

(1) TSO–C13d, Federal Aviation Administration Standard for Life Preservers, January 3, 1983, incorporation by reference approved for § 160.176–8.

(2) [Reserved]

(d) DLA Document Services, 700 Robbins Avenue, Building 4/D, Philadelphia, PA 19111–5094, 215–697–6396, <http://www.asistdocs.com>.

(1) In Federal Test Method Standard No. 191A (dated July 20, 1978) the following methods:

(i) Method 5100, Strength and Elongation, Breaking of Woven Cloth; Grab Method, incorporation by reference approved for § 160.176–13.

(ii) Method 5132, Strength of Cloth, Tearing; Falling-Pendulum Method, incorporation by reference approved for § 160.176–13.

(iii) Method 5134, Strength of Cloth, Tearing; Tongue Method, incorporation by reference approved for § 160.176–13.

(iv) Method 5804.1, Weathering Resistance of Cloth; Accelerated Weathering Method, incorporation by reference approved for § 160.176–8.

(v) Method 5762, Mildew Resistance of Textile Materials; Soil Burial Method, incorporation by reference approved for § 160.176–8.

(2) Federal Standard No. 751a, Stitches, Seams, and Stitching, January 25, 1965, incorporation by reference

(3) MIL–L–24611—Life Preserver Support Package For Life Preserver, MK 4, dated May 18, 1982, incorporation by reference approved for § 160.176–8.

(e) National Institute of Standards and Technology (NIST) (formerly National Bureau of Standards), c/o Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, 202.512.1800, <http://www.gpo.gov>.

(1) Special Pub. 440, *Color: Universal Language and Dictionary of Names*; “The Universal Color Language” and “The Color Names Dictionary”, 1976, incorporation by reference approved for § 160.176–9.

(2) [Reserved]

(f) Underwriters Laboratories Inc. (UL), 12 Laboratory Drive, Research Triangle Park, NC 27709–3995, 919–549–1400, <http://www.ul.com>.

(1) UL 1191, “Components for Personal Flotation Devices”, November 11, 1984, incorporation by reference approved for §§ 160.176–8; 160.176–13.

(2) [Reserved]

PART 162—ENGINEERING EQUIPMENT

■ 30. The authority citation for part 162 continues to read as follows:

Authority: 33 U.S.C. 1321(j), 1903; 46 U.S.C. 3306, 3703, 4104, 4302; E.O. 12234, 45

FR 58801, 3 CFR, 1980 Comp., p. 277; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; Department of Homeland Security Delegation No. 0170.1.

■ 31. In § 162.027–1, revise paragraph (b) to read as follows:

§ 162.027–1 Incorporation by reference.

* * * * *

(b) ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959, 877–909–2786, <http://www.astm.org>.

(1) ASTM F1546/F1546 M–96 (Reapproved 2012), Standard Specification for Fire Hose Nozzles (ASTM F 1546) (approved May 1, 2012), incorporation by reference approved for §§ 162.027–2; 162.027–3.

(2) [Reserved]

PART 193—FIRE PROTECTION EQUIPMENT

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

Authority: 46 U.S.C. 2213, 3102, 3306; E.O. 12234, 45 FR 58801, 3 CFR, 1980 Comp., p. 277; Department of Homeland Security Delegation No. 0170.1.

■ 33. In § 193.01–3, revise paragraph (b) introductory text and paragraph (b)(1) to read as follows:

§ 193.01–3 Incorporation by reference.

* * * * *

(b) ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959, 877–909–2786, <http://www.astm.org>.

(1) ASTM F1121–87 (Reapproved 2010), Standard Specification for International Shore Connections for Marine Fire Applications, (approved March 1, 2010), incorporation by reference approved for § 193.10–10.

* * * * *

Dated: February 11, 2013.

Kathryn A. Sinniger,
Chief, Office of Regulations and
Administrative Law U.S. Coast Guard.

[FR Doc. 2013–03724 Filed 2–26–13; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2012–0308; FRL–9379–9]

Pyroxasulfone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pyroxasulfone

in or on soybeans. K-I Chemical U.S.A., Inc., requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 27, 2013. Objections and requests for hearings must be received on or before April 29, 2013, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0308, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Kathryn Montague, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (703) 305-1243; email address: montague.kathryn@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through

the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-id?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0308 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before April 29, 2013. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0308, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- **Mail:** OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001.

- **Hand Delivery:** To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of May 23, 2012 (77 FR 30481) (FRL-9347-8), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide

petition (PP 2F8005) by K-I Chemical U.S.A., Inc., c/o Landis International, Inc., 3185 Madison Hwy., P.O. Box 5126, Valdosta, GA 31603-5126. The petition requested that EPA establish tolerances in 40 CFR part 180 for residues of the herbicide pyroxasulfone, 3-[(5-(difluoromethoxy)-1-methyl-3-(trifluoromethyl) pyrazole-4-ylmethanesulfonyl]-4,5-dihydro-5,5-dimethyl-1,2-oxazole, and its metabolites M-3, 5-difluoromethoxy-1-methyl-3-trifluoromethyl-1H-pyrazol-4-carboxylic acid; M-25, 5-difluoromethoxy-3-trifluoromethyl-1H-pyrazol-4-ylmethanesulfonic acid; and M-28, 3-[1-carboxy-2-(5,5-dimethyl-4,5-dihydroisoxazol-3-ylthio)ethylamino]-3-oxopropanoic acid, calculated as the stoichiometric equivalent of pyroxasulfone, in or on soybean, seed at 0.07 parts per million (ppm). The petition also requested that tolerances be established for residues of pyroxasulfone, 3-[(5-(difluoromethoxy)-1-methyl-3-(trifluoromethyl) pyrazole-4-ylmethanesulfonyl]-4,5-dihydro-5,5-dimethyl-1,2-oxazole, and its metabolites M-1, 5-difluoromethoxy-1-methyl-3-trifluoromethyl-1H-pyrazol-4-ylmethanesulfonic acid; M-3, 5-difluoromethoxy-1-methyl-3-trifluoromethyl-1H-pyrazol-4-carboxylic acid; and M-25, 5-difluoromethoxy-3-trifluoromethyl-1H-pyrazol-4-ylmethanesulfonic acid, calculated as the stoichiometric equivalent of pyroxasulfone in or on soybean, forage at 1.5 ppm and soybean, hay at 2.0 ppm. That document referenced a summary of the petition prepared by K-I Chemical U.S.A., Inc., the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA is establishing tolerances for residues of the herbicide pyroxasulfone and its metabolites as requested by the petitioner, except that the tolerance for residues in or on soybean, forage is lowered to 1.0 ppm and the tolerance for residues in or on soybean, seed is lowered to 0.06 ppm. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will

result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue.* * *

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for pyrooxasulfone including exposure resulting from the tolerances established by this action. EPA’s assessment of exposures and risks associated with pyrooxasulfone follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Pyrooxasulfone acute toxicity to mammals is low by all routes of exposure. Subchronic and chronic oral toxicity testing of pyrooxasulfone in mice, rats, and dogs produced a variety of adverse effects in several target organs. Effects seen in animal studies included cardiac toxicity (increased cardiomyopathy in mice and rats), liver toxicity (centrilobular hepatocellular hypertrophy, histopathological, and/or clinical pathological indicators), neurotoxicity characterized by axonal/myelin degeneration in the sciatic nerve (dog, mouse, and rat) and spinal cord sections (dog), skeletal muscle myopathy, kidney toxicity (increased incidence of chronic progressive nephropathy in dogs and retrograde nephropathy in mice), urinary bladder mucosal hyperplasia, inflammation, and urinary bladder transitional cell papillomas (rats). Decreased body weight and enzyme changes were noted in some studies. Immunotoxicity studies in rats and mice showed no evidence of

immunotoxic effects from pyrooxasulfone.

Pyrooxasulfone was moderately toxic to rats following a 4-week dermal exposure producing local inflammation and systemic effects of minimal to mild cardiac myofiber degeneration at the limit dose. No adverse effects were noted in a 28-day inhalation study at the highest-dose tested.

Pyrooxasulfone did not exhibit developmental toxicity in the rat developmental toxicity study and exhibited only slight developmental toxicity in rabbits (reduced fetal weight and resorptions) at the limit dose. However, developmental effects were noted in post-natal day (PND) 21 offspring in the rat developmental neurotoxicity (DNT) study characterized as decreased brain weight and morphometric changes. Developmental effects in the rabbit developmental study and DNT study occurred in the absence of maternal toxicity, indicating potential increased quantitative susceptibility of offspring. In a reproductive toxicity in rats reduced pup weight and body weight gains during lactation occurred at similar or higher doses causing pronounced maternal toxicity (reduced body weight, body weight gain, and food consumption and increased kidney weight, cardiomyopathy, and urinary bladder mucosal hyperplasia with inflammation).

In cancer studies in mice and rats, renal tubular adenomas were observed in male mice and urinary bladder transitional cell papillomas were observed in male rats. The kidney adenomas in male mice were determined to be spontaneous and not treatment-related based on the following considerations:

1. Absence of any cytotoxicity (degeneration or individual cell necrosis) in studies ranging from 14 days to 18 months at doses up to 15,000 ppm.
2. Absence of cell regeneration leading to precursor lesions such as atypical tubular hyperplasia at all time points and doses up to 15,000 ppm.
3. Lack of exacerbation of chronic progressive nephropathy, a spontaneous disease in rodents that results in cell regeneration which can result in renal tubule tumors in chronic studies.
4. Lack of a clear dose response in the distribution of tumors between test substance treated groups.

The urinary bladder tumors seen in male rats were determined to be a threshold effect. Pyrooxasulfone exposure causes the growth of crystals in the urinary tract with subsequent calculi formation resulting in cellular

damage. Crystal formation in the absence of calculi is not associated with hyperplasia or urinary bladder tumors; therefore, the formation of urinary bladder calculi is the prerequisite for subsequent hyperplasia and neoplasia. In other words, urinary bladder tumors do not develop at doses too low to produce calculi. There is also a clear threshold of 1,000 ppm (42.55 milligrams/kilogram/day (mg/kg/day)) for development of calculi and tumorigenesis. The point of departure (POD) of 50 ppm (2.0 mg/kg/day) selected for chronic risk assessment is not expected to result in urinary bladder calculi formation, which is a prerequisite for subsequent hyperplasia and neoplasia. Therefore, the Agency has determined that the quantification of risk using a non-linear approach (i.e., Reference dose (RfD)) will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to pyrooxasulfone. There is no concern for mutagenicity.

Specific information on the studies received and the nature of the adverse effects caused by pyrooxasulfone as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document “Pyrooxasulfone Human Health Risk Assessment for Use on Soybeans,” p. 34, in docket ID number EPA-HQ-OPP-2012-0308.

B. Toxicological Points of Departure/ Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies the toxicological POD and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a RfD—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the

general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for pyrooxasulfone used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** issue of February 29, 2012 (77 FR 12207) (FRL-9334-2).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to pyrooxasulfone, EPA considered exposure under the petitioned-for tolerances as well as all existing pyrooxasulfone tolerances in 40 CFR 180.659. EPA assessed dietary exposures from pyrooxasulfone in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Such effects were identified for pyrooxasulfone. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA assumed 100% of the crop was treated with pyrooxasulfone and that residues of the parent and the relevant metabolites of concern on soybeans are present at tolerance levels.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA (NHANES/WWEIA). As to residue levels in food, EPA made the same assumptions as in the acute dietary exposure assessment.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that a non-linear RfD approach is appropriate for assessing cancer risk to pyrooxasulfone. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.i.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for pyrooxasulfone. Tolerance level residues for soybean and 100 PCT were assumed for soybean commodities in the dietary assessment.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary

exposure analysis and risk assessment for pyrooxasulfone in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of pyrooxasulfone. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of pyrooxasulfone for acute exposures are estimated to be 17 parts per billion (ppb) for surface water and 210 ppb for ground water. EDWCs of pyrooxasulfone for chronic exposures for non-cancer assessments are estimated to be 3.2 ppb for surface water and 174 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 210 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 174 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure. Pyrooxasulfone is not registered for any specific use patterns that would result in residential exposure.

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

EPA has not found pyrooxasulfone to share a common mechanism of toxicity with any other substances, and pyrooxasulfone does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that pyrooxasulfone does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The prenatal and postnatal toxicity database for pyrooxasulfone includes developmental toxicity studies in rats and rabbits, a DNT study in rats, and a 2-generation reproduction toxicity study in rats. As discussed in Unit III.A., evidence of increased susceptibility of fetuses and offspring was seen in the DNT study and developmental toxicity study in rabbits following in utero or postnatal exposure to pyrooxasulfone. No increased susceptibility was seen in the rat developmental or reproduction toxicity studies. In rabbits, developmental toxicity was only seen at the limit dose of 1,000 mg/kg/day as reduced fetal weight and increased fetal resorptions with a NOAEL of 500 mg/kg/day for these effects, compared to no maternal toxicity at these doses. In a DNT study in rats, offspring toxicity (decreased brain weight and orphometric changes on PND 21) was seen at 300 mg/kg/day compared to no maternal toxicity at 900 mg/kg/day. The degree of concern for the increased susceptibility seen in these studies is low and there are no residual uncertainties based on the following considerations:

i. The increased susceptibility is occurring at high doses.

ii. NOAELs and LOAELs have been identified for all effects of concern, and thus a clear dose response has been well defined.

iii. The PODs selected for risk assessment are protective of the fetal/offspring effects.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for pyroxasulfone is complete.

ii. Pyroxasulfone is a neurotoxic chemical and there is evidence of increased susceptibility of offspring with regard to neurotoxic effects in the rat DNT study. There is also evidence of increased susceptibility of fetuses/offspring with regard to non-neurotoxic effects in the rabbit developmental toxicity study. However, the concern for the increased susceptibility is low for the reasons stated in Unit III.D.2., and EPA did not identify any residual uncertainties after establishing toxicity endpoints and traditional uncertainty factors (UFs) to be used in the risk assessment for pyroxasulfone.

iii. There are no residual uncertainties in the exposure database. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues), and EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to pyroxasulfone in drinking water. These assessments will not underestimate the exposure and risks posed by pyroxasulfone.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to pyroxasulfone will occupy 3.6% of the aPAD for infants less than 1 year old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to pyroxasulfone from food and water will utilize 48% of the cPAD for infants less than 1 year old, the population group receiving the greatest exposure. There are no residential uses for pyroxasulfone.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). A short-term adverse effect was identified; however, pyroxasulfone is not registered for any

use patterns that would result in short-term residential exposure; therefore, no further assessment of short-term risk is necessary.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term adverse effect was identified; however, pyroxasulfone is not registered for any use patterns that would result in intermediate-term residential exposure; therefore, no further assessment of intermediate-term risk is necessary.

5. *Aggregate cancer risk for U.S. population.* As explained in Unit III.A., the Agency has determined that the quantification of risk using a non-linear (i.e., RfD) approach will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to pyroxasulfone. Therefore, based on the results of the chronic risk assessment discussed in Unit III.E.2., pyroxasulfone is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to pyroxasulfone residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (a liquid chromatography/mass spectrometry/mass spectrometry (LC/MS/MS) method) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: residuemethods@epa.gov.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program,

and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for pyroxasulfone.

C. Revisions to Petitioned-for Tolerances

EPA has revised the tolerance levels for soybean, forage and soybean, seed as based on analysis of the field trial data using the tolerance MRL calculator in accordance with the Organization for Economic Cooperation and Development's "MRL Calculator User Guide Standard Operating Procedure (SOP)." Soybean, forage was decreased from 1.5 ppm to 1.0 ppm for residues of pyroxasulfone and its metabolites M-1, M-3, and M-25 and soybean, seed was decreased from 0.07 ppm to 0.06 ppm for residues of pyroxasulfone and its metabolites M-3, M-25, and M-28.

V. Conclusion

Therefore, tolerances are established for residues of the herbicide pyroxasulfone, 3-[[[5-(difluoromethoxy)-1-methyl-3-(trifluoromethyl)-1H-pyrazol-4-yl]methyl]sulfonyl]-4,5-dihydro-5,5-dimethylisoxazole, and its metabolites, 5-(difluoromethoxy)-1-methyl-3-(trifluoromethyl)-1H-pyrazol-4-ylmethanesulfonic acid (M-1); 5-(difluoromethoxy)-1-methyl-3-(trifluoromethyl)-1H-pyrazol-4-carboxylic acid (M-3); and [5-(difluoromethoxy)-3-(trifluoromethyl)-1H-pyrazol-4-yl]methanesulfonic acid (M-25), calculated as the stoichiometric equivalent of pyroxasulfone, in or on soybean, forage at 1.0 ppm; soybean, hay at 2.0 ppm; and pyroxasulfone, 3-[[[5-(difluoromethoxy)-1-methyl-3-(trifluoromethyl)-1H-pyrazol-4-yl]methyl]sulfonyl]-4,5-dihydro-5,5-dimethylisoxazole, and its metabolites, 5-(difluoromethoxy)-1-methyl-3-(trifluoromethyl)-1H-pyrazol-4-carboxylic acid (M-3); [5-(difluoromethoxy)-3-(trifluoromethyl)-1H-pyrazol-4-yl]methanesulfonic acid (M-25); and 3-[1-carboxy-2-(5,5-dimethyl-4,5-dihydroisoxazol-3-ylthio)ethylamino]-3-oxopropanoic acid (M-28), calculated as the stoichiometric equivalent of pyroxasulfone in or on soybean, seed at 0.06 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the

Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary

consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: February 20, 2013.

Lois Rossi,
Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.659:

■ a. Add alphabetically the following commodities to the table in paragraph (a)(2).

■ b. Add a new paragraph (a)(3).

The additions read as follows.

§ 180.659 Pyroxasulfone; tolerances for residues.

- (a) * * *
- (2) * * *

Commodity	Parts per million
* * * * *	
Soybean, forage	1.0
Soybean, hay	2.0

(3) Tolerances are established for residues of the herbicide pyroxasulfone, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of pyroxasulfone, 3-[[[5-(difluoromethoxy)-1-methyl-3-(trifluoromethyl)-1H-pyrazol-4-yl]methyl]sulfonyl]-4,5-dihydro-5,5-dimethylisoxazole, and its metabolites, 5-(difluoromethoxy)-1-methyl-3-(trifluoromethyl)-1H-pyrazol-4-carboxylic acid (M-3); [5-

(difluoromethoxy)-3-(trifluoromethyl)-1H-pyrazol-4-yl]methanesulfonic acid (M-25); and 3-[1-carboxy-2-(5,5-dimethyl-4,5-dihydroisoxazol-3-ylthio)ethylamino]-3-oxopropanoic acid (M-28), calculated as the stoichiometric equivalent of pyroxasulfone, in or on the commodity.

Commodity	Parts per million
Soybean, seed	0.06

* * * * *
[FR Doc. 2013-04559 Filed 2-26-13; 8:45 am]
BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2011-1002; FRL-9379-6]

Pyraflufen-ethyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pyraflufen-ethyl in or on multiple commodities which are identified and discussed later in this document. Nichino America, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 27, 2013. Objections and requests for hearings must be received on or before April 29, 2013, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2011-1002, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Bethany Benbow, Registration Division

(7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (703) 347-8072; email address: benbow.bethany@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/textidx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2011-1002 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before April 29, 2013. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be

disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2011-1002, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of March 14, 2012 (77 FR 15012) (FRL-9335-9), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1F7944) by Nichino America, Inc., 4550 New Linden Hill Road Suite 501, Wilmington, DE 19808. The petition requested that 40 CFR 180.585 be amended by establishing tolerances for residues of the herbicide pyraflufen-ethyl, ethyl 2-[2-chloro-5-(4-chloro-5-difluoromethoxy)-1-methyl-1H-pyrazol-3-yl]-4-fluorophenoxy] acetate and its acid metabolite, E-1, 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methyl-1H-pyrazol-3-yl)-4-fluorophenoxyacetic acid, expressed in terms of the parent, in or on hop, dried cone at 0.01 parts per million (ppm); peanut at 0.01 ppm; peanut, hay at 0.07 ppm; peanut, meal at 0.01 ppm; and peanut, refined oil at 0.01 ppm. That document referenced a summary of the petition prepared by Nichino America, Inc., the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA is establishing tolerances for peanut and peanut, hay but not establishing tolerances for hop, dried cone; peanut, meal; or peanut, refined oil. In addition, the current time-limited tolerances established for combined residues of pyraflufen-ethyl and metabolite E-1 in

milk and the meat by-products of cattle, goat, horse, and sheep at 0.02 ppm are being revised to permanent tolerances for combined residues of pyraflufen-ethyl and metabolites E-1 and E-9 at 0.03 ppm. Finally, permanent tolerances for combined residues of pyraflufen-ethyl and metabolites E-1 and E-9 are also being set for the fat and meat of cattle, goat, horse, and sheep at 0.03 ppm. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for pyraflufen-ethyl including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with pyraflufen-ethyl follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Pyraflufen-ethyl exhibits relatively low acute toxicity from oral, dermal, and inhalation exposure. It produces moderate eye

irritation and is not a dermal irritant or a dermal sensitizer. Following repeated short-term and chronic oral dosing, the liver, kidney, and hematopoietic system are the target organs for pyraflufen-ethyl in the rat and/or mouse. The rabbit appears to be the most sensitive species in the toxicity database with adverse effects, including mortality. Adverse effects were not noted in the dog following oral exposure or in the rat following dermal exposure. There was no evidence of increased susceptibility following pre-natal exposure to rats and rabbits in the developmental toxicity studies or following pre- and post-natal exposure to rats in the multi-generation reproduction study. Although not mutagenic in the mutagenicity battery or carcinogenic in the rat, pyraflufen-ethyl is classified as “Likely to be Carcinogenic to Humans” due to a compound-related increase in incidence of hepatocellular adenomas, carcinomas, and/or hepatoblastomas in male and female mice. A linear low-dose extrapolation approach is used to estimate human cancer risk (Q₁*) based on combined hepatocellular adenomas, carcinomas, and/or hepatoblastomas seen in male mice.

Since the last risk assessment, the neurotoxicity battery was reviewed and

determined to be negative for both acute and subchronic neurotoxicity. Additionally, the Agency reviewed an immunotoxicity study that showed a decreased immune response (decreases of anti-sheep red blood cell (SRBC) antibody forming cell (AFC) response in male rats), only at a dose level approaching the limit dose.

Specific information on the studies received and the nature of the adverse effects caused by pyraflufen-ethyl as well as the no observed adverse effect levels (NOAELs) and the lowest observed adverse effect levels (LOAELs) from the toxicity studies can be found at <http://www.regulations.gov> in document Pyraflufen-ethyl—Human Health Risk Assessment for a Section 3 Registration of New Food Uses on Hops and Peanuts at pages 44–48 in docket ID number EPA–HQ–OPP–2011–1002.

B. Toxicological Points of Departure/ Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological

POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for pyraflufen-ethyl used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR PYRAFLUFEN-ETHYL FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (General population including infants and children).		None	An endpoint attributable to a single dose was not identified for pyraflufen-ethyl from the available data.
Chronic dietary (All populations)	NOAEL = 20 mg/kg/day. UF _A = 10x UF _H = 10x FQPA SF = 1x	Chronic RfD = 0.20 mg/kg/day cPAD = 0.20 mg/kg/day.	Mouse carcinogenicity study. LOAEL = 98 mg/kg/day based on liver toxicity.
Incidental oral short-term (1 to 30 days).	NOAEL = 20 mg/kg/day. UF _A = 10x UF _H = 10x FQPA SF = 1x	LOC for MOE = 100	Developmental toxicity—rabbit. Maternal LOAEL = 60 mg/kg/day based on decreases in body weight and food consumption, gastrointestinal (GI) observations, and abortions.
Dermal short-term (1 to 30 days); Dermal intermediate-term (1 to 6 months).		None	28-day dermal toxicity—rats. No dermal or systemic toxicity was seen at the limit dose (1,000 mg/kg/day).

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR PYRAFLUFEN-ETHYL FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Inhalation short-term (1 to 30 days) and Intermediate and long term (1–6 months).	Inhalation (or oral) study NOAEL = 20 mg/kg/day (inhalation absorption rate = 100%). UF _A = 10x UF _H = 10x FQPA SF = 1x	Residential LOC for MOE = 100	Developmental toxicity-rabbit. LOAEL = 60 mg/kg/day based on decreases in body weight and food consumption, GI observations, and abortions.
Cancer (Oral, dermal, inhalation)	Classification: “Likely to be Carcinogenic to Humans” by the oral route. Q ₁ * = 3.32 × 10 ⁻² (mg/kg/day) ⁻¹		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest observed adverse effect level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no observed adverse effect level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to pyraflufen-ethyl, EPA considered exposure under the petitioned-for tolerances as well as all existing pyraflufen-ethyl tolerances in 40 CFR 180.585. EPA assessed dietary exposures from pyraflufen-ethyl in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for pyraflufen-ethyl; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the U.S. Department of Agriculture’s (USDA) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/ WWEIA). As to residue levels in food, EPA incorporated all current and proposed tolerances for combined residues of pyraflufen-ethyl and metabolite E-1 in plants and residues of pyraflufen-ethyl, metabolite E-1 and metabolite E-9 in animals and assumed 100% of crops were treated. The commodities of corn, wheat, soybeans, cottonseed, potatoes, pome fruit, stone fruit, pomegranates, olives, grapes, tree nuts, and pistachios were analyzed at 1/2 the combined levels of quantitation (LOQs) of the parent and metabolites for the residue values in the dietary assessment because the field trials showed that residues were lower than the LOQ. All other established and

proposed commodities were analyzed using tolerance-level residues. Because the commodity-specific processing studies did not show pyraflufen-ethyl concentration after processing, the chronic dietary exposure assessment did not incorporate processing factors for the following commodities: Treated corn grain, soybean seeds, wheat grain, apples, and grapes. However, default processing factors were used for dry potatoes (6.5X), peanut butter (1.89X), dried beef (1.92X), and corn syrup (1.5X). An empirical processing factor of 0.6X was used for cotton seed oil. The anticipated residue in meat, milk, fat, and meat byproducts was calculated to be 0.001 ppm. Chronic (non-cancer) dietary exposure from drinking water was determined based on a Tier 2 (surface water) drinking water estimate provided by the Environmental Fate and Effects Division (EFED). The chronic (annual average) estimate for drinking water was incorporated directly into the dietary assessment for the combined residues of pyraflufen-ethyl and its metabolic products, E-1, E-2, and E-3, which are the major residues present in the supporting studies.

iii. *Cancer.* Pyraflufen-ethyl is classified as “Likely to be Carcinogenic to Humans” by the oral route; therefore, a cancer dietary risk assessment was conducted. EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. If quantitative cancer risk assessment is appropriate, cancer risk may be quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or nonlinear approach is used and a cancer

RfD is calculated based on an earlier noncancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the data summarized in Unit III.A., EPA has concluded that pyraflufen-ethyl should be classified as “Likely to be Carcinogenic to Humans” and a linear approach has been used to quantify cancer risk.

All exposure inputs for the cancer assessment were the same as for the chronic dietary exposure assessment, except the estimated drinking water concentrations (EDWC). A Tier 2 drinking water (surface water) of a (30-year average) estimate for pyraflufen-ethyl and its metabolic products, E-1, E-2, and E-3, was incorporated directly into the dietary assessment to estimate chronic carcinogenic risk from drinking water containing pyraflufen-ethyl.

iv. *Anticipated residue information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for pyraflufen-ethyl in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of pyraflufen-ethyl. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of pyraflufen-ethyl acute exposures are estimated to be 0.640 parts per billion (ppb) for surface water and 0.0018 ppb for ground water. The estimated drinking water concentrations (EDWCs) of pyraflufen-ethyl for non-cancer chronic exposures are estimated to be 0.295 ppb for surface water and 0.0018 ppb for ground water. The EDWCs of pyraflufen-ethyl for chronic exposures for cancer assessments are estimated to be 0.268 ppb for surface water and 0.0018 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 0.295 ppb was used to assess the contribution to drinking water. For cancer dietary risk assessment, the water concentration of value 0.268 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Pyraflufen-ethyl is currently registered for the following uses that could result in residential exposures: Established ornamental turf lawns (residential, industrial, and institutional), parks, cemeteries, athletic fields, golf courses, sod farms, nurseries, ornamental plantings, and Christmas trees. EPA assessed residential handler exposure using the following assumptions: (1) Most residential uses will result in short-term (1–30 day) exposures, (2) residential handlers are assumed to be wearing short-sleeved shirts, short pants, shoes, and socks during pyraflufen-ethyl application, (3) various application methods may be used such as manually pressurized handwands, backpack sprayers, and hose-end sprayers.

When determining the potential for residential post-application exposure, the Agency considers residues from leaf to skin/hand residue transfer, children’s hand-to-mouth transfer, and exposure time. Because exposure to treated gardens and turf could be expected within the same day, adult post-application cancer exposure to treated trees and retail plants and turf were combined. The exposure assessment for treated plants is considered extremely conservative in that the plants are assumed to be treated the same day that residential post-application contact occurs, with no residue transfer between treatment and purchase of the plants. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at http://www.epa.gov/opp00001/science/USEPA-OPP-HED_Residential%20SOPs_Oct2012.pdf.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.” EPA has not found pyraflufen-ethyl to share a common mechanism of toxicity with any other substances, and pyraflufen-ethyl does not appear to produce a toxic metabolite which is also produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that pyraflufen-ethyl does not have a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA’s Web site at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different

additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is no evidence of increased susceptibility of rat or rabbit fetuses following *in utero* exposure in the developmental studies with pyraflufen-ethyl. There is no evidence of increased susceptibility of young rats in the pyraflufen-ethyl reproduction study and there are no residual uncertainties for pre- and/or postnatal exposure.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for pyraflufen-ethyl is complete.

ii. There is no indication that pyraflufen-ethyl is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that pyraflufen-ethyl results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% crop treated (CT) and tolerance-level residues for the proposed commodities, and residue inputs of 1/2 LOQ as refined estimates of the currently registered commodities. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to pyraflufen-ethyl in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of adults and children as well as incidental oral exposure of children. In addition, the residential exposure assessment is based on the updated 2012 Residential Standard Operating Procedures (SOPs) employing surrogate study data, including conservative exposure assumptions based on day 0 dermal/oral contact to turf and surfaces treated at the maximum application rate. These data are reliable and are not expected to underestimate risks to adults or children. The Residential SOPs are based upon reasonable “worst-case” assumptions and are not expected to underestimate risk. Although some of the residue values used in the dietary exposure assessment were refined, these assessments will not underestimate the exposure and risks posed by pyraflufen-ethyl.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, pyraflufen-ethyl is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to pyraflufen-ethyl from food and water will utilize < 1% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of pyraflufen-ethyl is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Pyraflufen-ethyl is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to pyraflufen-ethyl.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined chronic dietary and short-term residential exposures result in an adult (inhalation) non-cancer aggregate MOE of 290,000. The aggregate MOE for children 1–2 years old, including incidental oral exposures from treated turf, is 9,600. Because EPA's level of concern for pyraflufen-ethyl is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered

to be a background exposure level). An intermediate-term adverse effect was identified; however, pyraflufen-ethyl is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for pyraflufen-ethyl.

5. *Aggregate cancer risk for U.S. population.* The aggregate cancer risk assessment for the general U.S. population considers exposure estimates from dietary consumption of pyraflufen-ethyl in food and drinking water and exposure through residential uses of pyraflufen-ethyl. Exposures from residential uses are based on the lifetime average daily dose and assume an exposure period of 2 days per year and 35 years of exposure over a 78 year lifetime. Average food and water exposure to pyraflufen-ethyl was used in the aggregate assessment. Estimated cancer risk for the general U.S. population includes infants and children; therefore, a children's cancer risk estimate was not reported separately. The aggregate cancer risk estimate for pyraflufen-ethyl is 2.6×10^{-6} . EPA generally considers cancer risks in the range of one in one million (1×10^{-6}) or less to be negligible. The precision that can be assumed for cancer risk estimates is best described by rounding to the nearest integral order of magnitude on the log scale; for example, risks falling between 3×10^{-7} and 3×10^{-6} are expressed as risks in the range of 10^{-6} . Considering the precision with which cancer hazard can be estimated, the conservativeness of low-dose linear extrapolation, and the rounding procedure just described, cancer risk should generally not be assumed to exceed the benchmark level of concern of the range of 10^{-6} until the calculated risk exceeds approximately 3×10^{-6} . This is particularly the case where some conservatism is maintained in the exposure assessment. Although the pyraflufen-ethyl exposure risk assessment is somewhat refined, it retains significant conservatism due, among other things, to the assumption that 100% of registered crops are treated in the dietary cancer assessment and

100% dermal absorption was assumed in the residential exposure cancer assessment. Accordingly, EPA has concluded the cancer risk for all existing pyraflufen-ethyl uses and the uses associated with the tolerances established in this action falls within the range of 1×10^{-6} to 3×10^{-6} and is thus negligible. Therefore, the aggregate cancer risk estimate from pyraflufen-ethyl residues in food and drinking water is not of concern for the general U.S. population.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to pyraflufen-ethyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography-mass spectrometry (GC/MS)) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residue methods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for pyraflufen-ethyl.

C. Revisions to Petitioned-For Tolerances

Based on a lack of adequate residue data, the Agency is not granting tolerances for hops at this time. As permitted under 40 CFR 180.8, the petitioner has withdrawn its request for hop, dried cone tolerances.

In addition, the requested tolerances for peanut, meal and peanut, refined oil are not being granted since those residues will be covered by the proposed tolerance for peanut. Because peanut hay is fed to livestock and may affect residue levels, upon review of the data supporting the petitions, EPA determined that several livestock tolerances should be revised (from residues of the parent and metabolite E-1 in milk and meat by-products of cattle, goat, horse, and sheep at 0.02 ppm to residues of the parent and metabolites E-1 and E-9 at 0.03 ppm) and several new livestock tolerances should be established (residues of the parent and metabolites E-1 and E-9 in the fat and meat of cattle, goat, horse and sheep at 0.03 ppm). The Agency revised these tolerance levels based on analysis of the residue field trial data using the Organization for Economic Cooperation and Development (OECD) tolerance calculation.

Finally, based on data submitted with this petition, EPA is removing the time-limitations for these tolerances.

V. Conclusion

Therefore, permanent tolerances are established for the combined residues of pyraflufen-ethyl, metabolite E-1, and metabolite E-9 in or on (cattle, goat, horse, sheep) fat, meat, and meat by-products at 0.03 ppm; milk at 0.03 ppm; and new tolerances are established for the combined residues of pyraflufen-ethyl and metabolite E-1 in or on peanut at 0.01 ppm; and peanut, hay at 0.07 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under

Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides

and pests, Reporting and recordkeeping requirements.

Dated: February 20, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.585, revise paragraph (a) to read as follows:

§ 180.585 Pyraflufen-ethyl; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide, pyraflufen-ethyl, including its metabolites and degradates, in the commodities in the table below. Compliance with the plant commodity tolerance levels specified in the table is to be determined by measuring only the sum of the parent pyraflufen-ethyl, ethyl 2-[2-chloro-5-(4-chloro-5-difluoromethoxy)-1-methyl-1H-pyrazol-3-yl]-4-fluorophenoxy] acetate, and its acid metabolite, E-1, 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methyl-1H-pyrazol-3-yl)-4-fluorophenoxyacetic acid, calculated as the stoichiometric equivalent of pyraflufen-ethyl in or on the commodity. Compliance with the livestock commodity tolerance levels specified in the table is to be determined by measuring only the sum of the parent pyraflufen-ethyl, ethyl 2-[2-chloro-5-(4-chloro-5-difluoromethoxy)-1-methyl-1H-pyrazol-3-yl]-4-fluorophenoxy] acetate and its acid metabolites: E-1, 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methyl-1H-pyrazol-3-yl)-4-fluorophenoxyacetic acid, and E-9, 2-chloro-5-(4-chloro-5-difluoromethoxy-1H-pyrazol-3-yl)-4-fluorophenoxyacetic acid, both calculated as the stoichiometric equivalent of pyraflufen-ethyl in or on the commodity.

Commodity	Parts per million
Almond, hulls	0.02
Cattle, fat	0.03
Cattle, meat	0.03
Cattle, meat byproducts	0.03
Corn, field, forage	0.01
Corn, field, grain	0.01
Corn, field, stover	0.01
Cotton, gin byproducts	1.5
Cotton, undelinted seed	0.04
Fruit, pome, group 11-10	0.01
Fruit, stone, group 12	0.01
Goat, fat	0.03

Commodity	Parts per million
Goat, meat	0.03
Goat, meat byproducts	0.03
Grape	0.01
Grass, forage, group 17	1.0
Grass, hay, group 17	1.4
Horse, fat	0.03
Horse, meat	0.03
Horse, meat byproducts	0.03
Milk	0.03
Nut, tree, group 14	0.01
Olive	0.01
Peanut	0.01
Peanut, hay	0.07
Pistachio	0.01
Pomegranate	0.01
Potato	0.02
Sheep, fat	0.03
Sheep, meat	0.03
Sheep, meat byproducts	0.03
Soybean, forage	0.05
Soybean, hay	0.10
Soybean, seed	0.01
Wheat, forage	0.02
Wheat, grain	0.01
Wheat, hay	0.01
Wheat, straw	0.01

* * * * *

[FR Doc. 2013-04555 Filed 2-26-13; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0302; FRL-9377-6]

Acetochlor; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends inadvertent tolerances for residues of acetochlor in or on crop groups 15 and 16 for cereal grains by dropping the exclusion for rice grain and straw. Monsanto Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 27, 2013. Objections and requests for hearings must be received on or before April 29, 2013 and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0302, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency

Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Hope Johnson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (703) 305-5410; email address: johnson.hope@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0302 in the subject line on the first page of your submission. All

objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before April 29, 2013. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0302, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of July 25, 2012 (77 FR 43562) (FRL-9353-6), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2F7996) by Monsanto Company, 1300 I St. NW., Suite 450 East, Washington, DC 20005. The petition requested revisions to the current tolerances for residues of the herbicide acetochlor, 2-chloro-2'-methyl-6'-ethyl-N-ethoxymethylacetanilide and its metabolites containing either the 2-ethyl-6-methylaniline (EMA) or the 2-(1-hydroxyethyl)-6-methyl-aniline (HEMA) moiety, at 40 CFR 180.470 for grain, cereal, group 15, except corn, grain sorghum, rice, and wheat, grain and grain, cereal, forage, fodder and straw, group 16, except corn, grain sorghum, rice and wheat, straw.

Specifically the petition requested that crop groups 15 and 16 be amended

by dropping the exception for rice grain and rice straw, respectively. That document referenced a summary of the petition prepared by Monsanto Company, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

III. Tolerance Level

Monsanto sought the removal of the exception for rice and rice straw for the acetochlor tolerances for crop groups 15 and 16 so that rice crops could be rotated to fields previously treated with acetochlor. EPA determined that this revision to these tolerances was appropriate without modifying the tolerance value based upon translation of residue data reflecting analysis for residues of acetochlor and its metabolites in/on wheat and sorghum commodities planted after treatment with acetochlor. Residues in the wheat and sorghum grain were non-quantifiable, whereas finite residues that were below the existing crop group tolerance were reported in the straw.

IV. Aggregate Risk Assessment and Determination of Safety

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

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for acetochlor including exposure resulting from the tolerances established by this action.

EPA's assessment of exposures and risks associated with acetochlor follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Acetochlor has low acute toxicity by the oral, dermal, and inhalation routes of exposure and is mildly irritating to the eyes. The results of two dermal irritation studies indicate that it is a mild to strong skin irritant. Acetochlor is also a strong dermal sensitizer.

Evidence of neurotoxicity was observed in acute and subchronic neurotoxicity screening studies in rats, developmental toxicity studies in rats, and subchronic and chronic studies in dogs. In addition to the nervous system, the major target organs affected in subchronic and chronic studies in rats, dogs, and mice exposed to acetochlor are the liver, thyroid (secondary to liver), kidney, testes, and erythrocytes. Species-specific target organs include the nasal olfactory epithelium in rats and the lungs in mice.

There is no evidence of increased qualitative or quantitative susceptibility of fetuses or offspring to acetochlor exposure in the developmental and reproduction toxicity studies in rats and rabbits. In two developmental toxicity studies in rats, fetal effects (increased early resorptions, post-implantation loss, and decreased fetal weight) occurred at doses that also resulted in maternal toxicity (mortality, clinical signs of toxicity, and decreased maternal body weight gain). In two rabbit developmental toxicity studies there were no adverse fetal effects at the highest doses tested (HDT) (190 milligrams/kilograms/day (mg/kg/day) and 300 mg/kg/day); whereas maternal toxicity (body weight loss) was seen at 50 mg/kg/day in one study. In three reproduction toxicity studies in rats, offspring effects (decreased pup weights in the first two studies; decreased pup weights, decreased F2 litter size at birth, and focal hyperplasia and polypoid adenomata in nasal epithelium of adult F1 offspring at study termination in the third study) occurred at the same or higher doses than those resulting in parental toxicity (decreased body weight or weight gain in the first two studies; focal hyperplasia and polypoid adenomata in nasal epithelium of adult F1 offspring at study termination in the

third study). There was no evidence of reproductive toxicity observed at any dose tested in two of the three reproduction toxicity studies in rats. The third reproduction study in rats showed a decreased number of implantations at the HDT of 1,750 parts per million (ppm).

EPA has determined that quantification of carcinogenic risk on a linear, non-threshold basis is not appropriate for the mouse tumors. There are acceptable mode of action data for the rat tumors (nasal olfactory epithelial tumors and thyroid follicular cell tumors) which are adequate to support a non-linear, threshold approach for assessment of cancer risk. The rat nasal tumors are the most sensitive effect for cancer risk. However, because rat nasal tumors are not the most sensitive chronic effect, EPA has not conducted a separate cancer-only risk assessment but performed a single, chronic risk assessment that will be protective of both non-cancer and cancer effects, including rat nasal tumors, thyroid tumors, and mouse tumors.

Specific information on the studies received and the nature of the adverse effects caused by acetochlor as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in the document entitled "Acetochlor Human Health Risk Assessment for Proposed New Use of Acetochlor on Cotton and Soybeans" at page 41 in docket ID number EPA-HQ-OPP-2009-0002.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some

degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for acetochlor used for human risk assessment is discussed in Unit III.A of the final rule published in the **Federal Register** issue of September 16, 2009 (74 FR 47445) (FRL-8434-1).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to acetochlor, EPA considered exposure under the petitioned-for tolerances as well as all existing acetochlor tolerances in 40 CFR 180.470. EPA assessed dietary exposures from acetochlor in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Such effects were identified for acetochlor. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, entitled "What We Eat in America" (NHANES/WWEIA). This dietary survey was conducted from 2003 to 2008. As to residue levels in food, EPA assumed tolerance level residues and 100 percent crop treated (PCT) for all commodities.

Experimentally derived processing factors were used for cereal grain commodities. Default processing factors were used for all other commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2003-2008 NHANES/WWEIA. As to residue levels in food, EPA used anticipated residues from field trial data and 100 PCT assumptions for all commodities.

Experimentally derived processing factors were used for cereal grain commodities. Default processing factors were used for all other commodities.

iii. *Cancer.* EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. Cancer risk is quantified

using a linear or non-linear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or non-linear approach is used and a cancer RfD is calculated based on an earlier non-cancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the data summarized in Unit III.A., EPA has concluded that a non-linear RfD approach is appropriate for assessing cancer risk to acetochlor. However, cancer-only risk assessment was not conducted because the chronic RfD of 0.02 mg/kg/day will be protective of both non-cancer and cancer effects. The chronic exposure assessment described in Unit IV.C.1.ii. also accurately estimates exposure for the purposes of assessing cancer risk.

iv. *Anticipated residue information.* EPA used anticipated residues derived from the results of field trials in the chronic dietary exposure assessment.

Section 408(b)(2)(E) of FFDCFA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCFA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCFA section 408(b)(2)(E) and authorized under FFDCFA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for acetochlor in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of acetochlor. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Acetochlor parent residue exposure is generally higher and more widespread through surface water sources than ground water, therefore, the Agency generated the surface water concentrations using the PRZM (Pesticide Root Zone Model) and EXAMS (Exposure Analysis Modeling System). The estimated drinking water

concentrations (EDWCs) of acetochlor for acute exposures are estimated to be 75 parts per billion (ppb) for drinking water. For chronic exposures for non-cancer assessments are estimated to be 4.8 ppb for drinking water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 75 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 4.8 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Acetochlor is not registered for any specific use patterns that would result in residential exposure.

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

The chloroacetanilides have been evaluated by the Agency and the Federal Insecticides, Fungicides, and Rodenticides Act (FIFRA) Scientific Advisory Panel (SAP) as a related group of chemicals for this purpose. Acetochlor is included in a Cumulative Assessment Group (CAG) of chloroacetanilide pesticides. Structurally related chloroacetanilides include acetochlor, alachlor, butachlor, metolachlor, and propachlor. For purposes of a cumulative risk assessment, it was determined that the common mechanism of toxicity group consists of alachlor, acetochlor, and butachlor. Butachlor is excluded from the group for risk assessment purposes at present because there are no registered uses or tolerances for this chemical in the United States. The group was selected based on common endpoints of:

- Nasal turbinate tumors in rats, and a known mechanism of toxicity for development of these tumors.
- Induction of hepatic Uridine Diphosphate-Glucuronosyl Transferase (UDPGT), which results in increased incidence of thyroid follicular cell tumors secondary to disruption of pituitary-thyroid homeostasis.

Thyroid effects were not included in the final cumulative assessment of the chloroacetanilide herbicides because they were determined to occur at excessively toxic dose levels, and therefore were not considered relevant to human risk assessment. Nasal tumors represent the most sensitive endpoint for both compounds.

An updated cumulative risk assessment of the chloroacetanilide (CAG) pesticides acetochlor and alachlor conducted in April 2007 provides an assessment of existing and new uses of those chemicals to date. Based on the most recent chloroacetanilide CAG cumulative risk assessment, cumulative risk is not of concern. A revised quantitative cumulative assessment was not conducted because the proposed amended use would not affect the cumulative risk results. Not only is acetochlor a very minor contributor to chloroacetanilide cumulative risk when compared to alachlor, but removing the exception for rotation to rice will only have a minor impact on acetochlor exposure since finite residues on grains, including rice, are unlikely. In the residue data cited/translated to support this petition, non-quantifiable residues were reported in wheat and sorghum grains.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The prenatal and postnatal toxicity database for acetochlor includes two rat and two rabbit developmental toxicity studies and three reproduction toxicity studies in rats. As discussed in Unit IV.A., there was no evidence of qualitative or quantitative susceptibility of fetuses or offspring to acetochlor exposure in any of these studies.

3. *Conclusion.* EPA has determined that the FQPA SF of 10X may be reduced to 1X for the acetochlor acute

and chronic dietary risk assessment. That decision is based on the following findings:

i. The toxicity database for acetochlor is now complete. An immunotoxicity study has been reviewed and is acceptable/guideline. Immunotoxicity was not observed at the highest dose tested. The acute neurotoxicity (ACN) and subchronic neurotoxicity (SCN) studies have also been upgraded to acceptable/guideline based on acceptable positive control data and functional observational battery measures.

ii. Furthermore, EPA has determined that a developmental neurotoxicity study is not required since:

a. There is no evidence of increased susceptibility in the rat and rabbit in the prenatal and 2-generation reproduction postnatal studies.

b. Developmental effects were observed in the presence of maternal effects.

c. The effects observed in the neurotoxicity studies were only at high doses.

iii. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues or average residue levels derived from reliable field trials. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to acetochlor in drinking water. These assessments will not underestimate the exposure and risks posed by acetochlor.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to acetochlor will occupy <1% of the aPAD for infants <1 year old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded

that chronic exposure to acetochlor from food and water will utilize 6.2% of the cPAD for infants <1 year old the population group receiving the greatest exposure. There are no residential uses for acetochlor.

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

Because no short-term adverse effect was identified, acetochlor is not expected to pose a short-term risk.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Because no intermediate-term adverse effect was identified, acetochlor is not expected to pose an intermediate-term risk.

5. *Aggregate cancer risk for U.S. population.* The chronic RfD of 0.02 mg/kg/day will be protective of both non-cancer and cancer effects, including rat nasal tumors, thyroid tumors, and mouse tumors. Chronic dietary risks do not exceed the Agency's level of concern.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to acetochlor residues.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high performance liquid chromatography (HPLC) method with oxidative coulometric electrochemical detection (OCED)) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: residuemethods@epa.gov.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4).

The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDC section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for acetochlor.

VI. Conclusion

Therefore, the acetochlor tolerances for crop groups 15 and 16 are amended to drop the exception for rice and rice straw, respectively.

VII. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDC section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDC section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by

Congress in the preemption provisions of FFDC section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: February 15, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.470, revise the entries "grain, cereal, forage, fodder and straw, group 16, except corn, grain sorghum, rice and wheat, straw" and "grain, cereal, group 15, except corn, grain

sorghum, rice, and wheat, grain" in the table in paragraph (d) to read as follows:

§ 180.470 Acetochlor; tolerances for residues.

* * * * *
(d) * * *

Commodity	Parts per million
Grain, cereal, forage, fodder and straw, group 16, except corn, grain sorghum, and wheat, straw	0.3
Grain, cereal, group 15, except corn, grain sorghum, and wheat, grain	0.05

[FR Doc. 2013-04532 Filed 2-26-13; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL MARITIME COMMISSION

46 CFR Parts 501 and 540

[Docket No. 11-16]

RIN 3072-AC45

Passenger Vessel Operator Financial Responsibility Requirements for Nonperformance of Transportation

AGENCY: Federal Maritime Commission.

ACTION: Final rule.

SUMMARY: The Federal Maritime Commission amends its rules regarding the establishment of passenger vessel financial responsibility for nonperformance of transportation. The amount of coverage required for performance is modified to increase the cap on required performance coverage to \$30 million over a two year period and thereafter adjust the cap every two years using the Consumer Price Index; adjust the amount of coverage required for smaller passenger vessel operators by providing for consideration of alternative forms of protection; remove the application form for issuance of certificates of financial responsibility from the Commission's regulations and make it available at its Web site; add an expiration date to the Certificate (Performance); and make technical adjustments to the regulations.

DATES: The Final Rule is effective: April 2, 2013.

FOR FURTHER INFORMATION CONTACT: Karen V. Gregory, Secretary, Federal Maritime Commission, 800 North

Capitol Street NW., Washington, DC 20573-0001, Phone: (202) 523-5725, Email: secretary@fmc.gov. Vern W. Hill, Director, Bureau of Certification and Licensing, 800 North Capitol Street NW., Washington, DC 20573-0001, Phone: (202) 523-5787, Email: bcl@fmc.gov.

SUPPLEMENTARY INFORMATION:

By Notice of Proposed Rulemaking (NPRM) published on September 20, 2011, 76 FR 58227, the Federal Maritime Commission (Commission or FMC) proposed to amend its rules regarding the establishment of passenger vessel financial responsibility under 46 U.S.C. 44102 (formerly contained in section 3(a) of Pub. L. 89-777).¹ After receipt of public comments responding to the NPRM, the Commission issued a Request for Additional Comments and Information (RFI) relevant to the Commission's analysis whether revision of the Commission's regulations governing passenger vessel operators could have a significant economic impact on a substantial number of small entities.²

The Commission adopts the Final Rule as set forth below. Also the Chairman of the Commission certifies below pursuant to section 5 U.S.C. 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, that the Final Rule will not have a significant economic impact on a substantial number of small entities as none of the nine small PVOs that are subject to the Commission's Part 540 regulations are found to be significantly impacted by the changes adopted.

Current and Final Rules

The Commission's current rules provide that "[n]o person in the United States may arrange, offer, advertise or provide passage on a vessel unless a Certificate (Performance) has been issued to or covers such person," 46 CFR 540.3. Such persons must apply for a Certificate (Performance), 46 CFR 540.4, and provide financial responsibility "in an amount determined by the Commission to be no less than 110 percent of the unearned passenger revenue of the [PVO] applicant" for the two immediately preceding years, "reflect[ing] the greatest amount of unearned passenger revenue," 46 CFR 540.5.³ The amount of

required financial responsibility, however, is capped at \$15 million. 46 CFR 540.9(j).

Substantive Revisions. The final rule increases the cap on financial responsibility required of PVOs from \$15 million to \$30 million. The rule includes a phase-in period of two years in order to allow the industry time to adjust. One year after the rule becomes effective the cap increases to \$22 million. The second year after the rule goes into effect the cap increases to \$30 million. Biennially, thereafter, the limit will be adjusted to the nearest \$1 million using the Consumer Price Index for all Urban Consumers (CPI).⁴

Whereas the Supplementary Information of the NPRM provided for notice to be given of any increase in the cap, the proposed rule omitted the notice requirement. The attached final rule includes a formal notice, requiring the Bureau of Certification and Licensing (BCL) to calculate the adjusted cap amount and transmit that information to the Commission's Office of the Secretary (Secretary). The Secretary will then publish the notice of the new amount and the date on which it is to become effective on the Commission's Web site (www.fmc.gov) and in the **Federal Register**. The Secretary will establish an effective date that is no less than sixty (60) days after **Federal Register** publication.

The final rule also provides that PVOs with unearned passenger revenue (UPR) that is no more than 150% of the cap (i.e., UPR of \$45,000,000 or less) may request relief from coverage requirements by means of substituting alternative forms of protection. The Final Rule requires that requests be submitted to the Bureau of Certification and Licensing and authorizes the Director of BCL to grant requests based upon the already existing protections applicable to credit card receipts for PVOs whose payment policies provide for final payment by passengers to be made within 60 days of the vessel sailing.⁵ If such a request is granted, the PVO would meet its coverage requirements by a combination of the substituted financial responsibility alternative and financial responsibility covered by any insurance, guaranty, bond or escrow agreement.

Other Revisions. A number of other revisions are included that refine the rules to address issues and make corrections based upon the staff's experience. For example, the definition of "Unearned passenger revenue" in section 540.2(i) is revised to clarify that UPR "includes port fees and taxes paid" by passengers but excludes "such items as airfare, hotel accommodations, and tour excursions" that passengers also pay for but are not part of the passenger vessel transportation element of the cruise. The matter of whether port fees and taxes must be reimbursed has arisen repeatedly over the years. The staff has consistently advised that such costs are included in the water transportation related costs that are covered within the ambit of the statute and the Commission's regulations. This change will help PVOs and the public to quickly ascertain from the Commission's regulations that these amounts are reimbursable from the financial responsibility established by PVOs.

Sections 540.4(b) and 540.23(a) have been modified to direct applicants to file application form FMC-131 directly with the Bureau of Certification and Licensing, rather than the Office of the Secretary, reflecting actual practice over many years. The Final Rule removes form FMC-131 from the Commission's regulations, instead it will be made available on the Commission's web site (www.fmc.gov) or from the Bureau of Certification and Licensing.

The sample surety bond, guaranty, and escrow agreements that are set forth in the Commission's regulations are also amended and were included in the NPRM for public comment.⁶

Section 540.7 is revised to require that each Certificate (Performance) expires 5 years from the date of issuance. This varies from the current rule that provides that the certificate continues in effect for an indeterminate time. The Final Rule also provides that, for good cause shown, the Commission may issue a certificate with an expiration date less than 5 years.

Public Comments

1. Comments on the Current and New Caps

Cruise Lines International Association, Inc. (CLIA) submitted comments on behalf of its members, sixteen of which are PVOs currently in the Commission's program. All sixteen have UPR exceeding the current \$15 million cap. CLIA opined that the

⁶ These forms were submitted to the Office of Management and Budget for its review at the time of the NPRM was issued.

¹ See 46 U.S.C. 44102 (a) through (c).

² Docket No. 11-16, Request for Additional Comments and Information, 77 FR 11995 (February 28, 2012).

³ "Unearned passenger revenue" is defined as "passenger revenue received for water transportation and all other accommodations, services, and facilities relating thereto not yet performed." 46 CFR 540.2(i).

⁴ The Bureau of Labor Statistics' Consumer Price Index for all Urban Consumers is the most widely used measure to track changes in prices by federal agencies and financial institutions.

⁵ Corresponding revisions to sections 501.5(g)(2) and 501.26(d) are made to provide the necessary delegation of authority to BCL to review and grant requests for substituting alternative financial responsibility.

current cap of \$15 million was adequate, but did not oppose increasing the cap to \$30 million. CLIA indicated that a \$30 million cap would more than adequately cover the risks of nonperformance. CLIA also does not oppose the use of the CPI to adjust the \$30 million cap every two years.

Lindblad Expeditions, Inc., an operator of U.S. flag passenger vessels under the program, supports increasing the cap “commensurate with the UPR exposure of all PVOs” but indicates that such exposure “would best be accomplished by eliminating the cap altogether.” Linblad supported the adjustment of Part 540 financial responsibility coverage to take into consideration overlapping financial protection provided by credit card issuers. Specifically, Lindblad recommended the Commission take into account PVO bonds with the U.S. Tour Operator Association and private trip insurance.

American Cruise Lines, Inc. (ACL) (an operator of U.S. flag vessels), InnerSea Discoveries, LLC (InnerSea) (an operator of U.S. flag vessels), Congressman Andy Harris, M.D., the Passenger Vessel Association (PVA) (the national trade association representing owners and operators of U.S. flagged passenger vessels), the National Association of Surety Bond Producers (NASBP) oppose increasing the cap to \$30 million. The Surety & Fidelity Association of America (SFAA) neither supports nor opposes the increase.

ACL, Lindblad, InnerSea, PVA, and Congressman Harris assert that the current cap and increased cap unfairly discriminate against smaller U.S. flagged PVOs as they must devote a large portion of their capital to comply with the financial responsibility requirement of 110% UPR. In contrast, the larger, foreign-flagged PVOs have to cover a much smaller percentage of their UPR. ACL and InnerSea consider their financial responsibility burden to be disproportionate to their risk of nonperformance.

NASBP and SFAA advise that, because sureties demand reimbursement for losses, sureties conduct a thorough financial assessment of each PVO in order to assure the PVO has sufficient financial strength for the bond amount sought. NASBP and SFAA expressed concern that a PVO faced with a higher bond amount due to an increase in the cap may not be able to demonstrate financial strength necessary to obtain a bond. NASBP recommends that the Commission eliminate any cap and that a flat 15 percent of UPR be set as the financial responsibility level for all PVOs, regardless of size. NASBP

calculates that the flat rate would produce \$555 million in financial responsibility industry-wide (in comparison to the amount indicated in the Commission’s NPRM).

InnerSea proposes that regulations be adopted that concentrate on a PVO’s financial stability, regardless of size. InnerSea recommends that financial responsibility be tied to familiar financial ratios, such as debt to equity ratios, when setting coverage levels.

PVA suggests that a two-tier cap be implemented; one that applies a \$15 million cap to PVOs with UPR between \$15 million and \$30 million and a \$30 million cap for those PVOs with UPR of greater than \$30 million. PVA indicates that such a two-tier cap approach would protect small U.S. flagged operators from the adverse impact of the cap increase.

2. Comments on Alternative Forms of Financial Responsibility

ACL, Lindblad, PVA, Royal Caribbean and CLIA all support the concept of alternative protection in order to take into consideration duplicative coverage derived from sources other than the Part 540 financial responsibility. ACL and CLIA assert that such alternative protection should include consideration of credit card sales, given that additional financial protections exist for credit card purchasers under the Fair Credit Billing Act (FCBA), 15 U.S.C. 1666(a). CLIA also suggests, in its response to the NPRM, that the U.S. Bankruptcy Code protects passengers. CLIA points to protections provided to unsecured creditors under the Bankruptcy Code priority set out in section 503(a)(7), 11 U.S.C. 503(a)(7), which covers money paid for services that are not delivered. ACL and Lindblad suggest that the Commission needs to consider factors other than credit cards with respect to alternative forms of protection. Lindblad suggests that travel insurance be considered as alternative protection.

ACL supports reliance upon credit card refunds but cautions that credit card issuers may require increased collateral as further protection. ACL cites an American Express letter dated May 29, 2003 indicating that if the Commission offset bond amounts based upon refunds from credit card sales, then card issuers would “require PVOs to post collateral that covers all UPR charges [made] with the company’s credit cards.” PVA expressed a similar concern that if credit card companies perceive increased risk they would alter the terms of their agreements with PVOs. Lindblad indicates that PVOs are required to pay fees and establish cash

reserves with a third party which exceeds 10 percent of high UPR.

With respect to the requirement establishing the limitation for making a request at 150 percent of the highest UPR, ACL asserts that such a limit would create a disincentive to growth as smaller PVOs will attempt to assure that their UPR not reach \$45 million in order to continue qualifying for alternative protection consideration. CLIA likewise suggests that the 150 percent limitation is too low and will provide a disincentive for small cruise lines to embark passengers at U.S. ports as their UPR approaches the 150 percent mark.

Congressman Harris and InnerSea oppose reliance upon credit card refunds or travel insurance as sources for alternative financial protection. Echoing other PVOs, cited *supra*, Innersea states that greater industry reliance on credit cards and travel insurance will result in increased usage costs for these services to offset the increased risk to the credit card and travel insurance providers. InnerSea thus opposes this alternative as detrimental for the cruise industry as a whole.

Congressman Harris asserts that offsetting travel insurance and credit card payments would not eliminate the discriminatory effect against smaller, U.S. flag PVOs. Instead, the likely effect of recognizing such alternative methods is to substitute credit card issuers in place of the Commission as the party demanding increased financial security.

As indicated above, SFAA asserts that because sureties demand reimbursement for losses they conduct a thorough financial assessment of each PVO in order to assure it has sufficient financial strength to reimburse the surety. SFAA suggests that, in analyzing any alternative financial security, the Commission should consider whether the alternative security includes a process that performs a similar prequalification function (as that provided by sureties) as well as providing sufficient financial protection in the event the PVO defaults.

3. Other Comments

ACL and CLIA both recommend eliminating the 10 percent “administrative fee” for PVOs below the \$30 million cap. ACL asserts that it should be eliminated as it “is intended to cover the cost of administration” of the Commission’s “nonperformance financial security program” and that there is no sound basis for it being imposed on smaller U.S. flag coastwise trade PVOs and not on the larger PVOs that meet the cap. Similarly, CLIA suggests the “administrative fee” be

eliminated as requiring 100 percent of UPR is burdensome enough without the added 10 percent.

The NPRM also requested comment as to whether a model similar to PVO casualty requirements employing the number of berths on a PVO's largest vessel might be appropriate for the nonperformance program. ACL supports the idea from the standpoint that it would appear to eliminate the cap but is concerned whether it would foster growth in the industry. CLIA opposes a casualty model, asserting that Congress specifically created a model of financial security for death or injury and created a very different model for nonperformance. CLIA points out that Congress created the casualty provisions at the same time it created the nonperformance requirements of Public Law 89-777 and, in doing so, manifested a clear intention that the claims be treated differently.

Carnival suggests that financially sound PVOs that have a number of cruise brands be treated as a single applicant for purposes of the financial responsibility requirements. Carnival recommends that such applicants be covered by a single \$50 million bond backed by the parent company's guaranty. Carnival explains that such a bond and parental guaranty would provide greater security by assuring that the parent stands behind its group of companies.

Discussion

The \$30 Million Cap

Those opposing the increase in the cap are ACL and the PVA, which represents U.S. flag passenger vessel operators, including ACL, InnerSea and Lindblad. Their comments focus on the disparity between the 110 percent of UPR that they must secure versus the large PVOs, with UPR exceeding the current and increased cap limitations. Commission-mandated coverage for large PVOs has been capped for 20 years at \$15 million and, under the final rule, will rise to \$30 million. The comments underscore that small U.S. flag PVOs are particularly disadvantaged because they must operate vessels meeting U.S. build limitations and must hire U.S. crews, neither of which burden the large foreign flag PVOs. Congressman Harris shares this concern.

These comments accurately reflect that the large PVOs that qualify for the current cap have enjoyed unchanging financial responsibility burdens for all of their UPR above \$15 million for 20 years. In contrast, smaller PVOs' financial responsibility requirements have been subject to increases during

those 20 years, as their high two-year reported UPR increased. Those opposing the new cap do not see the increase as a change that meaningfully narrows the gap between the 110% financial responsibility requirements applicable to small PVOs vis-a-vis the small fraction of financial responsibility required of much larger PVOs.

It is clear that the larger PVOs with UPR exceeding the current cap have had the benefit of an unchanging burden of financial responsibility for the past twenty years; during this same period the PVO industry's highest UPR quadrupled from \$1 billion to approximately \$4 billion. In effect, the overall financial burdens of the Commission's requirements have diminished over time as the percentage of the UPR covered by financial responsibility dropped from 25% to 7.9% of UPR.⁷

The \$30 million cap will result in a significant increase in the UPR covered by PVOs' financial responsibility, with the preponderance of the increase falling on large PVOs. Based upon the recent reported UPR of PVOs providing nonperformance coverage, it appears that coverage requirements for fifteen of the large PVOs would increase to \$30 million, increasing total coverage for the industry by \$225 million. This would increase industry-wide coverage requirements to approximately 13.5 percent of outstanding UPR.

Without recognition of alternative forms of coverage, three of the commenting PVOs that benefit from the current cap would be immediately impacted by adoption of the rule, as they would be subject to increasing their financial responsibility. However, alternative forms of coverage, discussed below, would potentially reduce their coverage requirements below the \$15 million currently maintained by these PVOs.

Adoption of the \$30 million cap on the basis of the quadrupling of UPR for the largest PVOs over the past 20 years is sufficient reason for increasing the cap. However, the Commission has, in the past, found the effects of inflation are relevant to increasing the cap.⁸ In Docket No. 90-01, the Commission stated that the increase was "predicated, for the most part, upon the increase in

the consumer price index."⁹ Since 1967, when the cap was set at \$5 million, the Consumer Price Index has increased more than five-fold. Use of the CPI, adjusted from the last increase in 1990, would equate to a cap of over \$25 million. Yet, as described, the amount of UPR that is outstanding, and thus passenger monies at risk, has increased much more than general inflation based upon the CPI.

The Commission adopts the increased cap based upon the large increase of UPR of large PVOs over the last twenty years with no increase in the cap. The Commission also adopts the requirement that the \$30 million cap will be adjusted every two years based upon the CPI-U. Based on past history, the use of the CPI-U would not account for all of the increase in UPR of the largest PVOs, but will serve to capture some of the increases in large PVOs' UPR.

As described above, the final rule is amended to provide notice of each biennial cap adjustment. The final rule provides that: (1) the Bureau of Certification and Licensing will calculate the adjusted cap amount and transmit that information to the Secretary; and (2) the Secretary will then publish in the **Federal Register** and the Commission's Web site notice of the new amount and its effective date. The Secretary will establish an effective date for the new cap that is no less than sixty (60) days after **Federal Register** publication.

The suggestions by NASBP (that a flat 15% of UPR financial responsibility requirement be set for all PVOs), by InnerSea (that all PVOs' financial responsibility be established using familiar financial ratios such as debt/equity), and by PVA (that a two-tier cap system be put in place) create concerns and uncertainty that the final rule avoids. Application of the NASBP's flat 15% would apply a low and potentially inadequate percentage to all PVOs that do not meet the current \$15 million cap. Inasmuch as 12 of the 15 PVOs that have ceased operations since September 2000 were PVOs whose UPR was below that threshold, the Commission's experience is that smaller PVOs have greater risks that performance coverage will be required to reimburse passengers for losses. Without current coverage requirements, many passengers would have suffered significant losses.

InnerSea's suggestion that regulations should concentrate on a PVO's financial stability, regardless of size, would seem similarly problematic. The Commission

⁷ In 1990, the total financial coverage provided was nearly 25% of outstanding UPR, amounting to slightly more than \$250 million. With the total two-year high UPR for all PVOs in the Commission's program now at approximately \$4 billion, only 8% of UPR (\$323 million) is covered by financial responsibility.

⁸ Docket No. 79-93, Final Rule, 45 FR 23428 (April 7, 1980) and Docket No. 90-01, Final Rule, 55 FR 34564 (August 23, 1990).

⁹ Docket No. 90-01, Final Rule, 55 FR 34564, 34566 (August 23, 1990).

would need to define what sound financial health means and then conduct thorough and intrusive financial reviews to determine “financial health.” Experience has shown that financial reports significantly lag actual events. Under InnerSea’s suggestion, upon discovering a PVO no longer was of sound financial health, the Commission would likely be faced with the quandary of increasing coverage requirements at a time that would potentially expedite the PVO’s financial failure, or risk standing by while the PVO fails and leaves customers financially imperiled.

Those suggestions would require the Commission to continuously monitor the financial health of every PVO. Financial reports not required to be filed currently would of necessity be mandated. The Commission’s previous experience with American Classic Voyages Company (American Classic), when it ceased operating, demonstrated the short comings of reporting requirements as well as the inadequacy of self-insurance as a means for PVOs to meet their financial responsibility requirements. *See Financial Responsibility Requirements for Nonperformance of Transportation—Discontinuance of Self-Insurance and the Sliding Scale, and Guarantor Limitations*, 29 SRR 685 (June 26, 2002). The Commission noted that “experience demonstrates that the lag time in receiving financial data may prevent the Commission from knowing about a PVO’s financial deterioration until well after it is too late to remedy the lack of coverage.” *Id.* at 688.

PVA’s suggestion of a two-tier cap system would leave the \$15 million cap in place for those PVOs with up to \$30 million in UPR. While this would provide greater certainty, it would also necessitate a significant increase in requirements at the point \$30 million UPR is reached. A PVO would move immediately from a \$15 million cap to a \$30 million cap. The Commission’s final rule allows for alternative forms of coverage for those whose UPR is less than \$45 million and provides greater relief to smaller operators, such as those represented by PVA.

The Commission’s experience with respect to PVOs that have ceased operation is relevant to consideration of the \$30 million cap and to consideration of individual proposals for alternative financial protection, provided the PVO’s UPR is less than 150% of the cap. For example, American Classic had UPR of \$51 million.¹⁰ Approximately 60% of

American Classic’s passengers were reimbursed through credit card issuers and travel insurance. Only after ten years of bankruptcy proceedings did the remaining 40% of the American Classic passengers, specifically, those who had paid by cash or check, finally receive reimbursement of up to \$2,100 each. The \$2,100 reimbursement was the maximum amount provided for under the Bankruptcy Code priority applicable at the time.

CLIA indicated, in its response to the NOI, that it understood most of American Classic’s passengers received full “Fair Credit Billing Act * * * refunds” and refunds via the bankruptcy process. CLIA stated that the passengers of one American Classic vessel received “100 percent of their fare payments through the bankruptcy process within 17–18 months after the [American Classic] bankruptcy filing.” However, according to the bankruptcy plan administrator’s office, the 40% of passengers who paid by cash or check were classified as priority claimants in the bankruptcy proceeding and received only the maximum amount available under the bankruptcy code for that category of customer deposits, which was \$2100 per person at that time. If any individual passengers’ deposit equaled more than \$2100 per person, they would not have been fully reimbursed via the American Classic bankruptcy proceeding. With respect to passengers of the American Classic vessel M.S. PATRIOT, a compromise was structured after extensive negotiations whereby the passengers received reimbursements of 26% of their initial deposits.

Requests for Substitution of Alternative Forms of Financial Protection.

The final rule provides a process by which a PVO whose UPR is less than 150% of the \$30 million cap (i.e., \$45 million) may request relief from the Commission by seeking recognition of additional financial protection(s) in substitution for coverage otherwise required by the Commission’s regulations. This case-by-case process is supported broadly by the vessel interests that submitted comments. Alternative sources suggested include recognition of existing credit card refund requirements (whether under the Fair Credit Billing Act or not),

¹⁰ They were: Premier Cruise Operations Ltd. (Premier), New Commodore Cruise Lines Limited (New Commodore), Cape Canaveral Cruise Lines, Inc., MP Ferryman, Inc., American Classic, Royal Olympic, Regal Cruises, Ocean Club Cruise Line, Society Expeditions, Scotia Prince, Glacier Bay, Great American Rivers, RiverBarge Excursion Lines, Inc., Majestic America Line and West Travel, Inc. d/b/a Cruise West.

Bankruptcy Code priorities that allow recovery of consumer deposits made for services rendered but not performed, private travel insurance, and U.S. Tour Operator Association (USTOA) performance bonds that are purchased by some PVOs.

Several commenters indicate, however, that reliance on credit card refunds can be problematic in that, if the Commission grants a request, the credit card companies could increase security to cover some or all of the UPR relief granted. This could include hold-backs or letters of credit to protect the credit card company in the event of nonperformance. One commenter, InnerSea, indicates this outcome is a near-certainty.

The Commission has rarely recognized alternative forms of financial responsibility. The Commission decided to grant a request by a PVO for relief from the otherwise applicable financial responsibility requirements pursuant to 46 CFR 540.5. The Commission accepted credit card receipts and the PVO’s USTOA performance bond in recognition of the increased collateralization by its credit card company requiring funds to be held back to cover nonperformance. Since credit card issuers had set up a separate escrow type fund to protect its cardholders, it was deemed unnecessary to mandate a duplicate escrow set up under Commission regulations. A concern with the relief given to the PVO, however, was that the “hold-back” funds also would be available to be used to reimburse the passenger for services unrelated to the ocean transportation, including air fare, shore excursions, port transfer and baggage charges.

Comments responding to the NOI, NPRM and RFI indicate that PVO credit card receipts account for 50 percent to 94 percent of passenger fares. The concern was expressed that credit card sales in effect result in double coverage because some are required by the card companies to provide collateral and pay extra fees in addition to the costs associated with obtaining financial responsibility to comply with the Commission’s regulations in Part 540. Though the extra collateral and fees may be used to refund unearned revenues that fall under the Commission’s regulations, credit card refunds are not limited to payment of the unearned revenues covered by Part 540.

With respect to the consumer protections under the Fair Credit Billing Act, the cardholder must give written notice of non-performance to the card issuer within sixty days after the credit card issuer mailed the statement containing the charges. *See Federal*

¹⁰ Fifteen PVOs covered by the Commission’s regulations have ceased operations since 2000.

Trade Commission Letter, addressed to the Commission's General Counsel dated November 16, 2010. Though credit card issuers must give such refunds for billing error claims received within that 60-day window, they do not appear to be legally required to make refunds for written claims notified after 60 days of transmittal of billing statements.

As indicated in comments, common PVO industry practice requires full payment of cruise fares from 60 to 90 days prior to sailing, though booking usually occurs months before the sailing date. Passengers may be required to make substantial initial deposits at the time of booking. Such booking deposits may account for up to 30 percent of the total fare. Hence, booking deposits made by credit cards normally do not fall within the 60 day window of the FCBA. CLIA indicates in its response to the NOI, however, that approximately 50 percent of cruise fares are paid within the 60-day FCBA window.

Notwithstanding that credit card companies have consistently reimbursed cardholders, even where nonperformance occurred beyond the 60-day window, the increased reliance on credit card refunds as an alternative form of protection can present other concerns. For example, credit cardholder contracts vary by card issuer and cardholder, and are subject to unilateral changes by the card issuer; the Commission has no authority to assure that credit card issuers will make Part 540 refunds in preference to other non-statutory claims associated with passengers' broader travel plans (e.g., hotels, airfare, land-side excursions, etc.). There is no assurance that the card issuer will make such reimbursements in certain circumstances or, as a general matter, continue to make such refunds. Nonetheless, recognition of credit card protection may serve, on a case-by-case basis, as the primary source of alternative financial responsibility.

Credit card reimbursement requirements and policies exist regardless of Commission requirements. Such requirements may be imposed by statute, regulation or policies of credit card issuers. Consideration of credit card protections by the Commission does not change those requirements. However, it is true that credit card issuers may require collateral based upon a risk assessment of a PVO or other company. Nonetheless, imposition of such a requirement presumably is based on the perceived risk of failure of the enterprise. That risk would exist whether or not the Commission required

additional coverage.¹¹ Accordingly, requests to provide alternative financial responsibility based upon credit card reimbursements may be granted but the amount of such protection to be recognized will be determined on a case-by-case basis.

Private travel insurance policies differ widely. For example, some policies only reimburse passengers in the event the PVO formally declares bankruptcy. Others will reimburse passengers only after the PVO officially announces that it has suspended operations due to insolvency or bankruptcy. Still others may not cover nonperformance by the PVO, but only the inability of the passenger to travel as scheduled. Some PVOs offer travel insurance that have portions of coverage which are not in fact underwritten by insurance providers, with the passenger protected only to the extent of the PVO's ability to reimburse.¹²

The wide variability of travel insurance policies makes it difficult for the Commission to assure that the proceeds are adequately and reliably targeted to reimburse passengers for their unperformed water transportation. Therefore, it appears to the Commission that private travel insurance as a form of alternative financial responsibility is not sufficiently reliable at this time to support a request to provide substitute financial responsibility.

The performance bonds that PVOs purchase from the U.S. Tour Operators Association are also suggested as a source of substitute financial responsibility. The Commission has had some experience with respect to the USTOA bond performance. Unlike private travel insurance, the USTOA bond is an agreement between the PVO and the association, not the individual passenger. Also, the USTOA bond varies less from bond to bond and appears to have been administered with consistent results. The USTOA bond may merit consideration with respect to a request for relief, provided the bond text were amended to provide specifically for coverage of Part 540 unearned revenues; or if amended to provide a mechanism

¹¹ Of note, Commission filed bonds and guaranties historically have paid reimbursements only after existing protections have been exhausted. As credit card issuers have been found not to have subrogation rights to such instruments, they are responsible irrespective of Commission requirements.

¹² In addition to the Commission's concerns with one PVO over the use of hold back funds, the Commission learned that private travel insurance offered by the PVO proved illusory. When PVO failed to perform, the passengers were not reimbursed from the "insurance." The premiums paid by passengers to the PVO were gone; as the PVO had used the money for other purposes.

whereby passengers are paid directly, not via the insolvent PVO.

As indicated by passenger experience with respect to the American Classic bankruptcy, it would appear that the Bankruptcy Code priority for services not performed is a source of last resort for refund of unearned passenger revenues. Not only did some American Classic passengers have to wait almost ten years for refunds, some received refunds of only 26 percent. Bankruptcy would, therefore, be an unreliable source of passenger protection. Bankruptcy likely would not be anticipated and, even if a bankruptcy were to occur, there would be no assurance of sufficient assets to reimburse any passenger, much less fully reimburse all of them.

The process provided in the final rule enables the Commission, on a case-by-case basis, to consider additional protections submitted by an applicant. The rule provides that PVOs with UPR not exceeding 150% of the cap may submit requests for relief from coverage requirements by substituting alternative forms of protection. ACL and CLIA both suggest that the 150% level is too low, and that more small PVOs would be able to take advantage of the process if the level were higher. The most significant effect of increasing the percentage would be to lessen the amount of UPR that is covered by established financial instruments under the Commission's nonperformance program in substitution for security that is not as certain, such as credit card refunds.

Currently, 28 of the 40 PVOs in the Commission's program have UPR below \$45,000,000 and each therefore may qualify for lowering their current coverage requirements. However, raising it to 200% would allow consideration of only one additional PVO. Accordingly, the Commission adopts the 150% threshold for submission of requests for relief.

ACL commented that the Commission did not indicate what criteria governed the process. This point is well taken. Accordingly, the final rule has been amended to set out criteria the Commission will use in considering such requests.

The final rule requires that requests be submitted to the Bureau of Certification and Licensing. PVOs must include their most recently available annual and quarterly reports, irrespective of the alternative financial responsibility upon which a request may be based.

For requests based upon the already existing protections applicable to credit card receipts, the PVO must, for voyages

occurring during the most recent twelve months, include: The total deposits and payments received for passenger vessel transportation (whether by cash, checks or credit cards), the total credit card receipts; and a copy of the PVO's policy(ies) governing payments by passengers (i.e., deposits and the number of days prior to sailing the passenger must make final payment).

The final rule provides that the Commission may permit a reduction in financial responsibility to be based upon credit card receipts. The amount of such a reduction is determined by halving the proportion of credit card receipts to the PVO's total receipts, and applying the resulting percentage to the PVO's highest two-year UPR. For example, where the total credit card receipts for the twelve-month period equals 30 percent of the total receipts for the period, the PVO would receive a 15 percent reduction off of its highest UPR. Such requests ordinarily will be granted for PVOs whose payment policies provide for payment within 60 days of the vessel's sailing date and financial condition appears to be sound. Requests based upon payment policies that require final payment more than 60 days from the date of sailing may be granted for a lower percentage reduction. The Director of BCL, may, however, refer such requests to the Commission for decision.

The final rule also provides that the alternative financial responsibility granted will remain in effect until its Certificate (Performance) expires pursuant to 540.7(b) unless the Commission determines otherwise based upon paragraph 5 of this section.

Additionally, BCL may request additional information, at the time of the initial request, from the PVO. Such requests are made now by BCL when, for example, it receives information that may bear on a PVO's ability to perform. Similarly, the final rule adds a provision enabling the BCL to request such information from PVOs after their requests are granted. Of course, the PVO may provide any other information related to the alternative financial responsibility or its financial condition that it considers relevant to its request.

Other Matters Raised

ACL and CLIA each suggest elimination of the 10% "administrative fee." They refer to the last ten percent in the 110% of UPR required of PVOs that do not qualify for the cap. ACL asserts that the 10% is used to administer the Commission's nonperformance program. To clarify, the 10% is not an "administrative fee" in any sense and the Commission does not

receive any of the 10%. All 110 percent of a PVO's financial responsibility is devoted to refunds in the event of nonperformance and, in some instances, to cover costs associated with payment of reimbursements, such as standard check processing fees by banks.

Further, in promulgating the original regulations implementing section 3 of Public Law 89-777 in 1967, the Commission established the requirement that PVOs provide financial responsibility equal to 110% of UPR. The Commission stated that the rule is designed to recover 100% of unearned revenue based on two years' performance "to give an indication of the general operating condition of the applicant, plus a safety factor of 10 percent." 32 FR 3986 (March 11, 1967). In short, this 10 percent "safety factor" assures reimbursement where the actual amount of UPR at the time a PVO fails to perform is greater than the amount last reported.

For example, as reflected in the Regulatory Flexibility Act Threshold Analysis described below, escrow agreements are obtained more often by smaller PVOs. Such PVOs may have difficulty obtaining a bond or guaranty or have seasonal services or operations that otherwise experience drastic change in the amount of UPR through the year. Escrow agreements require a fixed 10% to be kept in escrow during the slow season and require that funds received from voyage deposits and final fare payments be deposited on a timely basis into the escrow account. Among other requirements, escrow PVOs are required to submit reports of monies received and deposited on a weekly and monthly basis so that the Commission can confirm that the rapidly accumulating funds have, in fact, been deposited. Most escrow agreements provide that "the Customer may, at any time, deposit additional funds consisting exclusively of UPR and the Fixed Amount into the Escrow Account." Hence, the 10 percent safety factor helps bridge gaps between the most recent report of weekly deposits and amounts received but not yet deposited.

As described by ACL and CLIA, their suggestion would result in an "across the board" cut for all PVOs that do not qualify for the cap. The recognition of alternative coverage to reduce current coverage requirements, however, negates the need to consider eliminating the 10% safety factor, as fewer small PVOs may be submitting coverage of 110% of UPR. Therefore in light of the Commission's experience that significant shortfalls in UPR (deposited and revenue received but not yet

deposited) frequently occur with respect to escrow agreements, the 110% coverage requirement remains unchanged for all PVOs, except those that qualify for the \$30 million cap or who receive relief under the new rule providing for substitution of alternative financial responsibility. In any event, escrow agreements will continue to require a minimum of 10 percent to be held in escrow at all times; even where an escrow PVO obtains relief to provide alternative financial responsibility for the remaining 90% of its UPR.

The Commission also requested comment as to whether nonperformance financial responsibility levels might be established using a methodology similar to that for the casualty program for PVO financial responsibility. CLIA commented in response to this suggestion and strongly opposes it, asserting that the casualty methodology was established by statute at the same time, and in the same statute, as the nonperformance provisions, which CLIA asserts indicates that Congress intended separate and distinct systems for casualty and performance coverage. CLIA's comments imply that new statutory authority would be needed to make such a change. ACL indicated that the idea had some merit but that they would need more information on such a proposal. As the Commission adopts the rule as proposed, there is no need to consider the use of a methodology similar to that for establishing financial responsibility under the Commission's casualty program.

As described above, Carnival suggests that financially sound PVOs that have a number of cruise brands be treated as a single applicant for purposes of the financial responsibility requirements. Carnival recommends that such applicants be covered by a single \$50 million bond backed by the parent company's guaranty. Carnival explains that such a bond and parental guaranty would provide greater security by assuring that the parent stands behind its group of companies. The adoption of the final rule also obviates the need to consider a financial responsibility methodology that would potentially reduce the financial responsibility requirements of larger PVOs.

Technical Changes

The Commission also adopts certain technical changes to its passenger vessel financial responsibility regulations in Part 540. Those changes include the revision of the definition of "unearned passenger revenue" in section 540.2(i) to clarify that UPR "includes port fees and taxes paid" by passengers but excludes "items as airfare, hotel

accommodations, and tour excursions.” The wording adopted varies from that contained in the NPRM but reflects the Commission intention to clarify the coverage of the term.

The changes to section 540.4(b) and section 540.23(a) are also adopted. Applicants will file their applications directly with the Bureau of Certification and Licensing instead of with the Office of the Secretary. Form FMC-131 will be deleted from the Code of Federal Regulations and instead made available on the Commission’s web site (www.fmc.gov) or directly from the Bureau of Certification and Licensing.

The revision to section 540.7 is adopted and requires that each Certificate (Performance) expire 5 years from the date of issuance. The current rule provides that the certificate may continue in effect indefinitely. The Final Rule does not, however, require expiration of the underlying financial responsibility instruments.

This revision will assist the U.S. Customs and Border Protection to verify the validity of a certificate under 46 U.S.C. 44105, and ensure that the Commission periodically confirms PVO information previously submitted. This change harmonizes the Commission’s PVO certificates with domestic and international certificates (e.g., the U.S. Coast Guard’s Certificate of Inspection, those issued under The Safety of Life at Sea Convention, and the International Convention on Load Lines).¹³ Further, the final rule also provides that the Commission, for good cause, could issue a certificate with an expiration date of less than 5 years, which creates a flexible process that permits short-term certificates to be issued to PVOs that operate from U.S. ports episodically.

NASBP supports expiration dates for each Certificate (Performance), indicating that surety bonds were not meant to be indefinite. The final rule, however, is not intended to affect the underlying financial responsibility. Rather the certificate expiration provides the opportunity for the updating of each PVO’s information with the Commission as well as the broader reasons indicated. However,

should the PVO and its surety include an expiration date less than five years for the underlying security, the certificate could be issued with that expiration date.

The sample surety bond, guaranty, and escrow agreement are amended as contained in the NPRM and will continue to be set out in the Commission’s regulations.

Regulatory Flexibility Act—Threshold Analysis

The Regulatory Flexibility Act of 1980 (RFA),¹⁴ as modified by the Small Business Regulatory Enforcement Fairness Act (SBREFA),¹⁵ requires Federal agencies to consider the impact of regulatory proposals on small entities and determine, in good faith, whether there were equally effective alternatives that would make the regulatory burden on small business more equitable.¹⁶ Agencies must first conduct a threshold analysis to determine whether regulatory actions are expected to have significant economic impact on a substantial number of small entities. If the threshold analysis indicates a significant economic impact on a substantial number of small entities, an “initial regulatory flexibility analysis” must be produced and made available for public review and comment along with the proposed regulatory action. A “final regulatory flexibility analysis” that considers public comments must then be produced and made publicly available with the final regulatory action. Agencies must publish a certification of no significant impact on a substantial number of small entities if the threshold analysis does not indicate such impacts.

The threshold analysis considered the economic impact on small businesses of the rule changes in Docket 11–16: *Passenger Vessel Operator Financial Responsibility Requirements for Nonperformance of Transportation*. It outlines the proceedings; provides a brief overview of the Passenger Vessel Operator (PVO), or cruise line, industry; discusses the small PVOs affected; and evaluates the economic impact of the rule on small PVOs based on the substantial number and the significant economic impact criteria of the RFA.

Based upon the following factual basis, the threshold analysis concludes

that none of the PVOs in the Commission’s program that are identified as small entities under the Small Business Act (SBA)¹⁷ will be significantly economically impacted by the Final Rule. Those small PVOs are all eligible to request reductions in their current financial responsibility by substituting alternative protection based upon credit card receipts.

1. Background

The Commission issued a Request for Additional Information and Comments (RFI) on February 22, 2012. Comments were submitted by four PVOs: Royal Caribbean, Carnival, American Cruise Lines, and InnerSeas Discoveries. The analysis compiles confidential data provided in response to the Commission’s questions about their companies’ operations and demonstrates the huge differences in operational scale among the respondents.

2. The Regulated Industry

The industry regulated under Part 540 of the Commission’s regulations consists of “persons” in the U.S. who arrange, offer, advertise or provide passage on a vessel having berth or state room accommodations for 50 or more passengers and embark passengers at U.S. ports.¹⁸ The industry is referred to as the U.S. cruise line industry. The North American Industry Classification System (NAICS) codes for the U.S. cruise industry include the following: 483112-Deep Sea Passenger Transportation, 483114-Coastal and Great Lakes Passenger Transportation, and 483212-Inland Water Passenger Transportation.

As of June 30, 2012, the FMC Passenger Vessel Operator program had 40 participants. The threshold analysis reviewed each of the 40 program participants along with their 2-year high UPR, amount of performance coverage, the type of instrument used, percentage of UPR protected by bonds or escrows, and the primary market segment in which they operate. The analysis determined whether a PVO meets or exceeds the SBA size standard for the NAICS codes identified.

¹⁷ 15 U.S.C. 632. The RFA uses the definition of small business found in the Small Business Act.

¹⁸ The Commission’s rules define “person” to include individuals, corporations, partnerships, associations, and other legal entities existing under or authorized by the laws of the United States or any State thereof or the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands or any territory or possession of the United States, or the laws of any foreign country. See 46 CFR 540.2 (a).

¹³ On October 31, 1988, the International Maritime Organization (IMO) convened the International Conference on the Harmonized Systems of Survey and Certification to adopt the Protocol of 1988 relating to the International Convention for Safety of Life at Sea (SOLAS), 1974, and the Protocol of 1988 relating to the International Convention on Load Lines, 1966. By adopting these 1988 Protocols, IMO standardized the term of validity for certificates and intervals for vessel inspections required by the Conventions. These 1988 Protocols entered into force as international law on February 3, 2000. See also 65 FR 6494 (February 9, 2000).

¹⁴ Regulatory Flexibility Act, Pub. L. 96–354, 94 Stat. 1164 (codified at 5 U.S.C. 601 et seq.).

¹⁵ Small Business Regulatory Enforcement Fairness Act of 1996, Pub. L. 104–121, 110 Stat. 857 (codified at 5 U.S.C. 601 et seq.).

¹⁶ The term “small entities” comprises small business and not-for-profit organizations that are independently owned and operated and are not dominant in their field, and governmental jurisdictions with populations of less than 50,000.

3. Description of Small PVOs Affected

The SBA defines a small business as any firm that is independently owned and operated and not dominant in its field of operation. The SBA size standard for a small company in the U.S. cruise industry is 500 or fewer employees. For the purposes of this analysis, any operator in the PVO program that is affiliated with, or a subsidiary of, a larger entity is considered to exceed the SBA size standard. For example, a PVO that operates one vessel in the Commission's PVO program, has a 2-year high UPR of less than \$1 million, and may have fewer than 500 employees in the U.S. However, it is considered to have exceeded the SBA size standard because it is a subsidiary of a large global enterprise. Such a single vessel operator does not meet the "independently owned and operated" criteria for a small business. A total of nine operators in the PVO program are considered to have exceeded the SBA size standard by the same reasoning.

Seven PVOs were eliminated from this analysis because they have either no UPR or no financial responsibility instrument (performance) on file with the Commission. These PVOs maintain a casualty certificate and many embark passengers from U.S. ports on a very limited basis (i.e., embark very few passengers at one U.S. port on a rare occasion or perform several short-term chartered cruises once a year or every 2 or 3 years). Historically, UPR for these seven PVOs has been well under the \$15 million cap.

Staff identified nine PVOs in the program that meet the SBA size standard and are considered to be small businesses. Six of the nine small PVOs are exploration/soft adventure operators which operate U.S. flag vessels in Alaska, U.S. coastal waters, or on inland waterways. These operators would be classified in the NAICS codes of 483112-Deep Sea Passenger Transportation, 483114-Coastal and Great Lakes Passenger Transportation, and 483212-Inland Water Passenger Transportation. Because they are U.S. flag operators, they are required to have U.S. ownership, use U.S.-built ships, and use U.S. citizens as crew members. The remaining three small PVOs are foreign flag operators operating in various U.S./foreign cruise and ferry markets using Panamanian and Bahamian flag vessels, and they are classified in NAICS code 483112-Deep Sea Passenger Transportation.

4. Economic Impact of the Rule on Small PVOs

Assessing economic impact involves estimating the cost of any increased financial performance coverage. On a per-passenger basis, the cost of financial coverage can vary significantly depending on the size of the PVO. For example, the cost per passenger for a large PVO whose coverage is capped at \$15 million level can be very small. In contrast, a small PVO's coverage can be many times that of the large operator for the same time period.

Increase of Financial Responsibility

The economic impact on small PVOs depends upon the instrument used to establish financial responsibility. Five of the program's small PVOs have bonds. Based on conversations with a surety association, BCL finds that the least risky PVOs would probably pay about 0.5 percent of the instrument's face value, while the most risky would probably pay about 3 percent. These estimates were used for the baseline estimate of economic impact of the current rule. The threshold analysis shows the range of possibilities for those small PVOs using bonds. The level of coverage based on 110% UPR with the increased cap also was calculated as was the range of annual premiums. Differences in anticipated annual premiums under the current and proposed rules were calculated. Only one operator with UPR exceeding the \$15 million cap would be expected to have increased premium costs.

One commenter provided the percentage of the bond amount that it must pay to its surety as an annual premium and advised that the surety requires it to obtain a letter of credit in an amount that is a percentage of the bond value. The PVO also provided the amount of its current letter of credit and advised that the process of obtaining the surety bond and letter of credit also incurs additional bank and legal fees.

The threshold analysis reviewed the estimated cost of increasing financial responsibility to \$30 million on the five small PVOs using bonds in comparison to their costs under the current rule using each PVO's current 2 year high UPR, its current performance coverage, the estimated cost of coverage using the .5 and 3 percentages provided by the surety association. One small PVO commented that one of the most important additional costs would be the opportunity cost of tying up additional credit availability to secure its bond.

The threshold analysis, however, indicated that the cost of coverage when the cap increases to \$30 million for one

PVO may increase the average ticket price by less than one percent. The other four PVOs using bonds would experience no increase in their surety bonds as a result of the cap increase.

The threshold analysis also reviewed the remaining four small PVOs that use escrow accounts. Balances in these accounts change weekly as additional fares are deposited; cruises are completed; and the "unearned" revenue associated with the completed cruise becomes "earned" and is withdrawn from the account. Escrow account holders are assessed administrative fees, unlike PVOs using surety bonds or guarantees that are charged premiums linked to the amount of the instrument. Administrative fees, on the other hand, are generally not based on the value of the account. Rather escrow agents or managers have fee schedules which are dependent upon the number and types of transactions or services provided. These include deposits, wire transfers, number of checks processed and issued, number of transfer payments, and documentation preparation. In addition, escrow agents may charge a monthly service fee. The new rule would not affect the basis on which administrative fees are assessed.

To determine the economic impact for these operators, the "opportunity cost"¹⁹ of the capital that the operators are required to maintain in the escrow accounts (but otherwise could have used for other purposes) was calculated. For the purposes of calculating this cost, it was assumed that the small PVOs would need to obtain commercial loans to meet working capital requirements or to fund capital investments or improvements, in lieu of not being able to use the funds held in escrow. For purposes of this analysis, and because escrow account balances change frequently, the mean of the operators' UPR reported weekly over a recent twelve month period (July 2011 through June 2012) was calculated for each operator using interest rates for short-term commercial loans.²⁰

Because these four small PVOs have UPR levels well below the current \$15 million cap, they will not be required to obtain additional performance coverage under the regulations. As a result, these small PVOs would not be subject to any immediate additional economic impact.

¹⁹ The opportunity cost of an action is the value of the foregone alternative action. Source: The MIT Dictionary of Modern Economics, 4th Edition, p. 315.

²⁰ Interest rate information for short-term loans obtained from the National Federation of Independent Business (NFIB), *NFIB Small Business Economic Trends*, July 2012, p. 14. The interest rate used assumes that the operators have good credit standing.

Additional Forms of Financial Protection

With respect to the new provision contained in the Final Rule at 46 CFR 540(j)(ii), based on the current levels of their 2-year high UPR with respect to the required cap (both existing and proposed), it appears that all nine small PVOs may be able to demonstrate the existence of additional forms of protection. To the extent that those proposals are acceptable to the Commission, it would be expected that the elimination of coverage duplication would result in no additional economic impact for any small PVO, and may even reduce it in some cases.

5. Threshold Analysis—Conclusion

Forty operators participate in the FMC's PVO program. Nine are small PVOs as defined by the SBA's small business size standards for NAICS codes of 483112-Deep Sea Passenger Transportation, 483114-Coastal and Great Lakes Passenger Transportation, and 483212-Inland Water Passenger Transportation.

With one exception, all small operators will be left unaffected economically by the rule changes, even without consideration of alternative forms of coverage. The amount of required coverage should remain the same for these operators. After the evaluation reflected in the threshold analysis, the economic impact on the one small operator does not appear likely to be significantly adverse. Should that operator not avail itself of a reduction under the alternative form of coverage provided in the Final Rule, the compliance cost increase brought about by the rule change would increase costs per passenger by a small amount. If this cost is passed on in its entirety to the cruise passengers, it would raise that operator's average fare by less than one percent and still leave the cruise line profitable. It does not seem likely that this level of impact will drive a small PVO out of business or decrease its ability to make future capital investments or harm its competitiveness against larger firms.

However, the Final Rule would allow the Commission, on a case-by-case basis, to recognize additional protections submitted by small PVOs with UPR not exceeding 150 percent of the \$30 million cap. Most likely, the one operator that would be affected by the increased cap, should it choose to avail itself of this provision, would be required to produce less coverage and incur less cost than it does now. Consequently, the threshold analysis does not indicate that the Final Rule in

this proceeding will have a significant economic impact on a substantial number of small business entities.

Even without recognition of alternative forms of coverage, the threshold analysis concludes that this rule will not have a significant economic impact on a substantial number of small entities and, therefore, the analysis recommends that the Chairman so certify pursuant to section 605(b) of the RFA.

The Final Rule Is Not a Major Rule

This rule is not a "major rule" under 5 U.S.C. 804(2).

As described in the NPRM, the collection of information requirements contained in the rule have been submitted to the Office of Management and Budget for review under section 3504(h) of the Paperwork Reduction Act of 1980, as amended. OMB has withheld approval of the forms affected by the rule pending receipt of a summary of comments pertaining to information collection burden imposed by the rule or change made in response to comments. No comments were received relating to information collection burden of the rule.

Inasmuch as the PVOs that are subject to the Commission's passenger vessel financial responsibility regulations at 46 CFR part 540 are already subject to requirements to submit application forms, financial responsibility instruments and periodic reports of their unearned passenger revenues, the final rule does not impose any new recordkeeping or reporting requirements on PVOs that would be "collection of information" requiring approval under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

List of Subjects

46 CFR Part 501

Administrative practice and procedure, Authority delegations, Organization and functions, Seals and insignia.

46 CFR Part 540

Insurance, Maritime carriers, Reporting and recordkeeping requirements, Surety bonds.

For the reasons stated in the supplementary information, the Federal Maritime Commission amends 46 CFR Parts 501 and 540 as follows.

PART 501—THE FEDERAL MARITIME COMMISSION—GENERAL

■ 1. Revise the authority citation for Part 501 to read as follows:

Authority: 5 U.S.C. 551–557, 701–706, 2903 and 6304; 31 U.S.C. 3721; 41 U.S.C. 414

and 418; 44 U.S.C. 501–520 and 3501–3520; 46 U.S.C. 301–307, 40101–41309, 42101–42109, 44101–44106; Pub. L. 89–56, 70 Stat. 195; 5 CFR Part 2638; Pub. L. 104–320, 110 Stat. 3870.

■ 2. Revise § 501.5(g)(2) to read as follows:

§ 501.5 Functions of the organizational components of the Federal Maritime Commission.

* * * * *

(g) * * *

(2) Through the Office of Passenger Vessels and Information Processing, has responsibility for reviewing applications for certificates of financial responsibility with respect to passenger vessels, reviewing requests for substitution of alternative forms of financial protection, managing all activities with respect to evidence of financial responsibility for OTIs and passenger vessel owner/operators, and for developing and maintaining all Bureau database and records of OTI applicants and licensees.

* * * * *

■ 3. Amend § 501.26 introductory text by removing the word "redelgated" and adding the word "re delegated" in its place, and add § 501.26(d) to provide as follows:

§ 501.26 Delegation to and redelegation by Director, Bureau of Certification and Licensing.

* * * * *

(d) Authority to the Director, Bureau of Certification and Licensing to grant requests to substitute alternative financial responsibility pursuant to § 540.9(l) of this chapter based upon existing protection available to purchases of passenger vessel transportation by credit card by an amount up to fifty (50) percent of the passenger vessel operator's highest two-year unearned passenger revenues.

PART 540—PASSENGER VESSEL FINANCIAL RESPONSIBILITY

■ 4. The authority citation for Part 540 continues to read as follows:

Authority: 5 U.S.C. 552, 553; 31 U.S.C. 9701; 46 U.S.C. 305, 44101–44106.

■ 5. Amend § 540.1 by revising the second sentence of paragraph (b) to read as follows:

§ 540.1 Scope.

* * * * *

(b) * * * Vessels operating without the proper certificate may be denied clearance by the Department of Homeland Security and their owners may also be subject to a civil penalty of not more than \$5,000 in addition to a civil penalty of \$200 for each passage

sold, such penalties to be assessed by the Federal Maritime Commission (46 U.S.C. 44101–44106, 60105).

■ 6. Amend § 540.2 by revising paragraphs (a) and (i) to read as follows:

§ 540.2 Definitions.

* * * * *

(a) *Person* includes individuals, limited liability companies, corporations, partnerships, associations, and other legal entities existing under or authorized by the laws of the United States or any State thereof or the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands or any territory or possession of the United States, or the laws of any foreign country.

* * * * *

(i) *Unearned passenger revenue* means that passenger revenue received for water transportation and all other accommodations, services, and facilities relating thereto not yet performed; this includes port fees and taxes paid, but excludes such items as airfare, hotel accommodations, and tour excursions.

* * * * *

■ 7. Revise § 540.4 to read as follows:

§ 540.4 Procedure for establishing financial responsibility.

(a) In order to comply with section 3 of Public Law 89–777 (46 U.S.C. 44101–44102, 44104–44106) enacted November 6, 1966, there must be filed with the Federal Maritime Commission an application on Form FMC–131 for a Certificate of Financial Responsibility for Indemnification of Passengers for Nonperformance of Transportation. Copies of Form FMC–131 may be obtained from the Commission’s Web site at <http://www.fmc.gov>, or from the Bureau of Certification and Licensing, Federal Maritime Commission, Washington, DC 20573.

(b) An application for a Certificate (Performance) shall be filed with the Bureau of Certification and Licensing, Federal Maritime Commission, by the vessel owner or charterer at least 60 days in advance of the arranging, offering, advertising, or providing of any water transportation or tickets in connection therewith except that any person other than the owner or charterer who arranges, offers, advertises, or provides passage on a vessel may apply for a Certificate (Performance). Late filing of the application will be permitted without penalty only for good cause shown.

(c) All applications and evidence required to be filed with the Commission shall be in English, and any monetary terms shall be expressed in terms of U.S. currency.

(d) The Commission shall have the privilege of verifying any statements made or any evidence submitted under the rules of this subpart.

(e) An application for a Certificate (Performance), excluding an application for the addition or substitution of a vessel to the applicant’s fleet, shall be accompanied by a filing fee remittance of \$2,767. An application for a Certificate (Performance) for the addition or substitution of a vessel to the applicant’s fleet shall be accompanied by a filing fee remittance of \$1,382. Administrative changes, such as the renaming of a vessel will not incur any additional fees.

(f) The application shall be signed by a duly authorized officer or representative of the applicant with a copy of evidence of his or her authority.

(g) In the event of any material change in the facts as reflected in the application, an amendment to the application shall be filed no later than fifteen (15) days following such change. For the purpose of this subpart, a material change shall be one which:

(1) Results in a decrease in the amount submitted to establish financial responsibility to a level below that required to be maintained under the rules of this subpart, or

(2) Requires that the amount to be maintained be increased above the amount submitted to establish financial responsibility.

(h) Notice of the application for issuance, denial, revocation, suspension, or modification of any such Certificate will be published on the Commission’s web site at <http://www.fmc.gov>.

■ 8. Amend § 540.5 as follows:

■ a. Revise paragraph (a)(1)(i) to read as follows; and

■ b. Amend paragraph (c) by adding a sentence at the end of the paragraph to read as follows.

§ 540.5 Insurance, guaranties, and escrow accounts.

* * * * *

(a) * * *

(1) * * * (i) Until notice in writing has been given to the assured or to the insurer and to the Bureau of Certification and Licensing at its office in Washington, DC 20573, by certified mail or courier service, * * *

* * * * *

(c) * * * Copies of Form FMC–133A may be obtained from the Commission’s Web site at <http://www.fmc.gov> or from the Bureau of Certification and Licensing.

* * * * *

■ 9. Amend § 540.6 by adding a sentence at the end of paragraph (a) to read as follows:

§ 540.6 Surety bonds.

(a) * * * Copies of Form FMC–132A may be obtained from the Commission’s Web site at <http://www.fmc.gov> or from the Bureau of Certification and Licensing.

* * * * *

■ 10. Revise § 540.7 to read as follows:

§ 540.7 Evidence of financial responsibility.

Where satisfactory proof of financial responsibility has been established:

(a) A Certificate (Performance) covering specified vessels shall be issued evidencing the Commission’s finding of adequate financial responsibility to indemnify passengers for nonperformance of water transportation.

(b) The period covered by the Certificate (Performance) shall be five (5) years, unless another termination date has been specified thereon.

■ 11. Amend § 540.8 by revising paragraphs (a) and (b)(3) to read as follows:

§ 540.8 Denial, revocation, suspension, or modification.

(a) Prior to the denial, revocation, suspension, or modification of a Certificate (Performance), the Commission shall notify the applicant of its intention to deny, revoke, suspend, or modify and shall include with the notice the reason(s) for such action. If the applicant, within 20 days after the receipt of such notice, requests a hearing to show that the evidence of financial responsibility filed with the Commission does meet the rules of this subpart, such hearing shall be granted by the Commission. Regardless of a hearing, a Certificate (Performance) shall become null and void upon cancellation or termination of the surety bond, evidence of insurance, guaranty, or escrow account.

(b) * * *

(3) Failure to comply with or respond to lawful inquiries, requests for information, rules, regulations, or orders of the Commission pursuant to the rules of this subpart.

* * * * *

■ 12. Amend § 540.9 by revising paragraphs (c), (e), (h), (j), and (k), and adding a new paragraph (l) to read as follows:

§ 540.9 Miscellaneous.

* * * * *

(c) The Commission’s bond (Form FMC–132A), guaranty (Form FMC–

133A), and application (Form FMC-131) forms may be obtained from the Commission's Web site at <http://www.fmc.gov> or from the Bureau of Certification and Licensing at its office in Washington, DC 20573.

* * * * *

(e) Each applicant, insurer, escrow agent and guarantor shall furnish a written designation of a person in the United States as legal agent for service of process for the purposes of the rules of this subpart. Such designation must be acknowledged, in writing, by the designee and filed with the Commission. In any instance in which the designated agent cannot be served because of death, disability, or unavailability, the Secretary, Federal Maritime Commission, will be deemed to be the agent for service of process. A party serving the Secretary in accordance with the above provision must also serve the certificant, insurer, escrow agent, or guarantor, as the case may be, by certified mail or courier service at the last known address of service on file with the Commission.

* * * * *

(h) Every person who has been issued a Certificate (Performance) must submit to the Commission a semi-annual statement of any changes with respect to the information contained in the application or documents submitted in support thereof or a statement that no changes have occurred. Negative statements are required to indicate no change. These statements must cover the 6-month period of January through June and July through December, and include a statement of the highest unearned passenger vessel revenue accrued for each month in the 6-month reporting period. Such statements will be due within 30 days after the close of every such 6-month period. The reports required by this paragraph shall be submitted to the Bureau of Certification and Licensing at its office in Washington, DC 20573 by certified mail, courier service, or electronic submission.

* * * * *

(j) The amount of: the insurance as specified in § 540.5(a), the escrow account as specified in § 540.5(b), the guaranty as specified in § 540.5(c), or the surety bond as specified in § 540.6 shall not be required to exceed \$15 million for one year after April 2, 2013. Twelve (12) months after April 2, 2013, the amount shall not exceed \$22 million, and twenty four (24) months after April 2, 2013, the amount shall not exceed \$30 million. Every two years, on the anniversary after the cap on required financial responsibility reaches \$30

million, the cap shall automatically adjust to the nearest \$1 million based on changes as reflected in the U.S. Bureau of Labor Statistics' Consumer Price Index. The Bureau of Certification and Licensing will determine the amount of each adjustment and transmit that information to the Secretary of the Federal Maritime Commission for publication on the Commission's Web site (www.fmc.gov) and in the **Federal Register** with an effective date that is no less than sixty (60) days after **Federal Register** publication.

(k) Every person in whose name a Certificate (Performance) has been issued shall be deemed to be responsible for any unearned passage money or deposits held by its agents or any other person authorized by the certificant to sell the certificant's tickets. Certificants shall promptly notify the Commission of any arrangements, including charters and subcharters, made by it or its agent with any person pursuant to which the certificant does not assume responsibility for all passenger fares and deposits collected by such person or organization and held by such person or organization as deposits or payment for services to be performed by the certificant. If responsibility is not assumed by the certificant, the certificant also must inform such person or organization of the certification requirements of Public Law 89-777 and not permit use of its vessel, name or tickets in any manner unless and until such person or organization has obtained the requisite Certificate (Performance) from the Commission. Failure to follow the procedures in this paragraph means the certificant shall retain full financial responsibility for indemnification of passengers for nonperformance of the transportation.

(l) *Requests to substitute alternative financial responsibility.* (1) A certificant whose unearned passenger revenue at no time for the two immediately prior fiscal years has exceeded 150% of the required cap may submit a request to the Director, Bureau of Certification and Licensing, to substitute alternative forms of financial protection to evidence the financial responsibility as otherwise provided in this part.

(2) The Commission will consider such requests on a case-by-case basis.

(3) The request must include copies of the requesting PVO's most recently available annual and quarterly financial and income statements. Other documents and information in support of its request may also be submitted.

(4) For requests based upon the already existing protections available to credit card purchases of passenger

vessel transportation, the requesting PVO must supply the following information for the most recent twelve months preceding the request: Total deposits and payments received for passenger vessel transportation; Credit card receipt totals; Copy of the PVO's policy(ies) governing payments by passengers (i.e., deposits and the number of days prior to sailing the passenger must make final payment).

(5) In determining whether and to what level to reduce the required amount, the Commission may consider the extent to which other statutory requirements provide relevant protections, the certificant's financial data, and other specific facts and circumstances.

(6) For PVOs with payment policies that provide for final payment for the passenger vessel transportation no later than 60 days before the vessel's sailing date, requests based upon credit card receipts may be granted by the Commission permitting a reduction in the financial responsibility otherwise required under this Part. The amount of such a reduction will be established by determining the proportion that the PVO's total credit card receipts bears to its total receipts and applying one half of that percentage to the PVO's highest two-year UPR.

(7) The Bureau of Certification and Licensing may request additional information as may assist it in considering the request.

(8) Where a request is granted, the alternative financial responsibility shall remain in effect until the PVO's Certificate (Performance) expires under § 540.7(b) or until the Director, Bureau of Certification and Licensing determines otherwise based upon changing information pursuant to this paragraph or paragraph (l)(5) of this section. Additional information may be requested at any time by the Commission or BCL from a PVO whose request under this section has been granted.

■ 13. Remove Form FMC-131 to Subpart A of Part 540.

■ 14. Revise Form FMC-132A to Subpart A of Part 540 to read follows:

FORM FMC-132A TO SUBPART A OF PART 540

FORM FMC-132A

FEDERAL MARITIME COMMISSION

Passenger Vessel Surety Bond (Performance)

Surety Co. Bond No. _____
FMC Certificate No. _____

Know all men by these presents, that we _____ (Name of

applicant), of _____ (City), _____ (State and country), as Principal (hereinafter called Principal), and _____ (Name of surety), a company created and existing under the laws of _____ (State and country) and authorized to do business in the United States as Surety (hereinafter called Surety) are held and firmly bound unto the United States of America in the penal sum of _____, for which payment, well and truly to be made, we bind ourselves and our heirs, executors, administrators, successors, and assigns, jointly and severally, firmly by these presents. Whereas the Principal intends to become a holder of a Certificate (Performance) pursuant to the provisions of subpart A of part 540 of title 46, Code of Federal Regulations and has elected to file with the Federal Maritime Commission such a bond to insure financial responsibility and the supplying transportation and other services subject to subpart A of part 540 of title 46, Code of Federal Regulations, in accordance with the ticket contract between the Principal and the passenger, and

Whereas this bond is written to assure compliance by the Principal as an authorized holder of a Certificate (Performance) pursuant to subpart A of part 540 of title 46, Code of Federal Regulations, and shall inure to the benefit of any and all passengers to whom the Principal may be held legally liable for any of the damages herein described. Now, therefore, the condition of this obligation is such that if the Principal shall pay or cause to be paid to passengers any sum or sums for which the Principal may be held legally liable by reason of the Principal's failure faithfully to provide such transportation and other accommodations and services in accordance with the ticket contract made by the Principal and the passenger while this bond is in effect for the supplying of transportation and other services pursuant to and in accordance with the provisions of subpart A of part 540 of title 46, Code of Federal Regulations, then this obligation shall be void, otherwise, to remain in full force and effect.

The liability of the Surety with respect to any passenger shall not exceed the passage price paid by or on behalf of such passenger. The liability of the Surety shall not be discharged by any payment or succession of payments hereunder, unless and until such payment or payments shall amount in the aggregate to the penalty of the bond, but in no event shall the Surety's obligation hereunder exceed the amount of said penalty. The Surety agrees to

furnish written notice to the Federal Maritime Commission forthwith of all suits filed, judgments rendered, and payments made by said Surety under this bond.

This bond is effective the _____ day of _____, 20____, 12:01 a.m., standard time at the address of the Principal as stated herein and shall continue in force until terminated as hereinafter provided. The Principal or the Surety may at any time terminate this bond by written notice sent by certified mail, courier service, or other electronic means such as email and fax to the other and to the Federal Maritime Commission at its office in Washington, DC, such termination to become effective thirty (30) days after actual receipt of said notice by the Commission, except that no such termination shall become effective while a voyage is in progress. The Surety shall not be liable hereunder for any refunds due under ticket contracts made by the Principal for the supplying of transportation and other services after the termination of this bond as herein provided, but such termination shall not affect the liability of the Surety hereunder for refunds arising from ticket contracts made by the Principal for the supplying of transportation and other services prior to the date such termination becomes effective.

The underwriting Surety will promptly notify the Director, Bureau of Certification and Licensing, Federal Maritime Commission, Washington, DC 20573, of any claim(s) or disbursements against this bond.

In witness whereof, the said Principal and Surety have executed this instrument on _____ day of _____, 20____.

PRINCIPAL

Name _____
 By _____
 (Signature and title)
 Witness _____

SURETY

[SEAL]
 Name _____
 By _____
 (Signature and title)
 Witness _____

Only corporations or associations of individual insurers may qualify to act as surety, and they must establish to the satisfaction of the Federal Maritime Commission legal authority to assume the obligations of surety and financial ability to discharge them.

■ 15. Revise Form FMC-133A to Subpart A of Part 540 to read as follows:

FORM FMC-133A TO SUBPART A OF PART 540

FORM FMC-133A

FEDERAL MARITIME COMMISSION

Guaranty in Respect of Liability for Nonperformance, Section 3 of the Act

Guaranty No. _____

FMC Certificate No. _____

1. Whereas _____ (Name of applicant) (Hereinafter referred to as the "Applicant") is the Owner or Charterer of the passenger Vessel(s) specified in the annexed Schedule ("the Vessels"), which are or may become engaged in voyages to or from United States ports, and the Applicant desires to establish its financial responsibility in accordance with section 3 of Pub. L. 89-777, 89th Congress, approved November 6, 1966 ("the Act") then, provided that the Federal Maritime Commission ("FMC") shall have accepted, as sufficient for that purpose, the Applicant's application, supported by this Guaranty, and provided that FMC shall issue to the Applicant a Certificate (Performance) ("Certificate"), the undersigned Guarantor hereby guarantees to discharge the Applicant's legal liability to indemnify the passengers of the Vessels for nonperformance of transportation within the meaning of section 3 of the Act, in the event that such legal liability has not been discharged by the Applicant within 21 days after any such passenger has obtained a final judgment (after appeal, if any) against the Applicant from a United States Federal or State Court of competent jurisdiction, or has become entitled to payment of a specified sum by virtue of a compromise settlement agreement made with the Applicant, with the approval of the Guarantor, whereby, upon payment of the agreed sum, the Applicant is to be fully, irrevocably and unconditionally discharged from all further liability to such passenger for such nonperformance.

2. The Guarantor's liability under this Guaranty in respect to any passenger shall not exceed the amount paid by such passenger; and the aggregate amount of the Guarantor's liability under this Guaranty shall not exceed \$_____.

3. The Guarantor's liability under this Guaranty shall attach only in respect of events giving rise to a cause of action against the Applicant, in respect of any of the Vessels, for nonperformance of transportation within the meaning of Section 3 of the Act, occurring after the Certificate has been granted to the Applicant, and before the expiration

date of this Guaranty, which shall be the earlier of the following dates:

(a) The date whereon the Certificate is withdrawn, or for any reason becomes invalid or ineffective; or

(b) The date 30 days after the date of receipt by FMC of notice in writing delivered by certified mail, courier service or other electronic means such as email and fax, that the Guarantor has elected to terminate this Guaranty except that: (i) If, on the date which would otherwise have been the expiration date under the foregoing provisions (a) or (b) of this Clause 3, any of the Vessels is on a voyage whereon passengers have been embarked at a United States port, then the expiration date of this Guaranty shall, in respect of such Vessel, be postponed to the date on which the last passenger on such voyage shall have finally disembarked; and (ii) Such termination shall not affect the liability of the Guarantor for refunds arising from ticket contracts made by the Applicant for the supplying of transportation and other services prior to the date such termination becomes effective.

4. If, during the currency of this Guaranty, the Applicant requests that a vessel owned or operated by the Applicant, and not specified in the annexed Schedule, should become subject to this Guaranty, and if the Guarantor accedes to such request and so notifies FMC in writing or other electronic means such as email and fax, then, provided that within 30 days of receipt of such notice, FMC shall have granted a Certificate, such Vessel shall thereupon be deemed to be one of the Vessels included in the said Schedule and subject to this Guaranty.

5. The Guarantor hereby designates _____, with offices at _____, as the Guarantor's legal agent for service of process for the purposes of the Rules of the Federal Maritime Commission, subpart A of part 540 of title 46, Code of Federal Regulations, issued under Section 3 of Pub. L. 89-777 (80 Stat. 1357, 1358), entitled "Security for the Protection of the Public."

(Place and Date of Execution)

(Type Name of Guarantor)

(Type Address of Guarantor)

By _____
(Signature and Title)

Schedule of Vessels Referred to in Clause 1

Vessels Added to This Schedule in Accordance With Clause 4

■ 16. Revise Appendix A to Subpart A of Part 540 to read as follows:

**Appendix A to Subpart A of Part 540—
Example of Escrow Agreement for Use
Under 46 CFR 540.5(b)**

ESCROW AGREEMENT

THIS ESCROW AGREEMENT, made as of this ___ day of (month & year), by and between (Customer), a corporation/company having a place of business at ("Customer")

_____ and
(Banking Institution name & address) a banking corporation, having a place of business at ("Escrow Agent").

Witnesseth:

WHEREAS, Customer wishes to establish an escrow account in order to provide for the indemnification of passengers in the event of non-performance of water transportation to which such passengers would be entitled, and to establish Customer's financial responsibility therefore; and

WHEREAS, Escrow Agent wishes to act as Escrow Agent of the escrow account established hereunder;

NOW, THEREFORE, in consideration of the premises and covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereto agree as follows:

1. Customer has established on (month, & year) (the "Commencement Date") an escrow account with the Escrow Agent which escrow account shall hereafter be governed by the terms of this Agreement (the "Escrow Account"). Escrow Agent shall maintain the Escrow Account in its name, in its capacity as Escrow Agent.

2. Customer will determine, as of the date prior to the Commencement Date, the amount of unearned passenger revenue, including any funds to be transferred from any predecessor Escrow Agent. Escrow Agent shall have no duty to calculate the amount of unearned passenger revenue. Unearned Passenger Revenues are defined as that passenger revenue received for water transportation and all other accommodations, services and facilities relating thereto not yet performed. 46 C.F.R. 540.2(i).

3. Customer will deposit on the Commencement Date into the Escrow Account cash in an amount equal to the amount of Unearned Passenger Revenue determined under Paragraph 2 above plus a cash amount ("the Fixed Amount") equal to (10 percent of the Customer's highest Unearned Passenger Revenue for the prior two fiscal years. For periods on or after (year of agreement (2009)), the Fixed Amount shall be determined by the Commission on an annual basis, in accordance with 46 CFR Part 540.

4. Customer acknowledges and agrees that until such time as a cruise has been completed and Customer has taken the actions described herein, Customer shall not be entitled, nor shall it have any interest in

any funds deposited with Escrow Agent to the extent such funds represent Unearned Passenger Revenue.

5. Customer may, at any time, deposit additional funds consisting exclusively of Unearned Passenger Revenue and the Fixed Amount, into the Escrow Account and Escrow Agent shall accept all such funds for deposit and shall manage all such funds pursuant to the terms of this Agreement.

6. After the establishment of the Escrow Account, as provided in Paragraph 1, Customer shall on a weekly basis on each (identify day of week), or if Customer or Escrow Agent is not open for business on (identify day of week) then on the next business day that Customer and Escrow Agent are open for business recompute the amount of Unearned Passenger Revenue as of the close of business on the preceding business day (hereinafter referred to as the "Determination Date") and deliver a Recomputation Certificate to Escrow Agent on such date. In each such weekly recomputation Customer shall calculate the amount by which Unearned Passenger Revenue has decreased due to (i) the cancellation of reservations and the corresponding refund of monies from Customer to the persons or entities canceling such reservations; (ii) the amount which Customer has earned as revenue as a result of any cancellation fee charged upon the cancellation of any reservations; (iii) the amount which Customer has earned due to the completion of cruises; and (iv) the amount by which Unearned Passenger Revenue has increased due to receipts from passengers for future water transportation and all other accommodations, services and facilities relating thereto and not yet performed.

The amount of Unearned Passenger Revenue as recomputed shall be compared with the amount of Unearned Passenger Revenue for the immediately preceding period to determine whether there has been a net increase or decrease in Unearned Passenger Revenue. If the balance of the Escrow Account as of the Determination Date exceeds the sum of the amount of Unearned Passenger Revenue, as recomputed, plus the Fixed Amount then applicable, then Escrow Agent shall make any excess funds in the Escrow Account available to Customer. If the balance in the Escrow Account as of the Determination Date is less than the sum of the amount of Unearned Passenger Revenue, as recomputed, plus an amount equal to the Fixed Amount, Customer shall deposit an amount equal to such deficiency with the Escrow Agent. Such deposit shall be made in immediately available funds via wire transfer or by direct transfer from the Customer's U.S. Bank checking account before the close of business on the next business day following the day on which the Recomputation Certificate is received by Escrow Agent. The Escrow Agent shall promptly notify the Commission within two business days any time a deposit required by a Recomputation Certificate delivered to the Escrow Agent is not timely made.

7. Customer shall furnish a Recomputation Certificate, in substantially the form attached hereto as Annex 1, to the Federal Maritime

Commission (the "Commission") and to the Escrow Agent setting forth the weekly recomputation of Unearned Passenger Revenue required by the terms of Paragraph 6 above. Customer shall mail or fax to the Commission and deliver to the Escrow Agent the required Recomputation Certificate before the close of business on the business day on which Customer recomputes the amount of Unearned Passenger Revenue.

Notwithstanding any other provision herein to the contrary, Escrow Agent shall not make any funds available to Customer out of the Escrow Account because of a decrease in the amount of Unearned Passenger Revenue or otherwise, until such time as Escrow Agent receives the above described Recomputation Certificate from Customer, which Recomputation Certificate shall include the Customer's verification certification in the form attached hereto as Annex 1. The copies of each Recomputation Certificate to be furnished to the Commission shall be mailed to the Commission at the address provided in Paragraph 25 herein. If copies are not mailed to the Commission, faxed or emailed copies shall be treated with the same legal effect as if an original signature was furnished. No repayment of the Fixed Amount may be made except upon approval of the Commission.

Within fifteen (15) days after the end of each calendar month, Escrow Agent shall provide to Customer and to the Commission at the addresses provided in Paragraph 25 below, a comprehensive statement of the Escrow Account. Such statement shall provide a list of assets in the Escrow Account, the balance thereof as of the beginning and end of the month together with the original cost and current market value thereof, and shall detail all transactions that took place with respect to the assets and investments in the Escrow Account during the preceding month.

8. At the end of each quarter of Customer's fiscal year, Customer shall cause the independent auditors then acting for it to conduct an examination in accordance with generally accepted auditing standards with respect to the weekly Recomputation Certificates furnished by Customer of the Unearned Passenger Revenues and the amounts to be deposited in the Escrow Account and to express their opinion within forty-five (45) days after the end of such quarter as to whether the calculations at the end of each fiscal quarter are in accordance with the provisions of Paragraph 6 of this Agreement. The determination of Unearned Passenger Revenue of such independent auditors shall have control over any computation of Unearned Passenger Revenue by Customer in the event of any difference between such determinations. To the extent that the actual amount of the Escrow Account is less than the amount determined by such independent auditors to be required to be on deposit in the Escrow Account, Customer shall immediately deposit an amount of cash into the Escrow Account sufficient to cause the balance of the Escrow Account to equal the amount determined to be so required. Such deposit shall be completed no later than the business day after receipt by the Escrow Agent of the auditor's opinion containing the amount of such deficiency.

The opinion of such independent auditors shall be furnished by such auditors directly to Customer, to the Commission and to the Escrow Agent at their addresses contained in this Agreement. In the event that a required deposit to the Escrow Agent is not made within one Business Day after receipt of an auditor's report or a Recomputation Certificate, Escrow Agent shall send notification to the Commission within the next two Business Days.

9. Escrow Agent shall invest the funds in the Escrow Account in Qualified Investments as directed by Customer in its sole and absolute discretion. "Qualified Investments" means, to the extent permitted by applicable law:

(a) Government obligations or obligations of any agency or instrumentality of the United States of America;

(b) Commercial paper issued by a United States company rated in the two highest numerical "A" categories (without regard to further gradation or refinement of such rating category) by Standard & Poor's Corporation, or in the two highest numerical "Prime" categories (without regard to further gradation or refinement of such rating) by Moody's Investor Services, Inc.;

(c) Certificates of deposit and money market accounts issued by any United States bank, savings institution or trust company, including the Escrow Agent, and time deposits of any bank, savings institution or trust company, including the Escrow Agent, which are fully insured by the Federal Deposit Insurance Corporation;

(d) Corporate bonds or obligations which are rated by Standard & Poor's Corporation or Moody's Investors Service, Inc. in one of their three highest rating categories (without regard to any gradation or refinement of such rating category by a numerical or other modifier); and

(e) Money market funds registered under the Federal Investment Company Act of 1940, as amended, and whose shares are registered under the Securities Act of 1933, as amended, and whose shares are rated "AAA", "AA+" or "AA" by Standard & Poor's Corporation.

10. All interest and other profits earned on the amounts placed in the Escrow Account shall be credited to Escrow Account.

11. This Agreement has been entered into by the parties hereto, and the Escrow Account has been established hereunder by Customer, to establish the financial responsibility of Customer as the owner, operator or charterer of the passenger vessel(s) (see Exhibit A), in accordance with Section 3 of Public Law 89-777, 89th Congress, approved November 6, 1966 (the "Act"). The Escrow Account shall be held by Escrow Agent in accordance with the terms hereof, to be utilized to discharge Customer's legal liability to indemnify the passengers of the named vessel(s) for non-performance of transportation within the meaning of Paragraph 3 of the Act. The Escrow Agent shall make indemnification payments pursuant to written instructions from Customer, on which the Escrow Agent may rely, or in the event that such legal liability has not been discharged by Customer within twenty-one (21) days after any such

passenger has obtained a final judgment (after appeal, if any) against Customer from a United States Federal or State Court of competent jurisdiction the Escrow Agent is authorized to pay funds out of the Escrow Account, after such twenty-one day period, in accordance with and pursuant to the terms of an appropriate order of a court of competent jurisdiction on receipt of a certified copy of such order.

As further security for Customer's obligation to provide water transportation to passengers holding tickets for transportation on the passenger vessel(s) (see Exhibit A) Customer will pledge to each passenger who has made full or partial payment for future passage on the named vessel(s) an interest in the Escrow Account equal to such payment. Escrow Agent is hereby notified of and acknowledges such pledges. Customers' instructions to Escrow Agent to release funds from the Escrow Account as described in this Agreement shall constitute a certification by Customer of the release of pledge with respect to such funds due to completed, canceled or terminated cruises. Furthermore, Escrow Agent agrees to hold funds in the Escrow Account until directed by Customer or a court order to release such funds as described in this Agreement. Escrow Agent shall accept instructions only from Customer, acting on its own behalf or as agent for its passengers, and shall not have any obligations at any time to act pursuant to instructions of Customer's passengers or any other third parties except as expressly described herein. Escrow Agent hereby waives any right of offset to which it is or may become entitled with regard to the funds on deposit in the Escrow Account which constitute Unearned Passenger Revenue.

12. Customer agrees to provide to the Escrow Agent all information necessary to facilitate the administration of this Agreement and the Escrow Agent may rely upon any information so provided.

13. Customer hereby warrants and represents that it is a corporation in good standing in its State of organization and that is qualified to do business in the State of . Customer further warrants and represents that (i) it possesses full power and authority to enter into this Agreement and fulfill its obligations hereunder and (ii) that the execution, delivery and performance of this Agreement have been authorized and approved by all required corporate actions.

14. Escrow Agent hereby warrants and represents that it is a national banking association in good standing. Escrow Agent further warrants and represents that (i) it has full power and authority to enter into this Agreement and fulfill its obligations hereunder and (ii) that the execution, delivery and performance of this Agreement have been authorized and approved by all required corporate actions.

15. This Agreement shall have a term of one (1) year and shall be automatically renewed for successive one (1) year terms unless notice of intent not to renew is delivered to the other party to this Agreement and to the Commission at least 90 days prior to the expiration of the current term of this Agreement. Notice shall be given by certified mail to the parties at the addresses provided

in Paragraph 25 below. Notice shall be given by certified mail to the Commission at the address specified in this Agreement.

16. (a) Customer hereby agrees to indemnify and hold harmless Escrow Agent against any and all claims, losses, damages, liabilities, cost and expenses, including litigation, arising hereunder, which might be imposed or incurred on Escrow Agent for any acts or omissions of the Escrow Agent or Customer, not caused by the negligence or willful misconduct of the Escrow Agent. The indemnification set forth herein shall survive the resignation or removal of the Escrow Agent and the termination of this agreement.

(b) In the event of any disagreement between parties which result in adverse claims with respect to funds on deposit with Escrow Agent or the threat thereof, Escrow Agent may refuse to comply with any demands on it with respect thereto as long as such disagreement shall continue and in so refusing, Escrow Agent need not make any payment and Escrow Agent shall not be or become liable in any way to Customer or any third party (whether for direct, incidental, consequential damages or otherwise) for its failure or refusal to comply with such demands and it shall be entitled to continue so to refrain from acting and so refuse to act until such conflicting or adverse demands shall finally terminate by mutual written agreement acceptable to Escrow Agent or by a final, non-appealable order of a court of competent jurisdiction.

17. Escrow Agent shall be entitled to such compensation for its services hereunder as may be agreed upon from time to time by Escrow Agent and Customer and which shall initially be set forth in a separate letter agreement between Escrow Agent and Customer. This Agreement shall not become effective until such letter agreement has been executed by both parties hereto and confirmed in writing to the Commission.

18. Customer may terminate this Agreement and engage a successor escrow agent, after giving at least 90 days written termination notice to Escrow Agent prior to terminating Escrow Agent if such successor agent is a commercial bank whose passbook accounts are insured by the Federal Deposit Insurance Corporation and such successor agrees to the terms of this agreement, or if there is a new agreement then such termination shall not be effective until the new agreement is approved in writing by the Commission. Upon giving the written notice to Customer and the Commission, Escrow Agent may terminate any and all duties and obligations imposed on Escrow Agent by this Agreement effective as of the date specified in such notice, which date shall be at least 90 days after the date such notice is given. All escrowed funds as of the termination date specified in the notice shall be turned over to the successor escrow agent, or if no successor escrow agent has been named within 90 days after the giving of such notice, then all such escrowed funds for sailing scheduled to commence after the specified termination date shall be returned to the person who paid such passage fares upon written approval of the Commission. In the event of any such termination where the Escrow Agent shall be returning payments to

the passengers, then Escrow Agent shall request from Customer a list of passenger names, addresses, deposit/fare amounts and other information needed to make refunds. On receipt of such list, Escrow Agent shall return all passage fares held in the Escrow Account as of the date of termination specified in the notice to the passengers, excepting only amounts Customer is entitled to receive pursuant to the terms of this Agreement for cruises completed through the termination date specified in the notice, and all interest which shall be paid to Customer.

In the event of termination of this Agreement and if alternative evidence of financial responsibility has been accepted by the Commission and written evidence satisfactory to Escrow Agent of the Commission's acceptance is presented to Escrow Agent, then Escrow Agent shall release to Customer all passage fares held in the Escrow Account as of the date of termination specified in the notice. In the event of any such termination where written evidence satisfactory to Escrow Agent of the Commission's acceptance has not been presented to Escrow Agent, then Escrow Agent shall request from Customer a list of passenger names, addresses, deposit/fare amounts and other information needed to make refunds. On receipt of such list, Escrow Agent shall return all passage fares held in the Escrow Account as of the date of termination specified in the notice to the passengers, excepting only amounts Customer is entitled to receive pursuant to the terms of this Agreement for cruises completed through the termination date specified in the notice, and all interest which shall be paid to Customer. Upon termination, Customer shall pay all costs and fees previously earned or incurred by Escrow Agent through the termination date.

19. Neither Customer nor Escrow Agent shall have the right to sell, pledge, hypothecate, assign, transfer or encumber funds or assets in the Escrow Account except in accordance with the terms of this Agreement.

20. This Agreement is for the benefit of the parties hereto and, accordingly, each and every provision hereof shall be enforceable by any or each or both of them. Additionally, this Agreement shall be enforceable by the Commission. However, this Agreement shall not be enforceable by any other party, person or entity whatsoever.

21. (a) No amendments, modifications or other change in the terms of this Agreement shall be effective for any purpose whatsoever unless agreed upon in writing by Escrow Agent and Customer and approved in writing by the Commission.

(b) No party hereto may assign its rights or obligations hereunder without the prior written consent of the other, and unless approved in writing by the Commission. The merger of Customer with another entity or the transfer of a controlling interest in the stock of Customer shall constitute an assignment hereunder for which prior written approval of the Commission is required, which approval shall not be unreasonably withheld.

22. The foregoing provisions shall be binding upon undersigned, their assigns, successors and personal representative.

23. The Commission shall have the right to inspect the books and records of the Escrow Agent and those of Customer as related to the Escrow Account. In addition, the Commission shall have the right to seek copies of annual audited financial statements and other financial related information.

24. All investments, securities and assets maintained under the Escrow Agreement will be physically located in the United States.

25. Notices relating to this Agreement shall be sent to Customer at (address) and to Escrow Agent at (address) or to such other address as any party hereto may hereafter designate in writing. Any communication sent to the Commission or its successor organization shall be sent to the following address: Bureau of Certification and Licensing, Federal Maritime Commission, 800 North Capitol NW., Washington, DC 20573-0001.

26. This agreement may be executed in any number of counterparts, each of which shall be deemed to be an original and all of which when taken together shall constitute one and the same instrument.

27. This Agreement is made and delivered in, and shall be construed in accordance with the laws of the State _____ of without regard to the choice of law rules.

IN WITNESS WHEREOF, the undersigned have each caused this Agreement to be executed on their behalf as of the date first above written.

By: _____

Title: _____

By: _____

Title: _____

EXHIBIT A

ESCROW AGREEMENT, dated _____ by and between (Customer) and (Escrow Agent).

Passenger Vessels Owned or Chartered

ANNEX 1

RECOMPUTATION CERTIFICATE

To: Federal Maritime Commission
And To: ("Bank")

The undersigned, the Controller of _____ hereby furnishes this Recomputation Certificate pursuant to the terms of the Escrow Agreement dated _____, between the Customer and ("Bank"). Terms herein shall have the same definitions as those in such Escrow Agreement and Federal Maritime Commission regulations.

I. Unearned Passenger Revenue as of ("Date") was: \$ _____

a. Additions to unearned Passenger Revenue since such date were:

- 1. Passenger Receipts: \$ _____
- 2. Other (Specify) \$ _____
- 3. Total Additions: \$ _____

b. Reductions in Unearned Passenger Revenue since such date were:

- 1. Completed Cruises: \$ _____
- 2. Refunds and Cancellations: \$ _____
- 3. Other (Specify) \$ _____
- 4. Total Reductions: \$ _____

II. Unearned Passenger Revenue as of the date of this Recomputation Certificate is: \$ _____

a. Excess Escrow Amount \$ _____
 III. Plus the Required Fixed Amount:
 \$ _____
 IV. Total Required in Escrow:
 \$ _____
 V. Current Balance in Escrow Account:
 \$ _____
 VI. Amount to be Deposited in Escrow
 Account: \$ _____
 VII. Amount of Escrow Account available to
 Operator: \$ _____
 VIII. I declare under penalty of perjury that
 the above information is true and correct.
 Dated: _____

(Signature)

Name: Title:

(Signature)

Name: Title:

By the Commission.

Karen V. Gregory,
Secretary.

[FR Doc. 2013-04417 Filed 2-26-13; 8:45 am]

BILLING CODE 6730-01-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 1206013412-2517-02]

RIN 0648-XC467

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; 2013 Accountability Measures for Gulf of Mexico Commercial Greater Amberjack

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

ACTION: Temporary rule; accountability
 measures.

SUMMARY: NMFS implements
 accountability measures (AMs) for
 commercial greater amberjack in the
 Gulf of Mexico (Gulf) reef fish fishery
 for the 2013 fishing year through this
 temporary final rule. This rule reduces
 the Gulf greater amberjack 2013
 commercial annual catch target (ACT)
 (equal to the commercial quota) to
 338,157 lb (153,385 kg) and reduces the
 2013 commercial annual catch limit
 (ACL) to 410,157 lb (186,044 kg), based
 on the 2012 commercial ACL overage.
 These actions are necessary to reduce
 overfishing of the Gulf greater amberjack
 resource.

DATES: This rule is effective February
 27, 2013, through December 31, 2013.

ADDRESSES: Electronic copies of
 Amendment 35 to the Fishery
 Management Plan for the Reef Fish

Resources of the Gulf (FMP), which
 includes an environmental assessment,
 an initial regulatory flexibility analysis,
 and a regulatory impact review, may be
 obtained from the Southeast Regional
 Office Web site at [http://
 sero.nmfs.noaa.gov/sf/
 GrouperSnapperandReefFish.htm](http://sero.nmfs.noaa.gov/sf/GrouperSnapperandReefFish.htm).

FOR FURTHER INFORMATION CONTACT: Rich
 Malinowski, telephone: 727-824-5305,
 or email: Rich.Malinowski@noaa.gov.

SUPPLEMENTARY INFORMATION: NMFS
 manages the reef fish fishery of the Gulf,
 which includes greater amberjack,
 under the FMP. The Gulf of Mexico
 Fishery Management Council (Council)
 prepared the FMP and NMFS
 implements the FMP under the
 authority of the Magnuson-Stevens
 Fishery Conservation and Management
 Act (Magnuson-Stevens Act) by
 regulations at 50 CFR part 622. All
 greater amberjack weights discussed in
 this temporary rule are in round weight.

Background

The 2006 reauthorization of the
 Magnuson-Stevens Act established new
 requirements including ACLs and AMs
 to end overfishing and prevent
 overfishing from occurring. AMs are
 management controls to prevent ACLs
 from being exceeded, and correct or
 mitigate overages of the ACL if they
 occur. Section 303(a)(15) of the
 Magnuson-Stevens Act mandates the
 establishment of ACLs at a level such
 that overfishing does not occur in the
 fishery, including measures to ensure
 accountability.

On November 13, 2012, NMFS
 published a final rule for Amendment
 35 (77 FR 67574). That final rule
 established the Gulf greater amberjack
 stock ACL equal to the greater
 amberjack stock allowable biological
 catch (ABC) at 1,780,000 lb (807,394 kg),
 with the greater amberjack stock ACT at
 1,539,000 lb (698,079 kg) based on the
 ACT Control Rule developed in the
 Generic Annual Catch Limits/
 Accountability Measures Amendment
 (Generic ACL Amendment) (76 FR
 82044, December 29, 2011).

Sector allocations were established in
 Amendment 30A to the FMP (73 FR
 38139, July 3, 2008) with 27 percent of
 the ACL allocated to the commercial
 sector and 73 percent of the ACL
 allocated to the recreational sector.
 Based on these allocations, the final rule
 for Amendment 35 established a greater
 amberjack commercial ACL of 481,000
 lb (218,178 kg) and the commercial ACT
 (equivalent to the commercial quota) of
 409,000 lb (185,519 kg). The commercial
 ACT is set 15 percent below the ACL to
 account for management uncertainty.

Accountability measures for Gulf
 greater amberjack were also revised by
 the final rule for Amendment 35. In
 accordance with regulations at 50 CFR
 622.49(a)(1)(i), when the commercial
 ACT (commercial quota) is reached, or
 projected to be reached, the Assistant
 Administrator for Fisheries, NOAA,
 (AA), will file a notification with the
 Office of the Federal Register to close
 the commercial sector for the remainder
 of the fishing year. If despite such
 closure, commercial landings exceed the
 commercial ACL, then during the
 following fishing year, both the
 commercial ACT (commercial quota)
 and the commercial ACL will be
 reduced by the amount of the prior
 year's commercial ACL overage.

Additionally, the final rule for
 Amendment 35 established a
 commercial trip limit for greater
 amberjack of 2,000 lb (907 kg). This trip
 limit is applicable until the commercial
 ACT (commercial quota) is reached or
 projected to be reached during a fishing
 year and the commercial sector is
 closed.

Management Measures Contained in This Temporary Rule

In 2012, the commercial sector of
 greater amberjack was closed on March
 1, when the adjusted commercial quota
 of 237,438 (107,700 kg), based on the
 2011 quota overage, was determined to
 be reached. Finalized 2012 commercial
 landings data indicated the adjusted
 2012 commercial quota of 237,438 lb
 (107,700 kg) was exceeded by 29.8
 percent, or 70,843 lb (32,134 kg).
 Therefore, the reduced 2013 commercial
 ACT (commercial quota) for Gulf greater
 amberjack is 338,157 lb (153,385 kg)
 (*i.e.*, 409,000-lb (185,519-kg)
 commercial ACT minus the overage of
 70,843 lb (32,134 kg)). The reduced
 2013 commercial ACL for Gulf greater
 amberjack is 410,157 lb (186,044 kg)
 (*i.e.*, 481,000-lb (218,178-kg)
 commercial ACL minus the overage of
 70,843 lb (32,134 kg)).

The 2014 commercial ACT
 (commercial quota) for greater
 amberjack will return to 409,000 lb
 (185,519 kg), as specified at 50 CFR
 622.42(a)(1)(v), and the commercial ACL
 for greater amberjack will return to
 481,000 lb (218,178 kg), as specified in
 50 CFR 622.49(a)(1)(i)(C), unless AMs
 are implemented due to a commercial
 ACL overage, or the Council takes
 subsequent regulatory action to adjust
 the commercial ACT (commercial quota)
 and commercial ACL.

Classification

The Regional Administrator, Southeast Region, NMFS, has determined this temporary rule is necessary for the conservation and management of the Gulf greater amberjack component of the Gulf reef fish fishery and is consistent with the Magnuson-Stevens Act, the FMP, and other applicable laws.

The temporary rule has been determined to be not significant for purposes of Executive Order 12866.

These measures are exempt from the procedures of the Regulatory Flexibility Act because the temporary rule is issued without opportunity for prior notice and comment.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive the requirements to provide prior notice and opportunity for public comment on this temporary

rule. Such procedures are unnecessary because the AMs established by Amendment 35 and located at 50 CFR 622.49(a)(1)(i) authorize the AA to file a notification with the Office of the Federal Register to reduce the commercial ACT (commercial quota) and commercial ACL the following fishing year when the commercial ACL is exceeded. The proposed rule for Amendment 35 (77 FR 42476, July 19, 2012) that implemented these AMs was already subject to notice and comment and all that remains is to notify the public of the 2013 commercial ACT (commercial quota) and commercial ACL for Gulf greater amberjack.

Additionally, prior notice and opportunity for public comment would be contrary to the public interest. Given the ability of the commercial sector to rapidly harvest fishery resources, there

is a need to immediately implement the reduced commercial ACT (commercial quota) and commercial ACL for the 2013 fishing year. Taking time to provide prior notice and opportunity for public comment creates a higher likelihood of the reduced commercial ACT (commercial quota) and commercial ACL being exceeded.

For the aforementioned reasons, the AA also finds good cause to waive the 30-day delay in the effectiveness of this action under 5 U.S.C. 553(d)(3).

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

Dated: February 22, 2013.

Kara Meckley,

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

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Proposed Rules

Federal Register

Vol. 78, No. 39

Wednesday, February 27, 2013

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 340

[Docket No. APHIS–2006–0124]

RIN 0579–AC08

Sharing Certain Business Information Regarding the Introduction of Genetically Engineered Organisms With State and Tribal Government Agencies

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend our regulations regarding genetically engineered organisms regulated by the United States Department of Agriculture by adding provisions for sharing certain business information with State and Tribal government agencies. The proposed provisions would govern the sharing of certain information contained in permit applications and notifications for importations, interstate movements, or releases into the environment of regulated articles. The procedures would allow the Animal and Plant Health Inspection Service (APHIS) to share certain business information with State and Tribal governments without impairing our ability to protect confidential business information from disclosure. APHIS currently withholds such information when it shares applications with non-Federal Government agencies. This action would improve our collaborative and cooperative efforts with State and Tribal governments as well as improve the effectiveness of our notification and permitting procedures as APHIS continues to regulate certain genetically engineered organisms.

DATES: We will consider all comments that we receive on or before April 29, 2013.

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

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/#!documentDetail;D=APHIS-2006-0124-0001>.

- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2006–0124, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2006-0124> or in our reading room, which 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) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Ms. Chessa Huff-Woodard, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 146, Riverdale, MD 20737–1236; (301) 851–3943.

SUPPLEMENTARY INFORMATION:

Background

The Animal and Plant Health Inspection Service (APHIS) regulates the introduction (importation, interstate movement, or release into the environment) of organisms altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests under 7 CFR part 340, “Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests” (referred to below as the regulations or as part 340). The regulations refer to such genetically engineered (GE) organisms and products as “regulated articles.” The purpose of the regulations is to prevent the dissemination of plant pests.

With certain limited exceptions, the regulations prohibit the introduction (importation, interstate movement, or release into the environment) of any regulated article unless APHIS has issued a permit for the introduction in accordance with § 340.4, or unless APHIS has been notified in accordance with § 340.3 for certain GE plants that meet specified eligibility requirements

and performance standards. Before APHIS authorizes the introduction, APHIS makes a determination on whether the actions under notification or permit are likely to result in the risk of introduction of a plant pest. In order to make that determination, APHIS requires applicants to provide essential information, some of which is designated by the applicant as confidential business information (CBI).

As provided in §§ 340.3 and 340.4, APHIS shares notifications and applications for permits for introductions, minus any information designated as confidential business information identified by the submitter, with State regulatory officials in the States of introduction. We now propose to share certain business information with State and Tribal regulatory officials. APHIS proposes to share certain business information only with those specific State or Tribal agencies that have legal jurisdiction over genetically engineered agricultural crops and/or products. No other State or Tribal agencies would have any access to the shared CBI. This information sharing would allow APHIS to share issues of concern with the officials of the State where the introduction is planned and would also enable the States to better review and comment on notifications and permits and provide information, advice, and recommendations to APHIS. APHIS would also share certain business information in notifications and applications for permits with Tribal government officials when introductions of regulated articles are proposed for Tribal lands.

Permit applications, notifications, and other information submitted to APHIS under the regulations frequently contain business information designated by the submitter to be confidential in nature and marked as such on the submission. CBI is protected from mandatory public disclosure under the Freedom of Information Act (FOIA), exemption 4 (5 U.S.C. 552(b)(4)). Exemption 4 covers two broad categories of information in Federal agency records: (1) Trade secret information and (2) information that is commercial or financial, obtained from a person and privileged or confidential. It has been APHIS policy¹ not to release

¹ See 50 FR 38561–38563, “Policy Statement on the Protection of Privileged or Confidential Business Information” in the **Federal Register**

designated CBI to State or Tribal government officials. The APHIS FOIA Office oversees any information release requested under FOIA.

APHIS' notification and permit procedures require that if an applicant claims submitted information to be CBI, that information must be clearly designated as such. In accordance with the regulations and guidance documents,² persons submitting either notifications or permit applications by mail who believe their submission contains CBI must submit two copies, one with all CBI material clearly marked and another with all CBI material deleted. For submissions by means of ePermits, the applicant encloses CBI material within brackets and appropriate versions are automatically generated for State distribution with the designated CBI deleted. APHIS may review the designated CBI material and may propose that the applicant make changes to the designated CBI material if APHIS determines that some of the designated CBI material is in fact not CBI material and should not be designated as CBI.

Currently, APHIS shares only "CBI-deleted" copies of notification or permit submissions with appropriate State or Tribal regulatory officials. State and Tribal officials may provide comments on the applications sent them, but are not required to do so.

Historically, applicants have claimed a wide range of information that they have to submit to APHIS as being CBI. For example, applicants have claimed the exact location of an introduction (facility address or GPS coordinates for an environmental release) as CBI. Applicants have also claimed confidentiality for genes, the gene donor, production details, and particular details about phenotype of the regulated article. Permit applications generally have more material designated as CBI than do notifications because permit applications have more detailed descriptions of the phenotype of the regulated article (described in § 340.4(b)(5)) than do notifications (described in § 340.3(d)(2)). Permit applications also contain a description of the methods for confinement of the regulated article during the

introduction. Other material often claimed as CBI in permit applications specifically for release into the environment includes the purpose of the environmental release, descriptions of the release, proposed procedures and confinement methods, and other safeguards and mitigation measures to prevent dissemination or persistence following the environmental release.

Currently, if a State or Tribal official desires to see information from notification or permit applications, acknowledged notifications, or issued permits and that information has been designated as CBI by the applicant, the official would need to contact the applicant for the information. However, APHIS has not always withheld designated CBI from State or Tribal regulatory officials. Around 1988, APHIS began sharing certain business information designated by submitters as CBI with State authorities if the State's attorney general submitted a letter to APHIS agreeing to protect the confidentiality of the information to be shared. Only a few States were authorized to receive designated CBI from APHIS using this mechanism. In 2001, this policy was discontinued because of concerns that sharing designated CBI with States could be deemed to constitute a waiver of the applicable exemption from disclosure under FOIA. During the period when we shared designated CBI with the States, the only shared records were paper documents, and there were no reports that a State's process to protect designated CBI shared with them by APHIS had failed, or that any such business information had been released to unauthorized persons.

On June 7, 2004, APHIS convened a meeting with the National Association of State Directors of Agriculture (NASDA). One of the main purposes of the meeting was to evaluate the quality of interactions between APHIS and State governments, especially with respect to biotechnology issues. At that meeting, State officials expressed the view that cooperation and collaboration between APHIS and the States in regulatory activities for agricultural biotechnology may not be as effective as possible because information withheld as CBI from notification and permit applications often appeared to be important to the State's review. State officials expressed concern about the adequacy of reviews conducted when important information was not available to them.

The discussions regarding sharing of designated CBI information initiated at the 2004 NASDA meeting have continued over time, along with

discussions covering a range of regulatory activities and compliance and enforcement issues arising within agricultural biotechnology. These discussions focused on methods of sharing designated CBI with the States that would be consistent with the ability of the States to prevent disclosure under State FOIA laws and other applicable disclosure statutes or policies of the States. As a result of these discussions, APHIS has developed this proposed rule to allow the sharing of certain business information desired by State and Tribal government authorities.

Purpose and Effects of the Proposed Rule

This proposed rule would establish a mechanism for APHIS to share certain information designated as CBI with State and Tribal government agencies. This sharing would provide benefits to APHIS, and to the States and Tribal governments, and strengthen the relationship between the Federal and other governments. For APHIS, a provision to share certain business information will benefit compliance activities, improve the efficiency of the permit and notification processes, and facilitate inspections by State regulators under the supervision of APHIS. For the State and Tribal governments, the proposed changes would enhance participation in the assessment process and encourage these entities to be more fully informed and involved. The proposed sharing of certain business information would be accomplished without compromising the protection afforded CBI under FOIA's Exemption 4.

Benefits to APHIS' Emergency Response Activities

Sharing certain business information with State and Tribal governments would support better contingency planning and disaster responses. In the event of a local emergency, such as a hurricane, tornado, or flooding, there may be a need to assess and potentially remediate locations where regulated articles were present as part of an environmental release or were in a containment facility that became damaged. In these events, State and Tribal government officials in proximity to the area of concern may be better prepared to respond to this situation if they already have knowledge of the regulated article, the location of the site, and the identities of the personnel responsible for the site. Because such business information is often designated as CBI, and if APHIS could not share certain CBI with the appropriate State and Tribal authorities, participation of the State or Tribes may be hampered,

September 23, 1985. The instructions for submitting designated CBI consistent with this policy are found in the BRS document titled "USDA-APHIS Biotechnology Regulatory Services User's Guide" (version 2/5/2008, on pp. 8-11). This information may be viewed on the Internet at http://www.aphis.usda.gov/brs/pdf/Doc_Prep_Guidance.pdf or obtained from the person listed under **FOR FURTHER INFORMATION CONTACT**.

² 7 CFR 340.4(a) and "USDA-APHIS Biotechnology Regulatory Services User's Guide."

making appropriate remedial action more difficult and a timely response less likely.

Improved Efficiency of Permits and Notification Process

The ability to share CBI would aid APHIS and State and Tribal governments by improving the efficiency of the notification and permitting processes. The proposed sharing of certain business information would help avoid the delays that frequently occur in the current APHIS permitting and notification process. These delays may occur when a State or Tribal government decides it must ask the developer of the regulated article for business information about a proposed introduction of the regulated article. The business information requested is often part of the CBI information the developer submitted in its application to APHIS, but deleted when the application was forwarded to the State or Tribal government. From previous experience, APHIS understands that such requests by State agencies or Tribal officials for certain business information from applicants can sometimes be lengthy processes. Because the applicant may not have a routine procedure to respond to a State or Tribal agency, requests for information may not be processed in a timely manner by the applicant.

State and Tribal Participation in the Assessment and Permitting Process

Under this proposed rule, only the appropriate State and Tribal agencies would be able to review the conditions assigned by APHIS for introduction of a regulated article and also to confer with APHIS on any additional issues related to a permit or notification. For example, feedback provided by State and Tribal agencies about the site of an environmental release or nearby areas may help APHIS to further review assigned confinement conditions. The goal of these conditions is to prevent possible unauthorized dissemination of plant pests. State and Tribal agencies may wish to discuss with APHIS any information regarding activities, commerce, and traffic in the area of an environmental release. Such local information may further inform APHIS about appropriate confinement conditions for an environmental release, ensure better compliance with the conditions of the permit, or help the applicant meet the performance standards for notifications.

In some cases, a State or Tribal regulatory official could assess citizen, consumer, or grower concerns about introductions at certain locations, and

then convey these issues to APHIS. In these situations, APHIS would receive valuable inputs from the State and Tribal agencies that would be used to confirm confinement protocols and advise product developers. Yet other activities might be facilitated by sharing of certain business information about the regulated crop and its planting location. In other cases, by working closely with State agencies or Tribal nations in possession of authorized shared CBI, APHIS may obtain certain information about environmental releases to assist in complying with other Federal statutes, e.g., the Endangered Species Act.

This proposal would improve Federal transparency because the appropriate State and Tribal government agencies receiving certain business information from APHIS would be better informed about introductions within their jurisdictions. Furthermore, when the State or Tribal agencies have accurate and detailed information about introductions, they would be better prepared to explain to their citizens the proposed introduction of genetically engineered organisms at publicly undisclosed sites within their jurisdiction. Consequently, the proposed sharing could increase public confidence in Federal, State and Tribal oversight of introductions of regulated articles.

Facilitating State Agency Inspections of Release Sites

Recent APHIS experience has demonstrated the value of sharing certain business information with States and Tribal governments. In 2005, APHIS initiated an ongoing pilot inspection project with some State plant regulatory agencies. APHIS evaluated whether State inspectors could supplement APHIS officers by performing inspections of environmental release sites for regulated articles. For this pilot project, State inspectors received the same training as APHIS officers, and then were to conduct inspections on behalf of APHIS. In the course of this pilot project, APHIS' lack of authority to share CBI with State cooperators prevented full employment of State inspectors to accomplish APHIS' regulatory objectives. Because CBI-deleted documents may not contain certain business information crucial to inspections, such as the contact information for the applicant's site cooperator, or the exact location of the environmental release, State inspectors had to obtain this information from the applicant. This extra step added time and uncertainty to the necessary inspections, which are scheduled to

correspond with the timing of certain biological and business activities related to the regulated article (pollination, harvest, etc.). This step of requesting information from the applicant may cause unacceptable delays that potentially interfere with timely completion of inspections.

Balancing the Benefits of Information Sharing and Confidentiality and Privacy Interests

Overall, APHIS anticipates that this new sharing activity for certain business information would benefit APHIS' compliance activities, enhance the effectiveness and efficiency of the permitting process, and allow the fullest use of State-employed inspectors. Increased participation by the States and Tribal governments in the permitting and notification processes would allow them to engage APHIS in mutually beneficial and constructive collaborations. By informing these governments about introductions into their State or Tribal lands, the sharing of certain business information will initiate a new level of transparency for APHIS with State and Tribal government stakeholders and enhance their ability to represent the interests of the public they represent.

Despite the benefits of this proposed activity, APHIS is required to choose a procedure that does not publicly disclose CBI submitted by the applicant. Except for the brief period 1988–2001, APHIS' communication with the States and Tribal governments generally had the same status as communication with any member of the public. In accordance with 5 U.S.C. 552(a)(3)(A), any record of the Agency that is disclosed in an authorized manner to any member of the public is available for disclosure to all members of the public.

There are times when public disclosure of information would undermine legitimate private rights and governmental responsibilities. As discussed above, FOIA Exemption 4 (5 U.S.C. 552(b)(4)) states that disclosure requirements do not apply to "trade secrets and commercial or financial information obtained from a person and privileged or confidential." This exemption applies to all notification and permit information that applicants designate as CBI and that APHIS accepts and treats as CBI as required by applicable Federal laws. Another FOIA exemption that is applicable to some or all of this material is Exemption 5 (5 U.S.C. 552(b)(5)), "inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with

the agency.” To the extent that applicant designated CBI is contained in APHIS inter-agency or intra-agency memorandums or letters, APHIS will review such documents to determine if such CBI material should be withheld pursuant to the applicable Federal laws. Exemption 6 (5 U.S.C. 552(b)(6)), “personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy,” would also apply in some cases where the disclosed information would, for example, lead to the identity of the landowner or leaseholder where the field test was being conducted.

Our proposed provisions for the sharing of certain business information would include a statement that the appropriate State and Tribal agencies receiving the shared information are not members of the public for purposes of disclosure of designated CBI submitted to APHIS by notification or permit applicants as required by part 340. Accordingly, disclosure of the authorized information by APHIS to the State or Tribal government would not constitute a waiver of any FOIA exemption protection.

Mechanisms for Safeguarding Shared Information

APHIS proposes to establish a new § 340.10 that would contain requirements for safeguarding shared business information and would also describe what types of CBI could be shared with States and Tribal governments. We propose that if any of this information is to be retained by the State or Tribal governments, only paper copies would be authorized for retention. Currently, APHIS is examining various electronic options to share certain business information, but a method for doing so has not been selected. We considered allowing regulators in authorized States and Tribal governments to share certain business information that was downloaded to a secure APHIS server, and then granting access to the authorized government entities. However, providing a new and separate secure system was not likely to be economically viable for APHIS. Although secured access to electronic records containing certain business information is not possible at this time, APHIS will continue to explore the possibility of sharing this information with authorized State or Tribal government officials by this means in the future. If APHIS finds an electronic means to share certain business information with these agencies, APHIS will deploy a system that conforms to

all appropriate Federal cyber security requirements and ensures the confidentiality and integrity of the CBI data. Also, as part of the implementation plan for this rule, APHIS will survey State and Tribal government agencies 6 and 12 months after initiating that system to determine whether the electronic means of sharing CBI meets the needs of the appropriate State and Tribal regulatory officials.

The Administrator may authorize sharing of information under proposed § 340.10 provided that five conditions are met by the appropriate State or Tribal government authority desiring the shared information, as stated in a written agreement between the State or Tribal governments and APHIS. Proposed § 340.10 (a)(1) would require the State or Tribal government officials to state their authority to protect from public disclosure permit and compliance information that has been designated CBI in the written agreement. Based on our preliminary review of State authorities, APHIS realizes that only some States have the legal authority to protect the specified types of business information from public disclosures. For example, the four States currently participating in the APHIS pilot program in 2009—Arkansas, Florida, Kansas, and North Carolina—were able to provide letters indicating that shared confidential business information could be protected if disclosed to State inspectors by the applicant. However, we particularly invite comments on whether limits to statutory authority in any State would preclude its participation in the proposed information sharing program.

Proposed § 340.10(a)(2) would require the State or Tribal government to have in place suitable procedures to ensure the security of the shared confidential business information and to specify and restrict which specific State or Tribal agency or agencies and their respective officials are allowed access to it. These officials would be required to complete the same annual “Confidential Business Information and Records Management” training that APHIS requires of employees handling CBI. State and Tribal procedures would have to be equivalent to those currently used by APHIS, which are specified in APHIS’ “Policy Statement on the Protection of Privileged or Confidential Business Information” cited above. At this time, APHIS would not allow State or Tribal agencies to store in electronic form or otherwise create any records of any CBI received from APHIS. Nevertheless, APHIS is exploring and seeking input on sharing certain business information with State and Tribal government

agencies by electronic means. This issue is discussed further in the first paragraph of this section above.

The goal of these security measures would be to safeguard documents containing information disclosed under the proposed provisions, i.e., to account for the location of documents at all times, control access to documents, and provide for secure transmittal, destruction, or return of documents to APHIS. If State or Tribal agencies employ methods equivalent to those used by APHIS, we are confident that they can review this information while effectively maintaining document security. Adaptations of these procedures that achieve an equivalent effect would be specified in the required written agreement between APHIS and a State or Tribal government agency.

Proposed § 340.10(a)(3) would require a commitment in the written agreement between APHIS and the State or Tribal government not to disclose CBI without the written permission of the submitter or written confirmation from APHIS that the information is no longer considered CBI as determined by APHIS pursuant to the applicable Federal laws. Proposed § 340.10(a)(4) would require a commitment in the written agreement by the State or Tribal government that all persons authorized to have access to CBI provided by APHIS will be trained by the State or Tribal authority on how to maintain the security of the shared CBI before having access to it. APHIS would provide the content of the required training.

This training requirement would also apply to situations where a State or Tribal authority needs to share certain business information with State or Tribal employees who are not regulatory officials (such as faculty of State universities) and APHIS agrees to allow the non-regulatory State or Tribal employees access to the shared CBI. Such persons would need training to protect this information from disclosure and in these cases, the parties would need to establish additional safeguards within the written agreement before those non-regulatory State or Tribal employees were allowed access to the shared CBI. For example, the State or Tribal authority would have to agree to appoint regulatory officials to oversee confidentiality rules and responsibilities for safeguarding business information shared with these other employees.

Each government agency entering into a written agreement with APHIS to receive certain business information would be obligated under the terms of the written agreement to safeguard the entrusted information. If a State or Tribal government intentionally or even

unintentionally releases certain authorized business information, APHIS would make a determination of whether or not to immediately void the written agreement and revoke the agency's privilege to receive future authorized information or whether to impose appropriate corrective actions, conditions, and/or requirements into the written agreement for the agency. Also, individuals who release protected information may be subject to penalties under applicable State or Tribal laws for the protection of trade secrets and confidential business information.

The final provision for the written agreement, proposed § 340.10(a)(5), would require inclusion of other needed terms agreed to by APHIS and the State or Tribal government regarding the shared information. This provision could take into account and incorporate administrative procedures or authorities that are unique to a State or Tribe.

Description of Information To Be Shared

Proposed § 340.10(b) describes the types of CBI from notifications and permit applications, acknowledged notifications, or issued permits that APHIS proposes to share with States and Tribal governments. APHIS developed these information categories based on our experience working with States and Tribes and our observations of what types of information prevented optimal cooperation from States or Tribes in application review, inspection, and other activities under the regulations. APHIS also used responses to a questionnaire developed and distributed by NASDA that identified information needs perceived by State regulatory officials. Respondents identified the following information as useful during their State review: Information about the regulated article and its phenotype, the location and contact information of any cooperators for the introduction, activity dates during the introduction (e.g., planting, inoculation, harvest dates for environmental releases), and protocols used during the introduction.

When information sharing is requested by the State or Tribal government agency, APHIS proposes to share:

- Information about the regulated article(s) being used during the introduction, including information in the notification or permit application, the acknowledged notification, or the issued permit regarding the phenotypic designation, and the phenotypic description of anticipated expression of the altered genetic material in the regulated article compared to the

expression in the non-modified parental organism;

- The location(s) of the introduction identified by the applicant within the territory of the State or Tribal nation of the requester, including the cooperator's address; GPS coordinates corresponding to multiple sites within the particular State or Tribe; and the number of acres for an environmental release;

- The dates of activity during the environmental release, including planting dates and termination dates for the release;

- The methods of confinement as they are approved by APHIS at the time of application (for permits, APHIS would share the mandatory and supplemental conditions required by APHIS and those cited in the permit application; for notifications, APHIS would provide design protocols for the regulated articles); and

- The name and contact information for the responsible person for the introduction.

Related Changes in Part 340

The regulations in § 340.4(b) and (c) currently state that when APHIS determines that a permit application is complete, we will submit to the State department of agriculture of the State where an introduction is planned a copy of the initial review along with the application marked "CBI Deleted" or "No CBI" for State notification and review. Because proposed § 340.10 would allow us to share CBI with the appropriate State or Tribal officials, we would amend § 340.4(b) and (c) to state that when an application contains designated CBI, the State or Tribal government will be provided a "CBI deleted" copy of the application unless the disclosure of certain business information to the State or Tribal government has been authorized in accordance with § 340.10 and is requested by the State or Tribal government.

The current regulations identify the procedures for a permit applicant to identify and mark CBI information in § 340.4(a). CBI information submitted in notification applications is identified and marked exactly the same way as such information is marked and identified in permit applications. However, APHIS neglected to include parallel language in the notifications section at the time the notifications procedure was added to part 340. APHIS proposes to take this opportunity to remedy that oversight by adding a reference in § 340.3(d) for submission of CBI in notifications. The section "Procedural requirements for notifying APHIS" will contain parallel language

to that in § 340.4(a) addressing CBI in permit applications.

Executive Orders 12866 and 13563 and Regulatory Flexibility Act

Executive Orders 13563 and 12866 direct 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, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

APHIS has prepared an economic analysis for this proposed rule, which is set out below. The analysis provides a cost-benefit analysis, as required by Executive Order 12866, and an analysis of the potential economic effects of this proposed rule on small entities, as required by the Regulatory Flexibility Act.

This proposal would amend APHIS' part 340 regulations regarding regulated articles to add provisions concerning the sharing of certain business information but only with certain officials of State and Tribal government agencies. The proposed provisions would create mechanisms for sharing certain business information contained in permit applications and notifications that are submitted to APHIS under the regulations, while continuing to allow APHIS to protect the confidentiality of the information.

Benefits

The benefits of the proposed rule include improving the effectiveness and efficiency of the notification and permitting processes of part 340. At the same time, the rule will enhance and maintain the rigorous regulation of regulated articles. Specifically, State and Tribal government officials could receive information from APHIS that APHIS would withhold as CBI under current procedures and that applicants may choose not to disclose if requested directly by States or Tribes. This would allow those State and Tribal government officials to provide more timely and more pertinent information to APHIS regarding site-specific issues related to notifications or permits. Although APHIS does not envision any efficiencies gained from reduced paper handling, efficiencies will derive from

fewer days required for APHIS to await State or Tribal responses to new permit and notification applications. The process and rationale for APHIS' decisions regarding introductions (e.g., assignment of permit conditions for specific environmental releases, importations and interstate movements) would be improved and would be more transparent to State and Tribal governments because they would also have certain business information APHIS used in its decisionmaking process. In addition, new collaborations with the States and Tribes on permit issues would be beneficial to the authorized State and Tribal authorities as well as to APHIS. A current pilot program that authorizes State inspectors to review compliance information for approved environmental release sites would be facilitated by making available information about regulated articles and the respective environmental release sites. Also, future compliance incidents could be assessed and remediated under APHIS direction by State employees, if provided with appropriate information about permits or notifications. By facilitating these actions, APHIS' effectiveness in the continuing and evolving oversight of regulated articles and their potential attainment of non-regulated status would be enhanced.

Costs

There would be minimal costs to the States and Tribes associated with sharing certain business information between these agencies and APHIS. Costs would be the resources required to draft and sign a written agreement, and the resources it would take to share the information, provide for the appropriate training of those State or Tribal officials that would have access to the CBI, and provide the appropriate mechanisms for safeguarding the shared CBI. State agencies and Tribal officials not currently equipped to handle CBI would incur costs of updating or equipping their facilities with secure filing systems, provided that they entered into a written agreement with APHIS. Because only the storage of paper documents would be authorized, not the storage of electronic documents, no computer security costs would be incurred. There would be no cost to the biotechnology industry as we expect the required measures will protect sensitive information. Costs to assess the business information proposed for sharing by APHIS are discretionary; if the information is not requested, APHIS would not provide it to the States and Tribal governments.

The cost to APHIS would consist mainly of salary for staff to implement

the procedures and to carry them out on a continuing basis. This should entail less than one full-time staff year during implementation, and decrease later as the procedures become routine for APHIS, States, and Tribes. We expect the benefits of sharing certain business information with State and Tribal agencies would outweigh the costs to the Federal government. The proposed rule would add transparency to the APHIS review process, as State and Tribal officials would have additional information about introductions conducted within their jurisdictions. Also, State citizens and Tribal members would have greater confidence in their regulatory officials and their ability to review permit and notification applications, and APHIS would have an additional means to strengthen its regulatory effort through improved process efficiency and effectiveness.

There are no unavoidable costs for States and Tribes under either the current application review process or the CBI sharing provisions that would be added by this proposed rule because APHIS does not require States or Tribes to reply to permit and notification review information shared with them. However, the States and Tribes involved have indicated they value the opportunity to do so. Frequently, information provided to APHIS during these reviews has allowed us to improve permit conditions and reduce risks, or to forestall operational or administrative problems that might have arisen during a permit period due to local conditions that State or Tribal officials explained to APHIS. Permit and notification review also allows States to better plan their logistics and workloads from year to year. If CBI information is shared as described in this proposal, States and Tribes would know more about the exact location of planned introductions, the methods for confinement of the regulated article, and other planned safeguards and mitigation measures. This would allow States to do better advance planning of the activities and movements of their inspectors who inspect and monitor release sites in accordance with a Memorandum of Understanding with APHIS. It would also allow them to be better prepared for responses during emergency situations, e.g., tornadoes or floods, because they would know well in advance what locations they might have to visit to assess possible releases and what types of confinement and mitigation systems they will encounter at the sites.

Alternatives Considered

APHIS considered a "no action" alternative under which we would

continue to delete CBI information from notification and permit applications, and then share only the CBI-deleted documents with States and Tribal governments. This alternative would avoid the implementation costs identified for this proposal, but would not accrue any of the benefits identified for sharing certain business information. The no action alternative could also result in continuing costs to the Federal government through reduced effectiveness of the regulatory program.

APHIS also considered various additional alternatives for how APHIS could share business information with the State or Tribal governments. These alternatives are discussed in detail above under the heading "*Mechanisms for Safeguarding Shared Information.*"

In the selected alternative, APHIS proposes to allow sharing of paper documents by only certain States or Tribal governments which are capable of preventing disclosure of such paper records to the public. These States or Tribal governments must also be able to comply with the requirements set forth in the proposed rule.

Effects on Small Entities

APHIS has not identified any private entities, large or small, that would be affected by this proposed rule. APHIS would share certain business information from both large and small entities with State agencies and Tribal officials, as the written agreement would provide. There would be no direct economic effect on entities submitting CBI. Some such entities might accrue minor savings in time they currently spend responding to State or Tribes' requests for information, if States or Tribes instead obtain the information through APHIS.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service determined that this action would 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 proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) No State or local laws or regulations will be preempted by this rule; (2) no retroactive effect will be

given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule. State or Tribal agencies must follow their respective State or Tribal laws regarding disclosure of information, and a State or Tribe with a law that precludes it from signing a written nondisclosure agreement with APHIS in accordance with proposed § 340.10 would not be able to participate in the business information sharing that would be authorized by this proposed rule.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this rule will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

National Environmental Policy Act

APHIS, in compliance with the National Environmental Policy Act (NEPA) of 1969, as amended (42 U.S.C. 4321 *et seq.*), categorically excluded the proposed sharing of CBI with States and Tribes consistent with the USDA Departmental NEPA implementing regulations specific to categorical exclusions for the implementation of a procedural policy (7 CFR 1b.3(1)).

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. APHIS-2006-0124. Please send a copy of your comments to: (1) Docket No. APHIS-2006-0124, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238, and (2) Clearance Officer, OCIO, USDA, room 404-W, 14th Street and Independence Avenue SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this proposed rule.

This proposed rule contains certain information collection and recordkeeping requirements that would apply to regulatory officials of the States that receive APHIS submissions of

notifications and permits for importations, interstate movements, and environmental releases that occur within the State or Tribal lands. The limited information presently shared with the States is authorized under §§ 340.3(e) and 340.4(b). The majority of the proposed requirements would apply to persons engaged in regulatory activities of regulated articles in the States or on Tribal Lands. The reporting burden for these officials under the proposed rule would be similar to the burden under the current regulations, except in those cases in which the State or Tribe desired more information about the details of introductions in the States or Tribes beyond that which they have historically been provided. Thus, all additional information received would be elective. The information is shared because APHIS desires to have States and Tribes better informed about introductions that occur in the States or Tribes, and because the States or Tribes may be able to provide additional assistance to APHIS in issuing the permit or acknowledging the notification. In some cases, the additional information would be shared with the State's or Tribe's inspectors when they are working with APHIS to conduct inspections, or when APHIS requests a State or a Tribe's assistance to aid with compliance and mitigation efforts. Major emergencies sometimes threaten confinement of a regulated article, and APHIS may require assistance in these circumstances.

Under proposed §§ 340.3(d)(2)(vi) and 340.4(b) and (c), State or Tribe officials would have available additional information to complete their reviews of APHIS notifications and permits. However, responses to APHIS would remain voluntary, as they are presently under § 340.3(e). Additional reading, assessment, and review writing may be required if the official desires to provide comments and information to APHIS on the business information shared under this proposed rule.

For those States or Tribes whose statutes authorize keeping business information confidential, and which have signed agreements with APHIS to protect the authorized data, additional recordkeeping requirements would be needed. As noted in the analysis of costs, safeguarding the information would require expenses of time and resources to update or establish approved systems to store certain business information as well as training the regulatory officials that would have access to the CBI. Some States may already have an approved mechanism for storing this information, and no

additional burden would be imposed on them.

One goal in proposing this rule is to create an efficient and streamlined system for information sharing with the State and Tribal governments and to ensure that the review process is conducted in a timely and effective manner. Permit applications for environmental releases may take up to 120 days to assess and review before APHIS decides to either issue or deny a permit, while movements (importations and interstate movements) alone may take up to 60 days prior to a decision. Notifications for environmental releases may take up to 30 days to assess and review before APHIS decides to either acknowledge or deny the notification, movements, importations, or interstate movements under notifications may require 10 days after application for an APHIS decision regarding them. Certain business information may be provided by APHIS directly to the States or Tribal agencies after a written agreement is in effect, replacing the necessity that information useful to the States or Tribal governments be provided by the applicant. Based on this sharing, the States and Tribal governments would review and provide comment to APHIS, and APHIS could complete the review process for permits and notifications in a timely manner.

We are soliciting comments from the public (as well as the affected agencies) concerning our proposed information collection and recordkeeping requirements. These comments will help us:

- (1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;
- (2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, 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 information collection on those who are to respond (such as 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).

Estimate of burden: Public reporting burden for this collection of information is estimated to average 8 hours for each written nondisclosure agreement signed by a State or Tribal government official and APHIS. Actual review by States and

Tribal authorities of CBI documents shared under the proposed rule is estimated to average 2 hours per permit and notification application. This is a decrease from the current review practice which can take up to 2 weeks when a State representative must obtain the business information directly from the applicant.

Respondents: Approximately 49 States or Territories, including the Northern Mariana Islands, Guam, Puerto Rico, and the U.S. Virgin Islands, as well as approximately 2 Tribes and 69 unique officials in these entities.

Estimated annual number of responses per respondent: Only one in the first year, then fewer. The written nondisclosure agreement between APHIS and the State or Tribal government is the primary new information collection imposed by this rule. Such agreements would presumably be signed in the first year of implementation, and be revised or renewed infrequently after that. Responses by States to the specific, individual permit applications or notifications they review already occur, and will continue to do so, and thus are not a new information collection.

Estimated annual number of responses: 51 or fewer written agreements.

Estimated total annual burden on respondents: 408 hours, declining over time.

Copies of this information collection can be obtained from Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851-2908.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance 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. For information pertinent to E-Government Act compliance related to this proposed rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851-2908.

List of Subjects in 7 CFR Part 340

Administrative practice and procedure, Biotechnology, Genetic engineering, Imports, Packaging and containers, Plant diseases and pests, Transportation.

Accordingly, we propose to amend 7 CFR part 340 as follows:

PART 340—INTRODUCTION OF ORGANISMS AND PRODUCTS ALTERED OR PRODUCED THROUGH GENETIC ENGINEERING WHICH ARE PLANT PESTS OR WHICH THERE IS REASON TO BELIEVE ARE PLANT PESTS

■ 1. The authority citation for part 340 continues to read as follows:

Authority: 7 U.S.C. 7701-7772 and 7781-7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

■ 2. In § 340.3, a new paragraph (d)(2)(vi) is added to read as follows:

§ 340.3 Notification for the introduction of certain regulated articles.⁵

* * * * *

(d) * * *

(2) * * *

(vi) If there are portions of the notification deemed to contain trade secret or confidential business information (CBI), and if submitted through ePermits, then all information entered into the forms that is designated CBI should be enclosed in brackets and all subsequent copies will be automatically labeled with appropriate CBI notations. If submitted on paper, two copies of the written notification shall be submitted. On one copy, each page of the application containing trade secret or CBI should be marked "CBI Copy." In addition, those portions of the notifications which are deemed "CBI" shall be so designated. The second copy shall have all such CBI deleted and shall be marked on each page of the application where CBI was deleted, "CBI Deleted." If a notification does not contain CBI, then the first page of both copies shall be marked "No CBI." When it is determined that a notification is complete, APHIS shall submit to the State department of agriculture of the State or the appropriate Tribal official of the Tribal land where the introduction is planned a copy of the notification for State or Tribal notification and review. When the application contains certain business information, the State or Tribal government will be provided a CBI deleted copy of the notification unless the disclosure of certain business information to the State or Tribal

⁵ APHIS may issue guidelines regarding scientific procedures, practices, or protocols which it has found acceptable in making various determinations under the regulations. A person may follow an APHIS guideline or follow different procedures, practices, or protocols. When different procedures, practices, or protocols are followed, a person may, but is not required to, discuss the matter in advance with APHIS to help ensure that the procedures, practices, or protocols to be followed will be acceptable to APHIS.

government has been authorized in accordance with § 340.10.

* * * * *

■ 3. Section 340.4 is amended as follows:

a. In paragraph (b), introductory text, by removing the sixth sentence and by adding in its place two new sentences to read as set forth below.

b. In paragraph (c), introductory text, by removing the last sentence and by adding in its place two new sentences to read as set forth below.

§ 340.4 Permits for the introduction of a regulated article.⁶

* * * * *

(b) * * * When it is determined that an application is complete, APHIS shall submit to the State department of agriculture of the State or the appropriate Tribal official of the Tribal land where the release is planned a copy of the initial review and a copy of the application for State or Tribal notification and review. When the application contains confidential business information (CBI), the State or Tribal government will be provided a CBI deleted copy of the application unless the disclosure of certain business information to the State or Tribal government has been authorized in accordance with § 340.10. * * *

* * * * *

(c) * * * When it is determined that an application is complete, APHIS shall submit to the State department of agriculture of the State of destination or to the appropriate Tribal official of the Tribal land of destination of the regulated article a copy of the initial review and a copy of the application for State or Tribal notification and review. When the application contains confidential business information (CBI), the State or Tribal government will be provided a CBI deleted copy of the application unless the disclosure of certain business information to the State has been authorized in accordance with § 340.10.

* * * * *

■ 4. A new § 340.10 is added to read as follows:

§ 340.10 Communications with State and Tribal government agencies.

The Administrator may authorize in accordance with the provisions of this section the disclosure of certain business information (CBI) to State or Tribal government agencies that has been submitted to APHIS or incorporated into Agency-prepared records.

⁶ See footnote 5 in § 340.3.

(a) Certain business information submitted to APHIS in notifications and applications for permits under this part may be disclosed to State or Tribal government agencies provided that the State or Tribal government agency has entered into a written agreement with APHIS that includes:

(1) A statement establishing the State's or Tribe's authority to protect certain business information from public disclosure;

(2) A statement by the State or Tribal government agency that it has suitable procedures in place to ensure the security of the business information, and the means to specify and restrict their respective officials allowed access to such information. Such procedures must be equivalent to those specified in APHIS' policy¹⁴ on the protection of privileged or confidential business information;

(3) A statement that the State or Tribal government agency will not disclose any business information provided by APHIS without the written permission of the submitter of the information or written confirmation by APHIS that the information no longer has confidential status;

(4) A statement that all persons with access to business information provided by APHIS will be trained by the State or Tribal authority on how to maintain the security of the shared APHIS documents before having access to the CBI;

(5) Any other terms as agreed to by APHIS and the State or Tribal government agency.

(b) The "certain business information" that APHIS may authorize to be shared under paragraph (a) of this section may include information about the regulated article, including details about the phenotype as provided by the applicant; the site(s) of the introduction including provision of accurate details of the location, acreage (for environmental releases), and purpose of the introduction if provided; dates of activities, including proposed planting and termination dates for the regulated article, actual dates when available; methods of confinement, including design protocols if available, and

description of disposition if provided; and site cooperator, including contact information for the responsible person or cooperator, depending upon what information the applicant has provided to APHIS. APHIS intends that the disclosure of information will be for the purpose of facilitating the State or Tribal agency review. In addition, the exchange of information may also be made in certain emergency situations with States or Tribal government agencies to support better disaster responses and maintain confinement of regulated articles. Also, information sharing will help facilitate participation in the inspection and compliance programs established between the States and Tribes and APHIS under specific agreements.

(c) Information APHIS discloses under this section is not a disclosure of information to the public. Disclosures made under this section do not waive any FOIA exemption protection.

Done in Washington, DC, this 20th day of February 2013.

Rebecca Blue,

Deputy Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 2013-04478 Filed 2-26-13; 8:45 am]

BILLING CODE 3410-34-P

FEDERAL RESERVE SYSTEM

12 CFR Part 252

[Regulation YY; Docket No. 1438]

RIN 7100-AD-86

Enhanced Prudential Standards and Early Remediation Requirements for Foreign Banking Organizations and Foreign Nonbank Financial Companies

AGENCY: Board of Governors of the Federal Reserve System (Board).

ACTION: Proposed rule; extension of comment period.

SUMMARY: On December 28, 2012, the Board published in the *Federal Register* a notice of proposed rulemaking to implement the enhanced prudential standards required to be established under section 165 of the Dodd-Frank Act and the early remediation requirements established under section 166 of the Act for foreign banking organizations and foreign nonbank financial companies supervised by the Board.

Due to the range and complexity of the issues addressed in the rulemaking, the Board has determined that an extension of the public comment period until April 30, 2013, is appropriate. This action will allow interested persons

additional time to analyze the proposed rules and prepare their comments.

DATES: The comment period for the proposed rule published December 28, 2012 (77 FR 76628) is extended from March 31, 2013 to April 30, 2013.

ADDRESSES: You may submit comments by any of the methods identified in the proposed rule.¹ Please submit your comments using only one method.

FOR FURTHER INFORMATION CONTACT: Molly E. Mahar, Adviser, (202) 973-7360, Division of Banking Supervision and Regulation; Ann Misback, Associate General Counsel, (202) 452-3788, or Christine Graham, Senior Attorney, (202) 452-3005, Legal Division.

SUPPLEMENTARY INFORMATION: On December 28, 2012, the Board published in the *Federal Register* a notice of proposed rulemaking to implement the enhanced prudential standards required to be established under section 165 of the Dodd-Frank Act and the early remediation requirements established under section 166 of the Act for foreign banking organizations and foreign nonbank financial companies supervised by the Board. The enhanced prudential standards include risk-based capital and leverage requirements, liquidity standards, risk management and risk committee requirements, single-counterparty credit limits, and stress test requirements, and a debt-to-equity limit for companies that the Financial Stability Oversight Council has determined pose a grave threat to financial stability.

In recognition of the complexities of the issues addressed and the variety of considerations involved with implementation of the proposal, the Board requested that commenters respond to numerous questions. The proposed rule stated that the public comment period would close on March 31, 2013.²

The Board has received a request from the public for an extension of the comment period to allow for additional time for comments related to the provisions of the proposed rule.³ The Board believes that the additional period for comment will facilitate public comment on the provisions of the proposed rule and the questions posed by the Board. Therefore, the Board is extending the end of the comment

¹ See Enhanced Prudential Standards and Early Remediation Requirements for Foreign Banking Organizations and Foreign Nonbank Financial Companies, 77 FR 76628 (December 28, 2012).

² *Id.*

³ See, e.g., Comment letter to the Board from The Institute of International Bankers *et al.* (January 31, 2013).

¹⁴ APHIS' "Policy Statement on the Protection of Privileged or Confidential Business Information" may be viewed on the APHIS Web site at http://www.aphis.usda.gov/animal_health/vet_biologics/publications/pel_1_2.pdf. The instructions for submitting CBI consistent with this policy are found in the BRS document titled "USDA-APHIS Biotechnology Regulatory Services User's Guide" (version 2/5/2008) and information may be viewed on the Internet at http://www.aphis.usda.gov/brs/pdf/Doc_Prep_Guidance.pdf or obtained from the person listed under **FOR FURTHER INFORMATION CONTACT**.

period for the proposed rule from March 31, 2013 to April 30, 2013.

By order of the Board of Governors of the Federal Reserve System, acting through the Secretary of the Board under delegated authority, February 22, 2013.

Robert deV. Frierson,
Secretary of the Board.

[FR Doc. 2013-04497 Filed 2-26-13; 8:45 am]

BILLING CODE 6210-01-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2013-0023; FRL-9380-2]

Receipt of Several Pesticide Petitions Filed for Residues of Pesticide Chemicals in or on Various Commodities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing of petitions and request for comment.

SUMMARY: This document announces the Agency's receipt of several initial filings of pesticide petitions requesting the establishment or modification of regulations for residues of pesticide chemicals in or on various commodities.

DATES: Comments must be received on or before March 29, 2013.

ADDRESSES: Submit your comments, identified by the docket identification (ID) number and the pesticide petition number (PP) of interest as shown in the body of this document, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: A contact person, with telephone number and email address, is listed at the end

of each pesticide petition summary. You may also reach each contact person by mail at Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

If you have any questions regarding the applicability of this action to a particular entity, consult the person listed at the end of the pesticide petition summary of interest.

B. What should I consider as I prepare my comments for EPA?

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

2. *Tips for preparing your comments.* When submitting comments, remember to:

- Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

II. What action is the Agency taking?

EPA is announcing its receipt of several pesticide petitions filed under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), (21 U.S.C. 346a), requesting the establishment or modification of regulations in 40 CFR part 180 for residues of pesticide chemicals in or on various food commodities. The Agency is taking public comment on the requests before responding to the petitioners. EPA is not proposing any particular action at this time. EPA has determined that the pesticide petitions described in this document contain the data or information prescribed in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the pesticide petitions. After considering the public comments, EPA intends to evaluate whether and what action may be warranted. Additional data may be needed before EPA can make a final determination on these pesticide petitions.

Pursuant to 40 CFR 180.7(f), a summary of each of the petitions that

are the subject of this document, prepared by the petitioner, is included in a docket EPA has created for each rulemaking. The docket for each of the petitions is available online at <http://www.regulations.gov>.

As specified in FFDCa section 408(d)(3), (21 U.S.C. 346a(d)(3)), EPA is publishing notice of the petitions so that the public has an opportunity to comment on the requests for the establishment or modification of regulations for residues of pesticides in or on food commodities. Further information on the petitions may be obtained through the petition's summary referenced in this unit.

New Tolerance

1. *PP 2E8126*. (EPA-HQ-OPP-2012-0980). Interregional Research Project Number 4 (IR-4), 500 College Road East, Suite 201W., Princeton, NJ 08540, requests to establish tolerances in 40 CFR part 180 for residues of the fungicide, mandipropamid, 4-chloro-N-[2-[3-methoxy-4-(2-propynyloxy)phenyl]ethyl]-alpha-(2-propynyloxy)-benzeneacetamide, in or on basil, fresh at 30 parts per million (ppm); basil, dried at 200 ppm; ginseng at 0.3 ppm; bean, succulent at 0.90 ppm; cowpea, forage at 15 ppm; vegetable, fruiting, group 8-10 at 1.0 ppm; fruit, small, vine climbing, subgroup 13-07F, except fuzzy kiwifruit at 2.0 ppm; onion, bulb, subgroup 3-07A at 0.1 ppm; and onion, green, subgroup 3-07B at 7.0 ppm. Analytical method RAM 415-01 was developed for determination of mandipropamid residues in crops. This method involves extraction of mandipropamid residues from crop samples by homogenization with acetonitrile: water (80:20 v/v). Extracts are centrifuged and aliquots diluted with water prior to being cleaned-up using polymeric solid-phase extraction cartridges. Residues of mandipropamid are quantified using high performance liquid chromatography with triple quadruple mass spectrometric detection (HPLC-MS/MS). Contact: Laura Nollen, (703) 305-7390, email address: nollen.laura@epa.gov.

2. *PP 2E8136*. (EPA-HQ-OPP-2013-0056). Interregional Research Project Number 4 (IR-4), requests to establish tolerances in 40 CFR part 180 for residues of the herbicide, clomazone, including its metabolites and degradates, determined by measuring only clomazone, 2-[[2-(2-chlorophenyl)methyl]-4,4-dimethyl-3-isoxazolidinone, in or on Brassica, head and stem, subgroup 5A at 0.10 ppm; rhubarb at 0.30 ppm; pea, southern, succulent, seed at 0.05 ppm; pea,

southern, dry seed at 0.05 ppm; and pea, southern, hay at 0.05 ppm. There is a practical analytical method for detecting and measuring levels of clomazone in or on raw agricultural commodities with a limit of detection that allows monitoring of food for residues at or above the levels proposed in this tolerance.

Samples are analyzed using an analytical method consisting of an acid reflux, a C₁₈ solid phase extraction (SPE), a Florisil SPE clean-up followed by gas chromatography (GC)-mass selective detection (MSD). Contact: Sidney Jackson, (703) 305-7610, email address: jackson.sidney@epa.gov.

3. *PP 3E8147*. (EPA-HQ-OPP-2012-0626). Interregional Research Project Number 4 (IR-4), requests to establish tolerances in 40 CFR part 180 for residues of the insecticide, acetamiprid, (1E)-N-[[6-chloro-3-pyridinyl)methyl]-N'-cyano-N-methylethanimidamide, including its metabolites and degradates, in or on corn, sweet, kernel plus cob with husks removed at 0.01 ppm; corn, sweet, forage at 15 ppm; and corn, sweet, stover at 30 ppm. Based upon the metabolism of acetamiprid in plants and the toxicology of the parent and metabolites, quantification of the parent acetamiprid is sufficient to determine residues of concern for enforcement purposes. As a result a method was developed that involves extraction of acetamiprid from crop matrices with a solvent followed by a decantation and filtration and finally analysis by a Liquid Chromatography with tandem Mass Spectrometry (LC/MS/MS) method. Contact: Andrew Ertman, (703) 308-9367, email address: ertman.andrew@epa.gov.

4. *PP 2F8088*. (EPA-HQ-OPP-2013-0038). ISK Biosciences Corporation, 7470 Auburn Road, Suite A, Concord, OH 44077, requests to establish tolerances in 40 CFR part 180 for the combined residues of the insecticide, flonicamid, N-(cyanomethyl)-4-(trifluoromethyl)-3-pyridinecarboxamide, and its metabolites, TFNA (4-trifluoromethyl nicotinic acid), TFNA-AM (4-trifluoromethylnicotinamide), and TFNG, N-(4-trifluoromethylnicotinoyl)glycine, calculated as the stoichiometric equivalent of flonicamid, in or on tree, nuts, crop group 14-12 at 0.09 ppm; almond at 0.09 ppm; pecan at 0.04 ppm; and almond, hulls at 10.0 ppm. The residue analytical method for the majority of crops includes an initial extraction with acetonitrile/deionized water, followed by a liquid-liquid partition with ethyl acetate. The residue method for wheat straw is similar, except that a C₁₈ solid phase extraction (SPE) is added prior to

the liquid-liquid partition. The final sample solution is quantitated using LC equipped with a reverse phase column and triple quadruple mass spectrometer (MS/MS). Contact: Carmen Rodia, (703) 306-0327, email address: rodia.carmen@epa.gov.

5. *PP 2F8130*. (EPA-HQ-OPP-2012-0576). Arysta LifeScience North America, LLC, 15401 Weston Parkway, Suite 150, Cary, NC 27513, requests to establish a tolerance in 40 CFR part 180 for residues of the fungicide fluoxastrobin, (1E)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimidinyl]oxy]phenyl][5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methylxime, and its Z isomer, (1Z)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimidinyl]oxy]phenyl][5,6-dihydro-1,4,2-dioxazin-3-yl)methanone O-methylxime, in or on wheat, grain at 0.15 ppm. Adequate analytical methodology is available for enforcement purposes. The method comprises microwave solvent extraction followed by a solid phase extraction clean up and quantification by HPLC/MS/MS. The individual detector responses for measured E- and Z-isomers is summed to give total residue. Contact: Heather Garvie, (703) 308-0034, email address: garvie.heather@epa.gov.

6. *PP 2F8133*. (EPA-HQ-OPP-2013-0071). BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709, requests to establish a tolerance in 40 CFR part 180 for residues of the herbicide pendimethalin, N-(1-ethylpropyl)-3,4-dimethyl-2,6-dinitrobenzenamine, and its 3,5-dinitrobenzyl alcohol metabolite (CL202347), in or on almond, hulls at 6.0 ppm. In plants, the practical method for detecting and measuring levels of pendimethalin is aqueous organic solvent extraction, column clean up, and quantitation by GC. Contact: Erik Kraft, (703) 308-9358, email address: kraft.erik@epa.gov.

7. *PP 2F8135*. (EPA-HQ-OPP-2013-0051). Syngenta Crop Protection LLC., P.O. Box 18300, Greensboro, NC 27419-8300, requests to establish a tolerance in 40 CFR part 180 for residues of the fungicide propiconazole, 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl] methyl]-1H-1,2,4-triazole and its metabolites determined as 2,4,-dichlorobenzoic acid and expressed as parent compound, in or on rapeseed, subgroup 20A at 0.3 ppm. The metabolism data in plants and animals suggest that analytical methods to detect either the phenyl or the triazole ring would be appropriate for the measurement of residues. However, because of the natural occurrence of

compounds that interfere with the measurement of triazoles, methods designed to detect this moiety have been proven unreliable and unacceptable. Conversely, conversion of phenyl moiety to 2,4-dichlorobenzoic acid (DCBA) has proven to be satisfactory for all agricultural products analyzed to date. Analytical methods AG-626 and AG-454A were developed for the determination of residues of propiconazole and its metabolites containing the DCBA moiety. Analytical method AG-626 has been accepted and published by EPA as the tolerance enforcement method for crops. Contact: Erin Malone, (703) 347-0253, email address: malone.erin@epa.gov.

8. *PP 2F8139*. (EPA-HQ-OPP-2013-0008). BASF Corporation, requests to establish a tolerance in 40 CFR part 180 for residues of the herbicide, saflufenacil, in or on crayfish at 0.01 ppm. Compliance with the tolerance levels is to be determined by measuring only saflufenacil, 2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2*H*)-pyrimidinyl]-4-fluoro-*N*-[[methyl(1-methylethyl)amino]sulfonyl]benzamide, in or on the commodities. Adequate enforcement methodology (LC/MS/MS) methods D0603/02 (plants) and L0073/01 (livestock) is available to enforce the tolerance expression. Contact: Bethany Benbow, (703) 347-8072, email address: benbow.bethany@epa.gov.

Amended Tolerance

1. *PP 2E8126*. (EPA-HQ-OPP-2012-0980). Interregional Research Project Number 4 (IR-4), requests to amend the tolerances in 40 CFR 180.637 for residues of the fungicide, mandipropamid, 4-chloro-*N*-[2-[3-methoxy-4-(2-propynyloxy)phenyl]ethyl]-alpha-(2-propynyloxy)-benzeneacetamide, by removing the previously established tolerances in or on grape at 1.4 ppm; onion, dry bulb at 0.05 ppm; onion, green at 4 ppm; okra at 1.0 ppm; and vegetable, fruiting, group 8 at 1.0 ppm, upon establishment of the tolerances listed under "New Tolerance" for PP 2E8126, elsewhere in this document. Contact: Laura Nollen, (703) 305-7390, email address: nollen.laura@epa.gov.

2. *PP 2E8136*. (EPA-HQ-OPP-2013-0056). Interregional Research Project Number 4 (IR-4), requests to amend the tolerance in 40 CFR 180.425 for residues of the herbicide, clomazone, including its metabolites and degradates, determined by measuring only clomazone, 2-[(2-chlorophenyl)methyl]-4,4-dimethyl-3-isoxazolidinone, by removing the previously established tolerance on cabbage at 0.10 ppm, upon

approval of the petitioned-for tolerance on brassica, stem and head subgroup 5A listed under "New Tolerance" for PP 2E8136, elsewhere in this document. Contact: Sidney Jackson, (703) 305-7610, email address: jackson.sidney@epa.gov.

3. *PP 3E8147*. (EPA-HQ-OPP-2012-0626). Interregional Research Project Number 4 (IR-4), requests to amend the tolerances in 40 CFR 180.578 for residues of the insecticide acetamiprid, (1*E*)-*N*-[(6-chloro-3-pyridinyl)methyl]-*N'*-cyano-*N*-methylethanimidamide, including its metabolites and degradates, by increasing the existing tolerances in meat, meat byproducts, and milk. Tolerances for cattle, goat, horse, and sheep meat are proposed at 0.30 ppm; cattle, goat, horse, and sheep fat at 0.20 ppm; cattle, goat, horse, and sheep meat byproducts at 0.70 ppm; and milk at 0.30 ppm. Based upon the metabolism of acetamiprid in plants and the toxicology of the parent and metabolites, quantification of the parent acetamiprid is sufficient to determine residues of concern for enforcement purposes. As a result, a method was developed that involves extraction of acetamiprid from crop matrices with a solvent followed by a decantation and filtration and finally analysis by a LC/MS/MS method. Contact: Andrew Ertman, (703) 308-9367, email address: ertman.andrew@epa.gov.

4. *PP 2F8130*. (EPA-HQ-OPP-2012-0576). Arysta LifeScience North America, LLC, requests to revise the tolerances in 40 CFR 180.609 for residues of the fungicide, fluoxastrobin, (1*E*)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimidinyl]oxy]phenyl](5,6-dihydro-1,4,2-dioxazin-3-yl)methanone *O*-methyloxime, and its *Z* isomer, (1*Z*)-[2-[[6-(2-chlorophenoxy)-5-fluoro-4-pyrimidinyl]oxy]phenyl](5,6-dihydro-1,4,2-dioxazin-3-yl)methanone *O*-methyloxime, and its phenoxy-hydroxyppyrimidine, 6-(2-chlorophenoxy)-5-fluoro-4-pyrimidinol, increasing the milk tolerance from 0.02 ppm to 0.03 ppm; and milk, fat from 0.50 ppm to 0.75 ppm. Adequate analytical methodology is available for enforcement purposes. The method comprises microwave solvent extraction followed by a solid phase extraction clean up and quantification by HPLC/MS/MS detection. The individual detector responses for measured *E*- and *Z*-isomers is summed to give total residue. Contact: Heather Garvie, (703) 308-0034, email address: garvie.heather@epa.gov.

New Tolerance Exemption

PP 2E8049. (EPA-HQ-OPP-2012-0585). Pennzoil-Quaker State Company,

700 Milam Street, Houston, TX 77002 c/o Wagner Regulatory Associates, 7217 Lancaster Pike, Suite A, Hockessin, DE 19707, requests to establish an exemption from the requirement of a tolerance for residues of Distillates (Fishcher-Tropsch), heavy, C₁₈-C₅₀, branched, cyclic and linear (CAS Reg. No. 848301-69-9) under 40 CFR 180.910 when used as a pesticide inert ingredient in pesticide formulations as a solvent, diluent and dust suppressant without limitations in pesticide formulations. The petitioner believes no analytical method is needed because it is not required for the establishment of a tolerance exemption for inert ingredients. Contact: Mark Dow, (703) 305-5533, email address: dow.mark@epa.gov.

Amended Tolerance Exemption

1. *PP 2E8080*. (EPA-HQ-OPP-2013-0098). Toxcel, LLC, 7140 Heritage Village Plaza, Gainesville, VA 20156 on behalf of Penn A Kem, LLC, 3324 Chelsea Avenue, Memphis, TN 38108, requests to amend an exemption from the requirement of a tolerance in 40 CFR 180.1263 for residues of tetrahydrofurfuryl alcohol (THFA), (CAS Reg. No. 97-99-4), when used as a pesticide inert ingredient in the form of a solvent/co-solvent in pesticide formulations, by allowing one pre-boot herbicide application to all small cereal grains, and by extending use on canola to early bolting stage, and use on soybeans up to bloom stage. The petitioner believes no analytical method is needed because it is not required for the amendment of a tolerance exemption for inert ingredients. Contact: Janet Whitehurst, (703) 305-6129, email address: whitehurst.janet@epa.gov.

2. *PP IN-10541*. (EPA-HQ-OPP-2013-0093). Nichino America, Inc., 4550 New Linden Hill Road, Suite 501, Wilmington DE 19808 c/o Wagner Regulatory Associates, 7217 Lancaster Pike, Suite A, Hockessin, DE 19707, requests to amend an exemption from the requirement of a tolerance in 40 CFR 180.1130 for residues of *N*-(*n*-octyl)-2-pyrrolidone, (CAS Reg. No. 2687-94-7), when used as a pesticide inert ingredient to include use in pesticide formulations containing the pyraflufen ethyl active ingredient. The petitioner believes no analytical method is needed because it is not required for the amendment of a tolerance exemption for inert ingredients. Contact: David Lieu, (703) 305-0079, email address: lieu.david@epa.gov.

List of Subjects in 40 CFR Part 180

Environmental protection, Agricultural commodities, Feed

additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 20, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2013-04594 Filed 2-26-13; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 37

[Docket No. DOT-OST-2013-0014]

Notice of Retrospective Review of the Americans With Disabilities Act Regulations for Over-the-Road Bus Operators; Request for Comments

AGENCY: Office of the Secretary (OST), U.S. Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: The DOT is seeking comments to help conduct a review of some of the requirements of the Americans with Disabilities Act of 1990 (ADA) implementing regulations for over-the-road bus (OTRB) operators. The DOT will review regulations specified in the **SUPPLEMENTARY INFORMATION** section. Your comments will assist DOT with making decisions to modify or retain certain requirements found in these ADA regulations.

DATES: Please send your comments by April 29, 2013.

ADDRESSES: Interested persons are invited to submit written comments to assist in our review of 49 CFR part 37 subpart H to the Office of General Counsel. Mail or hand deliver comments to the Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590; submit electronically at <http://www.regulations.gov>; or fax comments to 202-366-9313. 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 may print the acknowledgment page that appears after submitting comments electronically. Anyone is able to search the electronic form of all comments in any one of our dockets by the name of

the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, or labor union). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477).

FOR FURTHER INFORMATION CONTACT: Jill Laptosky, Attorney-Advisor, Office of Regulation and Enforcement (C-50), U.S. Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590, 202-493-0308 (telephone), 202-366-9313 (fax), jill.laptosky@dot.gov.

SUPPLEMENTARY INFORMATION: On September 28, 1998, the U.S. Department of Transportation (DOT or the Department) issued final regulations, in response to the ADA (Pub. L. 101-336, 104 Stat. 327, 42 U.S.C. 225 and 611), which required the accessibility of new over-the-road buses (OTRBs) and accessible OTRB service. An OTRB is defined as "a bus characterized by an elevated passenger deck located over a baggage compartment." 49 CFR 37.3. The regulations require commercial OTRB operators to ensure that passengers with disabilities have access to OTRB transportation. The DOT is required by 49 CFR 37.215 to review various requirements within the ADA regulations for OTRB operators. These requirements include the following: the purchase and lease requirements of new OTRBs by operators of fixed-route systems (§ 37.183), the fleet accessibility requirements for OTRB fixed-route systems of large operators (§ 37.185), the interline service requirements (§ 37.187), the service requirement for OTRB demand-responsive systems (§ 37.189), the special provision for small mixed-service operators (§ 37.191), and the interim service requirements for fixed-route operators (§ 37.193(a)). We are not reviewing any other requirements in the ADA regulations for OTRB operators *at this time*.

As part of this review, DOT is required to consider certain factors, including the percentage of accessible OTRBs in the fleets of OTRB operators, the success of such operators at meeting the requests of passengers with disabilities for accessible OTRBs in a timely manner, ridership of OTRBs by passengers with disabilities, volume of complaints by passengers with disabilities, and the cost and service impacts of these requirements. After the review, DOT will decide whether it is appropriate to revise the part 37 ADA regulations for OTRB operators or retain the current regulations without change.

The DOT will publish a notice, after the review is complete, that announces our decision and our justification.

To this end, DOT requests comments and information so the Department can better review such ADA regulations and make an informed decision on whether to initiate a rulemaking to propose revisions to any of the regulations involving OTRBs and, if so, how to develop a notice of proposed rulemaking. Specifically, comments about OTRB fleet accessibility, fulfillment of accessible OTRB service requests, and ridership and volume of complaints by passengers with disabilities, would be helpful. The DOT welcomes comments from the public, including OTRB operators and individuals with disabilities, on any aspect of this notice. The Department is particularly interested in comments from OTRB operators, both large and small, on the following:

1. *The accessibility of your OTRB fleet.* How many OTRBs do you own? Of the OTRBs that you own, how many are accessible? How many OTRBs are term-leased longer than 30 days? Of the OTRBs that are term-leased, how many are accessible? Have you been successful at meeting the requests of passengers with disabilities for accessible OTRBs in a timely manner, and what challenges continue to exist in meeting these requests?

2. *Accessibility arrangements.* If your company does not own or lease an accessible OTRB, what arrangements have you made to meet the requirements to provide accessible transportation? For example, has your company made arrangements with another company that operates an accessible OTRB to provide accessible OTRB service on behalf of your company when a 48-hour advance notice request for accessible OTRB service is received?

3. *Received requests.* Within the previous 12 months, have you received any of the following inquiries, requests, or complaints, and, if so, how many?

- Inquiries regarding whether your company owns or leases an accessible OTRB,
- Inquiries regarding whether your company can provide accessible OTRB service,
- Requests for accessible OTRB service that were received with a minimum of 48-hour advance notice and satisfied according to the requested provisions,
- Number of passengers with disabilities who have used your company's accessible OTRB service, and
- Complaints regarding denial of accessible OTRB service to an individual with a disability.

4. *Costs and Service Impacts.* What are your company's costs of providing accessible OTRB service? Please provide specific cost data broken down into various cost categories (e.g., maintenance). What effect does accessible transportation compliance have on your overall operation?

5. *Other Comments.* The Department is also interested in your input on whether any specific requirement under

review should be changed and why. Please provide supporting information for your recommended change, and explain whether the recommended regulatory change would affect all types of OTRB operators or just one type, such as large fixed-route, small fixed-route, or all demand-responsive operators.

Your comments will help the Department conduct a review of its ADA regulations for OTRB operators and

decide whether to propose any regulatory revisions. At this time, there are no pending proposed revisions to DOT's ADA regulations for OTRB operators.

Issued in Washington, DC, on February 19, 2013.

Robert S. Rivkin,
General Counsel.

[FR Doc. 2013-04309 Filed 2-25-13; 8:45 am]

BILLING CODE 4910-9X-P

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-2013-0001]

Notice of Request for Extension of Approval of an Information Collection; Importation of Fruits and Vegetables

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request an extension of approval of an information collection associated with the regulations for the importation of certain fruits and vegetables into the United States.

DATES: We will consider all comments that we receive on or before April 29, 2013.

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

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/>#!/documentDetail;D=APHIS-2013-0001-0001.

- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS-2013-0001, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/>#!/docketDetail;D=APHIS-2013-0001 or in our reading room, which 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) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the importation of fruits and vegetables, contact Mr. Tony Román, Regulatory Policy Specialist, PHP, PPQ, 4700 River Road Unit 133, Riverdale, MD 20737; (301) 851-2242. For copies of more detailed information on the information collection, contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851-2908.

SUPPLEMENTARY INFORMATION:

Title: Importation of Fruits and Vegetables.

OMB Number: 0579-0316.

Type of Request: Extension of approval of an information collection.

Abstract: The Plant Protection Act (PPA, 7 U.S.C. 7701 *et seq.*) authorizes the Secretary of Agriculture to restrict the importation, entry, or interstate movement of plants, plant products, and other articles to prevent the introduction of plant pests into the United States or their dissemination within the United States. As authorized by the PPA, the Animal and Plant Health Inspection Service (APHIS) regulates the importation of certain fruits and vegetables in accordance with the regulations in "Subpart—Fruits and Vegetables" (319.56-1 through 319.5658).

Under these regulations, certain fruits and vegetables may be imported into the United States under specific conditions to prevent the introduction of plant pests into the United States. These conditions involve the use of information collection activities, including the issuance of phytosanitary certificates, trapping surveys, inspections by the exporting country, labeling of boxes, and recordkeeping. An additional information collection is the completion of the U.S. Department of Agriculture, APHIS, Plant Protection and Quarantine (PPQ), Application for Permit to Import Plants or Plant Products (PPQ Form 587).

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our

information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the 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, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; e.g., permitting electronic submission of responses.

Estimate of burden: The public reporting burden for this collection of information is estimated to average 1.4963 hours per response.

Respondents: Importers and exporters of fruits and vegetables, and national plant protection organizations of exporting countries.

Estimated annual number of respondents: 2,959.

Estimated annual number of responses per respondent: 28.18.

Estimated annual number of responses: 83,389.

Estimated total annual burden on respondents: 124,779 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

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.

Done in Washington, DC, this 20th day of February 2013.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2013-04495 Filed 2-26-13; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE**Animal and Plant Health Inspection Service**

[Docket No. APHIS-2012-0109]

Notice of Request for Extension of Approval of an Information Collection; Spring Viremia of Carp; Import Restrictions on Certain Live Fish, Fertilized Eggs, and Gametes**AGENCY:** Animal and Plant Health Inspection Service, USDA.**ACTION:** Extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request an extension of approval of an information collection associated with the regulations for the importation of live fish, fertilized eggs, and gametes to prevent the introduction of spring viremia of carp into the United States.

DATES: We will consider all comments that we receive on or before April 29, 2013.

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

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/#!documentDetail;D=APHIS-2012-0109-0001>.

- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS-2012-0109, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road, Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0109> or in our reading room, which 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) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the regulations for the importation of live fish, fertilized eggs, and gametes, contact Dr. Christa Speekmann, Import/Export Specialist-Aquatic Animals, National Center for Import and Export, VS, APHIS, 4700 River Road, Unit 39, Riverdale MD 20737; (301) 851-3365. For copies of more detailed information on the information collection, contact Mrs.

Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851-2908.

SUPPLEMENTARY INFORMATION:

Title: Spring Viremia of Carp; Import Restrictions on Certain Live Fish, Fertilized Eggs, and Gametes.

OMB Number: 0579-0301.

Type of Request: Extension of approval of an information collection.

Abstract: Under the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture is authorized, among other things, to prohibit or restrict the importation and interstate movement of animals and animal products to prevent the introduction into and dissemination within the United States of livestock diseases and pests. To carry out this mission, APHIS regulates the importation of animals and animal products into the United States. These regulations are contained in title 9, parts 92 through 98, of the Code of Federal Regulations. Sections 93.900 through 93.906 contain requirements to prevent the introduction of spring viremia of carp (SVC) into the United States. SVC is a disease of certain species of finfish that is caused by an eponymous rhabdovirus. The disease is considered extremely contagious, and there are currently no U.S.-approved vaccines or treatments for the virus.

In accordance with the regulations, APHIS restricts the importation of live fish, fertilized eggs, and gametes of SVC-susceptible species and the importation of diagnostic specimens or research materials containing viable SVC virus. The regulations involve information collection activities, including an Application for Import or in Transit Permit (Animals, Animal Semen, Animal Embryos, Birds, Poultry, or Hatching Eggs) (VS Form 17-129), Application for Permit to: Import or Transport Controlled Material or Organisms or Vectors (VS Form 16-3), Refusal of Entry and Order to Dispose of Fish (VS Form 17-136), and Declaration of Importation (Animals, Animal Semen, Animal Embryos, Birds, Poultry, or Hatching Eggs) (VS Form 17-29). In addition to the listed forms, additional information collection activities include a health certificate, cleaning and disinfection certificate, and 72-hour notification to APHIS before arrival of a shipment in the United States. Lastly, recordkeeping is also required.

Since the last extension of approval for these information collection activities, APHIS has refined the number of respondents and number of responses collected, resulting in a

decrease of the estimated annual number of respondents from 462 to 76. In addition, APHIS has also improved estimates of the time necessary for completion of these activities, as well as the number of recordkeepers, which was adjusted from 12,010 to 1,072. The estimated total annual burden hours has now decreased from 2,018.21 hours to 1,016 hours.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the 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, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; e.g., permitting electronic submission of responses.

Estimate of burden: The public reporting burden for this collection of information is estimated to average 0.189164029 hours per response.

Respondents: Brokers, personnel at aquatic pathogen detection laboratories, salaried veterinary officers of the national government of the exporting region or designated certifying officials, and importers of SVC-susceptible live fish, fertilized eggs, and gametes.

Estimated annual number of respondents: 76.

Estimated annual number of responses per respondent: 70.67.

Estimated annual number of responses: 5,371.

Estimated total annual burden on respondents: 1,016 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

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.

Done in Washington, DC, this 20th day of February 2013.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2013-04496 Filed 2-26-13; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2012-0024]

Syngenta Biotechnology, Inc.; Determination of Nonregulated Status of Corn Genetically Engineered for Insect Resistance

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination that a corn line developed by the Syngenta Biotechnology, Inc., designated as event SYN-05307-1, which has been genetically engineered for resistance to corn rootworm, an insect pest of corn, is no longer considered a regulated article under our regulations governing the introduction of certain genetically engineered organisms. Our determination is based on our evaluation of data submitted by Syngenta Biotechnology, Inc., in its petition for a determination of nonregulated status, our analysis of available scientific data, and comments received from the public in response to our previous notice announcing the availability of the petition for nonregulated status and its associated environmental assessment and plant pest risk assessment. This notice also announces the availability of our written determination and finding of no significant impact.

DATES: *Effective Date:* February 27, 2013.

ADDRESSES: You may read the documents referenced in this notice and the comments we received 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) 799-7039 before coming. Those documents are also available on the Internet at http://www.aphis.usda.gov/biotechnology/not_reg.html and are posted with the

previous notice and the comments we received on the Regulations.gov Web site at <http://www.regulations.gov/#/docketDetail;D=APHIS-2012-0024>.

FOR FURTHER INFORMATION CONTACT: Dr. John Turner, Director, Environmental Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 851-3954, email: john.t.turner@aphis.usda.gov. To obtain copies of the documents referenced in this notice, contact Ms. Cindy Eck at (301) 851-3892, email: cynthia.a.eck@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests," regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered organisms and products are considered "regulated articles."

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. Paragraphs (b) and (c) of § 340.6 describe the form that a petition for a determination of nonregulated status must take and the information that must be included in the petition.

APHIS received a petition (APHIS Petition Number 10-336-01p) from Syngenta Biotechnology, Inc., (Syngenta) of Research Triangle Park, NC, seeking a determination of nonregulated status of corn (*Zea mays* L.) designated as event SYN-05307-1, which has been genetically engineered for resistance to corn rootworm, an insect pest of corn. The petition states that this corn is unlikely to pose a plant pest risk and, therefore, should not be a regulated article under APHIS' regulations in 7 CFR part 340.

In a notice¹ published in the **Federal Register** on July 13, 2012 (77 FR 41366-41367, Docket No. APHIS-2012-0024), APHIS announced the availability of the Syngenta petition, a plant pest risk

assessment (PPRA), and a draft environmental assessment (EA) for public comment. APHIS solicited comments on the petition, whether the subject corn is likely to pose a plant pest risk, the draft EA, and the PPRA for 60 days ending on September 11, 2012.

APHIS received 86 comments during the comment period, with 14 commenters expressing support of the EA's preferred alternative to make a determination of nonregulated status and the remaining 72 commenters expressing opposition. One of the comments opposing a determination of nonregulated status included submitted electronic attachments that consisted of many signed letters containing identical material (4,601 letters). Issues raised during the comment period included adequacy of the EA, effects on nontarget organisms, and potential effects on human and animal health. APHIS has addressed the issues raised during the comment period and has provided responses to these comments as an attachment to the finding of no significant impact.

National Environmental Policy Act

To provide the public with documentation of APHIS' review and analysis of any potential environmental impacts associated with the determination of nonregulated status of Syngenta's corn event SYN-05307-1, an EA has been prepared. The EA was 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 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372). Based on our EA, the response to public comments, and other pertinent scientific data, APHIS has reached a finding of no significant impact with regard to the preferred alternative identified in the EA.

Determination

Based on APHIS' analysis of field and laboratory data submitted by Syngenta, references provided in the petition, peer-reviewed publications, information analyzed in the EA, the PPRA, comments provided by the public, and information provided in APHIS' response to those public comments, APHIS has determined that Syngenta's corn event SYN-05307-1 is unlikely to pose a plant pest risk and therefore is no longer subject to our regulations governing the introduction of certain genetically engineered organisms.

¹To view the notice, petition, draft EA, the PPRA, and the comments we received, go to <http://www.regulations.gov/#/docketDetail;D=APHIS-2012-0024>.

Copies of the signed determination document, as well as copies of the petition, PPRA, EA, finding of no significant impact, and response to comments are available as indicated in the **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT** sections of this notice.

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 22nd day of February 2013.

Michael Gregoire,

Deputy Administrator, Biotechnology Regulatory Services, Animal and Plant Health Inspection Service.

[FR Doc. 2013–04517 Filed 2–26–13; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2012–0033]

Stine Seed Farm, Inc.; Availability of Plant Pest Risk Assessment, Environmental Assessment, and Preliminary Decision for an Extension of a Determination of Nonregulated Status of Corn Genetically Engineered for Herbicide Tolerance

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 a preliminary decision regarding a request from Stine Seed Farm, Inc., to extend to maize line HCEM485, which has been genetically engineered to be tolerant to the herbicide glyphosate, our determination of nonregulated status of Roundup Ready® corn line GA21. We are seeking comment on whether this genetically engineered corn is likely to pose a plant pest risk. We are making available for public comment our plant pest risk assessment and draft environmental assessment for the proposed determination of nonregulated status.

DATES: We will consider all comments that we receive on or before March 29, 2013.

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

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/documentDetail;D=APHIS-2012-0033-0001>.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No.

APHIS–2012–0033, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/documentDetail;D=APHIS-2012-033> or in our reading room, which 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) 799–7039 before coming.

The extension request, draft environmental assessment, and plant pest risk assessment are also available on the APHIS web site at http://www.aphis.usda.gov/brs/aphisdocs/09_06301p.pdf, http://www.aphis.usda.gov/brs/aphisdocs/09_06301p_dea.pdf, and http://www.aphis.usda.gov/brs/aphisdocs/09_06301p_dpra.pdf.

FOR FURTHER INFORMATION CONTACT: Dr. John Turner, Director, Environmental Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147 Riverdale, MD 20737–1236; (301) 851–3954, email: john.t.turner@aphis.usda.gov. To obtain copies of the supporting documents, contact Ms. Cindy Eck at (301) 851–3885, email: cynthia.a.eck@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

Under the authority of the plant pest provisions of the Plant Protection Act (PPA) (7 U.S.C. 7701 *et seq.*), the regulations in 7 CFR part 340, “Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests,” regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered organisms (GE) and products are considered “regulated articles.”

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. Further, the regulations in § 340.6(e)(2)

provide that a person may request that APHIS extend a determination of nonregulated status to other organisms. Such a request must include information to establish the similarity of the antecedent organism and the regulated article in question.

In a notice published in the **Federal Register** on December 5, 1997 (62 FR 64350–64351, Docket No. 97–052–2), APHIS announced our determination of nonregulated status of Roundup Ready® corn line GA21. APHIS has received a request for an extension of a determination of nonregulated status (APHIS Number 09–063–01p) of Roundup Ready® corn line GA21 to maize line HCEM485¹ from Stine Seed Farm, Inc., (Stine Seed) of Research Triangle Park, NC. Stine Seed seeks a determination of nonregulated status of corn designated as maize line HCEM485, which has been genetically engineered to be glyphosate tolerant. In its request, Stine Seed stated that this corn is similar to Roundup Ready® corn line GA21 and, based on the similarity to the antecedent organism, is unlikely to pose a plant pest risk and, therefore, should not be a regulated article under APHIS’ regulations in 7 CFR part 340.

As described in the extension request, maize line HCEM485 has been genetically engineered by a 6.0 kb corn genomic fragment, originally isolated from a bacterial chromosome library derived from the corn inbred line B73, containing a modified form of the endogenous *Zea mays* EPSPS encoding gene. The antecedent organism, Roundup Ready® corn line GA21, was made with a 1.3kb restriction fragment of the corn EPSPS gene. Both corn lines were produced with the same mutations responsible for conferring glyphosate herbicide tolerance. Maize line HCEM485 is currently regulated under 7 CFR part 340. Interstate movements and field tests of maize line HCEM485 have been conducted under notifications acknowledged by APHIS.

Field tests conducted under APHIS oversight allowed for evaluation in a natural agricultural setting while imposing measures to minimize the risk of persistence in the environment after completion of the test. Data are gathered on multiple parameters and used by the applicant to evaluate agronomic characteristics and product performance. These and other data are used by APHIS to determine whether the new variety poses a plant pest risk.

¹ The terms “corn” and “maize” both refer to *Zea mays*. In this notice, we refer to “maize line HCEM485” as this is the name used by Stine Seed in its extension request to identify its GE corn. Otherwise, we use the more common term “corn” when referring to *Zea mays*.

In section 403 of the PPA, “plant pest” is defined as any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant product: A protozoan, a nonhuman animal, a parasitic plant, a bacterium, a fungus, a virus or viroid, an infectious agent or other pathogen, or any article similar to or allied with any of the foregoing. APHIS prepared a plant pest risk assessment (PPRA) and has concluded that maize line HCEM485 is similar to the antecedent organism and is unlikely to pose a plant pest risk.

APHIS has also prepared a draft environmental assessment (EA) in which it presents two alternatives based on its analyses of data submitted by Stine Seed, a review of other scientific data, and field tests conducted under APHIS oversight. APHIS is considering the following alternatives: (1) Take no action, i.e., APHIS would not change the regulatory status of maize line HCEM485 and it would continue to be a regulated article, or (2) make a determination of nonregulated status of maize line HCEM485.

The draft EA has been prepared to provide the APHIS decisionmaker with a review and analysis of any potential environmental impacts associated with the proposed determination of nonregulated status of maize line HCEM485. The draft EA was 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); (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 1b); and (4) APHIS’ NEPA Implementing Procedures (7 CFR part 372).

Based on APHIS’ analysis of field and laboratory data submitted by Stine Seed, references provided in the extension request, peer-reviewed publications, information analyzed in the EA, and the similarity of maize line HCEM485 to the antecedent organism, Roundup Ready® corn line GA21, APHIS has determined that maize line HCEM485 is unlikely to pose a plant pest risk. We have therefore reached a preliminary decision to approve the request to extend the determination of nonregulated status of Roundup Ready® corn line GA21 to maize line HCEM485, whereby maize line HCEM485 would no longer be subject to our regulations governing the

introduction of certain genetically engineered organisms.

Paragraph (e) of § 340.6 provides that APHIS will publish a notice in the **Federal Register** announcing all preliminary decisions to extend determinations of nonregulated status for 30 days before the decisions become final and effective. In accordance with § 340.6(e) of the regulations, we are publishing this notice to inform the public of our preliminary decision to extend the determination of nonregulated status of Roundup Ready® corn line GA21 to maize line HCEM485.

APHIS will accept written comments on the draft EA and PPRA regarding a determination of nonregulated status of maize line HCEM485 for a period of 30 days from the date this notice is published in the **Federal Register**. The draft EA and PPRA, as well as the extension request and preliminary determination for maize line HCEM485, are available for public review as indicated under **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT** above. Copies of these documents may also be obtained by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

After the comment period closes, APHIS will review all written comments received during the comment period and any other relevant information. All comments received regarding the EA and PPRA will be available for public review. After reviewing and evaluating the comments on the EA and PPRA, APHIS will furnish a response to the petitioner regarding our final regulatory determination. APHIS will also publish a notice in the **Federal Register** announcing the regulatory status of maize line HCEM485 and the availability of APHIS’ written environmental decision and regulatory determination.

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 22nd day of February 2013.

Michael Gregoire,

Deputy Administrator, Biotechnology Regulatory Services, Animal and Plant Health Inspection Service.

[FR Doc. 2013–04520 Filed 2–26–13; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2012–0009]

Notice of Decision To Issue Permits for the Importation of Strawberry Fruit From Egypt Into the Continental United States

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our decision to begin issuing permits for the importation into the continental United States of fresh strawberry fruit from Egypt. Based on the findings of a pest risk analysis, which we made available to the public for review and comment through a previous notice, we believe that the application of one or more designated phytosanitary measures will be sufficient to mitigate the risks of introducing or disseminating plant pests or noxious weeds via the importation of fresh strawberry fruit from Egypt.

DATES: *Effective Date:* February 27, 2013.

FOR FURTHER INFORMATION CONTACT: Mr. Marc Phillips, Regulatory Policy Specialist, Regulations, Permits, and Manuals, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737–1231; (301) 851–2114.

SUPPLEMENTARY INFORMATION:

Background

Under the regulations in “Subpart—Fruits and Vegetables” (7 CFR 319.56–1 through 319.56–58, referred to below as the regulations), the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture prohibits or restricts the importation of fruits and vegetables into the United States from certain parts of the world to prevent plant pests from being introduced into and spread within the United States.

Section 319.56–4 of the regulations contains a performance-based process for approving the importation of commodities that, based on the findings of a pest risk analysis (PRA), can be safely imported subject to one or more of the designated phytosanitary measures listed in paragraph (b) of that section. Under that process, APHIS publishes a notice in the **Federal Register** announcing the availability of the PRA that evaluates the risks associated with the importation of a particular fruit or vegetable. Following the close of the 60-day comment period,

APHIS may begin issuing permits for importation of the fruit or vegetable subject to the identified designated measures if: (1) No comments were received on the PRA; (2) the comments on the PRA revealed that no changes to the PRA were necessary; or (3) changes to the PRA were made in response to public comments, but the changes did not affect the overall conclusions of the analysis and the Administrator's determination of risk.

In accordance with that process, we published a notice¹ in the **Federal Register** on April 16, 2012 (77 FR 22557–22558, Docket No. APHIS–2012–0009), in which we announced the availability, for review and comment, of a PRA that evaluates the risks associated with the importation into the continental United States of fresh strawberry (*Fragaria* spp.) fruit with calyx and short stalk from Egypt. We solicited comments on the notice for 60 days ending on June 15, 2012. We received three comments by that date. They were from a State department of agriculture, an agricultural research center, and a non-profit industry representative.

In the PRA, APHIS determined that three plant pests have a high risk potential of being introduced into the United States via the pathway of fresh strawberry fruit from Egypt. Those pests are: *Chrysodeixis chalcites*, *Eutetranychus orientalis*, and *Spodoptera littoralis*. The PRA notes that *Eutetranychus orientalis* could potentially avoid detection beneath the calyx of the strawberries due to its small size. One commenter cited this potential risk as a phytosanitary concern. The commenter stated that they would be willing to revisit this issue if current mitigation procedures are proven to be effective and without any detections of this mite.

We acknowledge the risk that this plant pest could potentially evade detection and be introduced into the United States in the manner referred to by the commenter. However, while the pest itself may potentially evade detection by its small size, its presence can be detected by visible signs of discoloration and damage to fruits and leaves. Additionally, good agricultural practices can effectively suppress or eliminate this pest from fields or prevent infestation. Successful control programs typically include monitoring, cultural, biological, and chemical components, all of which are used as part of Egypt's standard pre- and post-

harvest practices for the production of export strawberries. Moreover, APHIS has permitted the entry of commercial strawberries from several countries in Asia, Europe, and South America where this pest of concern occurs. Over several decades, there has only been one interception of *Eutetranychus orientalis* in strawberry consignments.

Another commenter stated that the PRA does not provide for adequate phytosanitary security against any tetranychid mite.

In the risk assessment portion of the PRA, the only tetranychid species identified as likely to follow the importation pathway was *Eutetranychus orientalis*. For the reasons detailed above, we have determined that the application of certain phytosanitary measures coupled with standard industry practices will be adequate to mitigate the risk posed by this pest. Other tetranychid species identified as pests of fresh strawberry were: *Tetranychus cinnabarinus* (Boisduval), *Tetranychus ludeni* Zacher, *Tetranychus neocalendonicus* André, and *Tetranychus urticae* Koch, which are reported as being present in Egypt, but do not meet the definition of quarantine pests, and *Tetranychus turkestanii*, which has been reported as being present in the region, but APHIS did not find sufficient evidence the pest is present in Egypt. The commenter did not discuss any particular species of tetranychid which they believe to be of concern, nor did they present evidence contradicting the information presented in the risk assessment.

The third commenter recommended that we adopt specific phytosanitary measures to address the pest risks discussed in the PRA.

APHIS has permitted the entry of commercial strawberries from several countries in Asia, Europe, and South America with similar lists of pests of concern (e.g., Jordan and Israel). Based on our knowledge and experience in relation to importation of fresh strawberry fruit from these countries with similar pest lists, we are confident of the efficacy of the designated measures in mitigating the phytosanitary risks posed by the importation of strawberry from Egypt.

Finally, the commenter added that we should intensively monitor fresh strawberry from Egypt at the port of entry.

An integral part of standard APHIS phytosanitary practices is inspection at the port of entry.

For these reasons, together with Egypt's use of integrated pest management practices in the production of commercial strawberries, APHIS has

concluded that commercial strawberries for export from Egypt are unlikely to contain the identified quarantine pests. Accordingly, we have determined that no changes to the PRA are necessary based on these comments.

Therefore, in accordance with the regulations in § 319.56–4(c)(2)(ii), we are announcing our decision to begin issuing permits for the importation into the continental United States of fresh strawberry fruit from Egypt subject to the following phytosanitary measures:

- The fresh strawberry fruit may be imported into the continental United States in commercial consignments only;
- Each consignment of fresh strawberry fruit must be inspected by the national plant protection organization of Egypt and accompanied by a phytosanitary certificate that includes an additional declaration stating that the consignment was inspected and found free of *Chrysodeixis chalcites*, *Eutetranychus orientalis*, and *Spodoptera littoralis*; and
- The fresh strawberry fruit is subject to inspection upon arrival at the U.S. port of entry.

These conditions will be listed in the Fruits and Vegetables Import Requirements database (available at <http://www.aphis.usda.gov/favir>). In addition to these specific measures, fresh strawberry fruit from Egypt will be subject to the general requirements listed in § 319.56–3 that are applicable to the importation of all fruits and vegetables.

Authority: 7 U.S.C. 450, 7701–7772, and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 20th day of February 2013.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2013–04475 Filed 2–26–13; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2012–0090]

Syngenta Seeds, Inc., and Bayer CropScience AG; Availability of Petition for Determination of Nonregulated Status of Soybean Genetically Engineered for Herbicide Tolerance

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

¹ To view the notice, the PRA, and the comments we received, go to <http://www.regulations.gov/#/docketDetail;D=APHIS-2012-0009>.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service (APHIS) has received a petition from Syngenta Seeds, Inc., and Bayer CropScience AG seeking a determination of nonregulated status of soybean designated as event SYHTOH2, which has been genetically engineered for tolerance to the herbicides glufosinate and mesotrione. The petition has been submitted in accordance with our regulations concerning the introduction of certain genetically engineered organisms and products. We are making the Syngenta Seeds, Inc., and Bayer CropScience AG petition available for review and comment to help us identify potential environmental and interrelated economic issues and impacts that APHIS may determine should be considered in our evaluation of the petition.

DATES: We will consider all comments that we receive on or before April 29, 2013.

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

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/#!documentDetail;D=APHIS-2012-0090-0001>.

- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS-2012-0090, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0090> or in our reading room, which 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) 799-7039 before coming.

The petition is also available on the APHIS Web site at http://www.aphis.usda.gov/brs/aphisdocs/12_21501p.pdf.

FOR FURTHER INFORMATION CONTACT: Dr. John Turner, Director, Environmental Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 851-3954, email: john.t.turner@aphis.usda.gov. To obtain copies of the petition, contact Ms. Cindy Eck at (301) 851-3892, email: cynthia.a.eck@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

Under the authority of the plant pest provisions of the Plant Protection Act (7 U.S.C. 7701 *et seq.*), the regulations in 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests," regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered (GE) organisms and products are considered "regulated articles."

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. Paragraphs (b) and (c) of § 340.6 describe the form that a petition for a determination of nonregulated status must take and the information that must be included in the petition.

APHIS has received a petition (APHIS Petition Number 12-215-01p) from Syngenta Seeds, Inc., and Bayer CropScience (BCS) AG of Research Triangle Park, NC, seeking a determination of nonregulated status of soybean designated as event SYHTOH2, which has been genetically engineered to tolerate exposure to the herbicides glufosinate and mesotrione. Glufosinate tolerance is not a new engineered trait in GE soybean, while mesotrione tolerance is a new trait. The petition states that this soybean event is unlikely to pose a plant pest risk and, therefore, should not be a regulated article under APHIS' regulations in 7 CFR part 340.

As described in the petition, soybean event SYHTOH2 has been genetically engineered for tolerance to herbicides that inhibit *p*-hydroxyphenylpyruvate dioxygenase (HPPD), such as mesotrione, and tolerance to applications of glufosinate-ammonium herbicide. Soybean derived from transformation event SYHTOH2 was developed through *Agrobacterium*-mediated transformation to stably incorporate the genes *avhppd-03* and *pat* into the soybean genome. The gene *avhppd-03* encodes the enzyme *p*-hydroxyphenylpyruvate dioxygenase (AvHPPD-03) derived from oat (*Avena sativa*). AvHPPD-03 has lower binding affinity to mesotrione than does native soybean HPPD. When expressed in soybean, *avhppd-03* conveys pre-and post-emergence tolerance to mesotrione.

The gene *pat* encodes the enzyme phosphinothricin acetyltransferase (PAT) which, when produced in plants, acetylates L-phosphinothricin, the active form of glufosinate-ammonium herbicide, resulting in post-emergence tolerance. Soybean event SYHTOH2 is currently regulated under 7 CFR part 340. Interstate movement and field tests of soybean event SYHTOH2 have been conducted under notifications acknowledged by APHIS.

Field tests conducted under APHIS oversight allowed for evaluation in a natural agricultural setting while imposing measures to minimize risk of persistence in the environment after completion of the test. Data are gathered on multiple parameters and used by the applicant to evaluate agronomic characteristics and product performance. These and other data are used by APHIS to determine if the new variety poses a plant pest risk.

Paragraph (d) of § 340.6 provides that APHIS will publish a notice in the **Federal Register** providing 60 days for public comment for petitions for a determination of nonregulated status. On March 6, 2012, we published in the **Federal Register** (77 FR 13258-13260, Docket No. APHIS-2011-0129) a notice¹ describing our process for soliciting public comment when considering petitions for determinations of nonregulated status for GE organisms. In that notice we indicated that APHIS would accept written comments regarding a petition once APHIS deemed it complete.

In accordance with § 340.6(d) of the regulations and our process for soliciting public input when considering petitions for determinations of nonregulated status for GE organisms, we are publishing this notice to inform the public that APHIS will accept written comments regarding the petition for a determination of nonregulated status from interested or affected persons for a period of 60 days from the date of this notice. The petition is available for public review, and copies are available as indicated under **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT** above.

We are interested in receiving comments regarding potential environmental and interrelated economic issues and impacts that APHIS may determine should be considered in our evaluation of the petition. We are particularly interested in receiving comments regarding biological, cultural, or ecological issues,

¹To view the notice, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0129>.

and we encourage the submission of scientific data, studies, or research to support your comments. We also request that, when possible, commenters provide relevant information regarding specific localities or regions as soybean growth, crop management, and crop utilization may vary considerably by geographic region.

After the comment period closes, APHIS will review all written comments received during the comment period and any other relevant information; any substantive issues identified by APHIS based on our review of the petition and our evaluation and analysis of comments will be considered in the development of our decisionmaking documents.

As part of our decisionmaking process regarding a GE organism's regulatory status, APHIS prepares a plant pest risk assessment to assess its plant pest risk and the appropriate environmental documentation—either an environmental assessment (EA) or an environmental impact statement (EIS)—in accordance with the National Environmental Policy Act (NEPA), to provide the Agency with a review and analysis of any potential environmental impacts associated with the petition request. For petitions for which APHIS prepares an EA, APHIS will follow our published process for soliciting public comment (see footnote 1) and publish a separate notice in the **Federal Register** announcing the availability of APHIS' EA and plant pest risk assessment. Should APHIS determine that an EIS is necessary, APHIS will complete the NEPA EIS process in accordance with Council on Environmental Quality regulations (40 CFR part 1500–1508) and APHIS' NEPA implementing regulations (7 CFR part 372).

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 22nd day of February 2013.

Michael Gregoire,

Deputy Administrator, Biotechnology Regulatory Services, Animal and Plant Health Inspection Service.

[FR Doc. 2013–04521 Filed 2–26–13; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2012–0110]

Dow AgroSciences LLC; Availability of Petition for Determination of Nonregulated Status of Soybean Genetically Engineered for Insect Resistance

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service (APHIS) has received a petition from Dow AgroSciences LLC (DAS) seeking a determination of nonregulated status of soybean designated as DAS–81419–2, which has been genetically engineered for resistance to certain lepidopteran pests. The petition has been submitted in accordance with our regulations concerning the introduction of certain genetically engineered organisms and products. We are making the DAS petition available for review and comment to help us identify potential environmental and interrelated economic issues and impacts that APHIS may determine should be considered in our evaluation of the petition.

DATES: We will consider all comments that we receive on or before April 29, 2013.

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

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/#!documentDetail;D=APHIS-2012-0110-0001>.

- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2012–0110, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0110> or in our reading room, which 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) 799–7039 before coming.

The petition is also available on the APHIS Web site at http://www.aphis.usda.gov/brs/aphisdocs/12_27201p.pdf.

www.aphis.usda.gov/brs/aphisdocs/12_27201p.pdf.

FOR FURTHER INFORMATION CONTACT: Dr. John Turner, Director, Environmental Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737–1236; (301) 851–3954, email: john.t.turner@aphis.usda.gov. To obtain copies of the petition, contact Ms. Cindy Eck at (301) 851–3892, email: cynthia.a.eck@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

Under the authority of the plant pest provisions of the Plant Protection Act (7 U.S.C. 7701 *et seq.*), the regulations in 7 CFR part 340, “Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests,” regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered (GE) organisms and products are considered “regulated articles.”

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. Paragraphs (b) and (c) of § 340.6 describe the form that a petition for a determination of nonregulated status must take and the information that must be included in the petition.

APHIS has received a petition (APHIS Petition Number 12–272–01p) from Dow AgroSciences LLC of Indianapolis, IN, seeking a determination of nonregulated status of soybean (*Glycine max*) designated as event DAS–81419–2, which has been genetically engineered for resistance to certain lepidopteran pests. The petition states that this soybean is unlikely to pose a plant pest risk and, therefore, should not be a regulated article under APHIS' regulations in 7 CFR part 340.

As described in the petition, soybean event DAS–81419–2 has been genetically engineered to express two insecticidal proteins, Cry1Ac and Cry1F, and phosphinothricin acetyltransferase, or PAT, protein. Soybean event DAS–81419–2 is currently regulated under 7 CFR part 340. Interstate movements and field tests of soybean event DAS–81419–2

have been conducted under notifications acknowledged by APHIS.

Field tests conducted under APHIS oversight allowed for evaluation in a natural agricultural setting while imposing measures to minimize the risk of persistence in the environment after completion of the test. Data are gathered on multiple parameters and used by the applicant to evaluate agronomic characteristics and product performance. These and other data are used by APHIS to determine if the new variety poses a plant pest risk.

Paragraph (d) of § 340.6 provides that APHIS will publish a notice in the **Federal Register** providing 60 days for public comment for petitions for a determination of nonregulated status. On March 6, 2012, we published in the **Federal Register** (77 FR 13258–13260, Docket No. APHIS–2011–0129) a notice¹ describing our process for soliciting public comment when considering petitions for determinations of nonregulated status for GE organisms. In that notice we indicated that APHIS would accept written comments regarding a petition once APHIS deemed it complete.

In accordance with § 340.6(d) of the regulations and our process for soliciting public input when considering petitions for determinations of nonregulated status for GE organisms, we are publishing this notice to inform the public that APHIS will accept written comments regarding the petition for a determination of nonregulated status from interested or affected persons for a period of 60 days from the date of this notice. The petition is available for public review, and copies are available as indicated under **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT** above.

We are interested in receiving comments regarding potential environmental and interrelated economic issues and impacts that APHIS may determine should be considered in our evaluation of the petition. We are particularly interested in receiving comments regarding biological, cultural, or ecological issues, and we encourage the submission of scientific data, studies, or research to support your comments. We also request that, when possible, commenters provide relevant information regarding specific localities or regions as soybean growth, crop management, and crop utilization may vary considerably by geographic region.

¹ To view the notice, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0129>.

After the comment period closes, APHIS will review all written comments received during the comment period and any other relevant information; any substantive issues identified by APHIS based on our review of the petition and our evaluation and analysis of comments will be considered in the development of our decisionmaking documents.

As part of our decisionmaking process regarding a GE organism's regulatory status, APHIS prepares a plant pest risk assessment to assess its plant pest risk and the appropriate environmental documentation—either an environmental assessment (EA) or an environmental impact statement (EIS)—in accordance with the National Environmental Policy Act (NEPA), to provide the Agency with a review and analysis of any potential environmental impacts associated with the petition request. For petitions for which APHIS prepares an EA, APHIS will follow our published process for soliciting public comment (see footnote 1) and publish a separate notice in the **Federal Register** announcing the availability of APHIS' EA and plant pest risk assessment. Should APHIS determine that an EIS is necessary, APHIS will complete the NEPA EIS process in accordance with Council on Environmental Quality regulations (40 CFR part 1500–1508) and APHIS' NEPA implementing regulations (7 CFR part 372).

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 22nd day of February 2013.

Michael Gregoire,

Deputy Administrator, Biotechnology Regulatory Services, Animal and Plant Health Inspection Service.

[FR Doc. 2013–04523 Filed 2–26–13; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2012–0097]

Monsanto Co.; Availability of Petition for Determination of Nonregulated Status of Dicamba and Glufosinate Tolerant Cotton

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service (APHIS) has received a petition from the Monsanto Company

(Monsanto) seeking a determination of nonregulated status of cotton designated as MON 88701, which has been genetically engineered for tolerance to the herbicides dicamba and glufosinate. The petition has been submitted in accordance with our regulations concerning the introduction of certain genetically engineered organisms and products. We are making the Monsanto petition available for review and comment to help us identify potential environmental and interrelated economic issues and impacts that APHIS may determine should be considered in our evaluation of the petition.

DATES: We will consider all comments that we receive on or before April 29, 2013.

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

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/#!documentDetail;D=APHIS-2012-0097-0001>.

- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2012–0097, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0097> or in our reading room, which 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) 799–7039 before coming.

The petition is also available on the APHIS Web site at http://www.aphis.usda.gov/brs/aphisdocs/12_18501p.pdf.

FOR FURTHER INFORMATION CONTACT: Dr. John Turner, Director, Environmental Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737–1236; (301) 851–3954, email: john.t.turner@aphis.usda.gov. To obtain copies of the petition, contact Ms. Cindy Eck at (301) 851–3892, email: cynthia.a.eck@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

Under the authority of the plant pest provisions of the Plant Protection Act (7 U.S.C. 7701 *et seq.*), the regulations in 7 CFR part 340, “Introduction of

Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests," regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered (GE) organisms and products are considered "regulated articles."

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. Paragraphs (b) and (c) of § 340.6 describe the form that a petition for a determination of nonregulated status must take and the information that must be included in the petition.

APHIS has received a petition (APHIS Petition Number 12-185-01p) from the Monsanto Company (Monsanto) of St. Louis, MO, seeking a determination of nonregulated status of cotton designated as event MON 88701, which has been genetically engineered for tolerance to the herbicides dicamba and glufosinate. The petition states that this cotton is unlikely to pose a plant pest risk and, therefore, should not be a regulated article under APHIS' regulations in 7 CFR part 340.

As described in the petition, cotton event MON 88701 has been genetically engineered to allow in-crop applications of dicamba herbicide for the control of broadleaf weeds from preemergence to 7 days preharvest and glufosinate herbicide for broad spectrum weed control from emergence through early bloom growth stage. Cotton event MON 88701 provides dicamba tolerance that allows for the in-crop application of dicamba beyond the current preplant uses in cotton and also provides glufosinate tolerance equivalent to current commercial glufosinate-tolerant cotton events. Cotton event MON 88701 is currently regulated under 7 CFR part 340. Interstate movements and field tests of cotton event MON 88701 have been conducted under notifications acknowledged by APHIS.

Field tests conducted under APHIS oversight allowed for evaluation in a natural agricultural setting while imposing measures to minimize the risk of persistence in the environment after completion of the test. Data are gathered on multiple parameters and used by the applicant to evaluate agronomic characteristics and product performance. These and other data are

used by APHIS to determine if the new variety poses a plant pest risk.

Paragraph (d) of § 340.6 provides that APHIS will publish a notice in the **Federal Register** providing 60 days for public comment for petitions for a determination of nonregulated status. On March 6, 2012, we published in the **Federal Register** (77 FR 13258-13260, Docket No. APHIS-2011-0129) a notice¹ describing our process for soliciting public comment when considering petitions for determinations of nonregulated status for GE organisms. In that notice we indicated that APHIS would accept written comments regarding a petition once APHIS deemed it complete.

In accordance with § 340.6(d) of the regulations and our process for soliciting public input when considering petitions for determinations of nonregulated status for GE organisms, we are publishing this notice to inform the public that APHIS will accept written comments regarding the petition for a determination of nonregulated status from interested or affected persons for a period of 60 days from the date of this notice. The petition is available for public review, and copies are available as indicated under

ADDRESSES and **FOR FURTHER INFORMATION CONTACT** above. We are interested in receiving comments regarding potential environmental and interrelated economic issues and impacts that APHIS may determine should be considered in our evaluation of the petition. We are particularly interested in receiving comments regarding biological, cultural, or ecological issues, and we encourage the submission of scientific data, studies, or research to support your comments. We also request that, when possible, commenters provide relevant information regarding specific localities or regions as cotton growth, crop management, and crop utilization may vary considerably by geographic region.

After the comment period closes, APHIS will review all written comments received during the comment period and any other relevant information; any substantive issues identified by APHIS based on our review of the petition and our evaluation and analysis of comments will be considered in the development of our decisionmaking documents.

As part of our decisionmaking process regarding a GE organism's regulatory status, APHIS prepares a plant pest risk assessment to assess its plant pest risk

and the appropriate environmental documentation—either an environmental assessment (EA) or an environmental impact statement (EIS)—in accordance with the National Environmental Policy Act (NEPA), to provide the Agency with a review and analysis of any potential environmental impacts associated with the petition request. For petitions for which APHIS prepares an EA, APHIS will follow our published process for soliciting public comment (see footnote 1) and publish a separate notice in the **Federal Register** announcing the availability of APHIS' EA and plant pest risk assessment. Should APHIS determine that an EIS is necessary, APHIS will complete the NEPA EIS process in accordance with Council on Environmental Quality regulations (40 CFR part 1500-1508) and APHIS' NEPA implementing regulations (7 CFR part 372).

Authority: 7 U.S.C. 7701-7772 and 7781-7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 22nd day of February 2013.

Michael Gregoire,
Deputy Administrator, Biotechnology Regulatory Services, Animal and Plant Health Inspection Service.

[FR Doc. 2013-04522 Filed 2-26-13; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2012-0030]

ArborGen Inc.; Availability of Petition, Notice of Intent To Prepare an Environmental Impact Statement for Determination of Nonregulated Status of Freeze Tolerant Eucalyptus Lines, and Notice of Virtual Public Meetings

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 received a petition from ArborGen Inc. seeking a determination of nonregulated status of Freeze Tolerant Eucalyptus lines designated 427 and 435, which have been genetically engineered (GE) to be more tolerant of cold conditions. The incorporation of the GE trait allows these eucalyptus hybrid trees to be grown in a broader geographic area than non-GE eucalyptus hybrid trees. The petition has been submitted in accordance with our regulations concerning the introduction of certain

¹To view the notice, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0129>.

GE organisms and products. We are making available for public comment the ArborGen Inc. petition and are soliciting comments on whether these GE eucalyptus lines are likely to pose a plant pest risk. We are also announcing to the public our intent to prepare an environmental impact statement (EIS) on the action with regard to the petition for nonregulated status, identifying potential issues and alternatives that may be studied in the EIS, and requesting public comments to further delineate the scope of the alternatives and environmental impacts and issues. We are also announcing that APHIS will be hosting two virtual meetings during the comment period. The purpose of the meetings will be to further delineate the scope of alternatives and environmental impacts and issues discussed in the EIS.

DATES: We will consider all comments that we receive on or before April 29, 2013. We will also consider comments made at virtual public meetings that will be held during the comment period.

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

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/#!documentDetail;D=APHIS-2012-0030-0001>.

- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS-2012-0030, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0030> or in our reading room, which 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) 7997039 before coming.

The petition is also available on the APHIS Web site at http://www.aphis.usda.gov/brs/aphisdocs/11_01901p.pdf.

Other Information: Details regarding the virtual meetings, including times, dates, and how to participate, will be available at <http://www.aphisvirtualmeetings.com>.

FOR FURTHER INFORMATION CONTACT: Dr. John Turner, Director, Environmental Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1238; (301) 851-3954. To obtain copies of the petition, contact Ms. Cindy Eck at

(301) 851-851-3882, email: cynthia.a.eck@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

Under the authority of the plant pest provisions of the Plant Protection Act (PPA) (7 U.S.C. 7701 *et seq.*), the regulations in 7 CFR part 340, “Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason To Believe Are Plant Pests,” regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered (GE) organisms and products are considered “regulated articles.”

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. Paragraphs (b) and (c) of § 340.6 describe the form that a petition for a determination of nonregulated status must take and the information that must be included in the petition.

Proposed Action

APHIS has received a petition (APHIS Petition Number 11-019-01p) from ArborGen Inc. of Summerville, SC, seeking a determination of nonregulated status of two Freeze Tolerant Eucalyptus (FTE) lines designated 427 and 435. The petition states that these eucalyptus trees are unlikely to pose a plant pest risk and, therefore, should not be a regulated article under APHIS’ regulations in 7 CFR part 340. These regulations are authorized by the PPA to prevent the introduction or dissemination of plant pests, and the decision on whether or not to grant the petition will be based on this standard.

As described in the petition, FTE lines 427 and 435 have been genetically engineered to express the CBF2 gene to be more tolerant of cold conditions and a gene expression cassette that prevents pollen development. FTE lines 427 and 435 are currently regulated under 7 CFR part 340. Field tests of FTE lines 427 and 435 have been conducted under permits issued by APHIS at multiple sites representing both freeze stress and freeze stress-free environments in the southeastern United States, Alabama, Florida, Georgia, Louisiana, Mississippi, South Carolina, and Texas.

APHIS has conducted three separate environmental assessments (EA) on actions related to permitting confined field releases of FTE trees under conditions designed to prevent spread of the trees outside the field test area, and in each case announced the availability of the EA in the **Federal Register**. These notices¹ were published on April 20, 2007 (Docket No. APHIS-2007-0027, 72 FR 19876-19877), June 3, 2009 (Docket No. APHIS-2008-0059, 74 FR 26648-26649), and February 10, 2012 (Docket No. APHIS-2011-0130; 77 FR 7123-7124). In these assessments, APHIS concluded that the field trials would not pose a plant pest risk and that issuing permits for the field trials would not significantly affect the quality of the human environment.

In accordance with § 340.6(d) of the regulations and our process for soliciting public input when considering petitions for determinations of nonregulated status for GE organisms, we are publishing this notice to inform the public that APHIS will accept written comments regarding the petition for a determination of nonregulated status from interested or affected persons for a period of 60 days from the date of this notice. The petition is available for public review, and copies are available as indicated under **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT** above.

After the comment period closes, APHIS will review all written comments received during the comment period and any other relevant information. All comments received will be available for public review. Any substantive issues identified by APHIS based on our review of the petition and our evaluation and analysis of the comments will be considered in the development of our decisionmaking documents.

As part of our decisionmaking process regarding a GE organism’s regulatory status, APHIS prepares a plant pest risk assessment to assess its plant pest risk and the appropriate environmental documentation—either an EA or an environmental impact statement (EIS)—in accordance with the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 *et seq.*) (NEPA), to provide the Agency with a review and analysis of any potential environmental impacts associated with the petition request. Upon completion of these documents, APHIS will furnish

¹ The notices and environmental assessments are available at <http://www.regulations.gov/#!docketDetail;D=APHIS-2007-0027>, <http://www.regulations.gov/#!docketDetail;D=APHIS-2008-0059>, and <http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0130>.

a response to the petitioner and will notify the public of our regulatory determination.

Under the provisions of NEPA, Federal agencies must examine the potential environmental impacts of proposed Federal actions before actions are taken. In accordance with NEPA, regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), U.S. Department of Agriculture (USDA) regulations implementing NEPA (7 CFR part 1b) and APHIS' NEPA Implementing Procedures (7 CFR part 372), APHIS has considered how to properly examine these potential environmental impacts. In each of the previous three APHIS actions concerning FTE trees, we determined that an EA was the appropriate means to consider and document environmental impacts. Also, in response to a legal challenge to the adequacy of these EAs and the NEPA process, the United States District Court for the Southern District of Florida granted summary judgment affirming the APHIS actions (Case No. 10–14175–CIV–MOORE/LYNCH).

An EA might also be used in this case, where the relevant Federal action would be determination of nonregulated status of two FTE lines. However, APHIS is choosing the option of preparing an EIS to analyze the potential environmental impacts of responding to this petition request.

APHIS is exercising its option to prepare an EIS rather than an EA to address unresolved proposed or adopted local, regional, State, interstate, or Federal land use plans or policies that may result in adverse environmental impacts. In preparing an EIS, APHIS would be responsive to other agencies that have an interest in the possible future establishment of FTE trees in forest areas. Federal and State agencies have expressed interest in this issue from several perspectives. The USDA Forest Service has agreed to serve as a cooperating agency in the preparation of this EIS and will provide expertise in hydrology, to assess the effects of eucalyptus on water resources, and economic modeling, to predict where in the United States FTE trees may be adopted. The United States Department of Energy considers eucalyptus as a candidate bioenergy feedstock. The United States Fish and Wildlife Service has expressed interest in studies of the impacts of eucalyptus tree plantations on wildlife diversity and ecosystem sustainability. Various States, including Georgia and Florida, have conducted studies or hearings on the possible use

of tree plantations as sources of bioenergy feedstocks. APHIS believes that choosing to prepare an EIS rather than an EA would allow us to fully consider potential environmental impacts of the Federal action under consideration and would also provide, in an efficient way, data that could address a wide variety of government interests and could shed light on issues relevant to possible future actions under the jurisdiction of interested agencies. By preparing an EIS at this time, APHIS may provide agencies with an opportunity to adopt all or part of the EIS for future actions in accordance with the adoption provisions of the Council on Environmental Quality's NEPA implementing regulations (40 CFR 1506.3).

Alternatives

This notice identifies reasonable alternatives and potential issues that may be studied in the EIS. We are requesting public comments to further delineate the scope of alternatives and environmental impacts and issues. We will be hosting two virtual meetings during the comment period to discuss the scope of the EIS (see **ADDRESSES** above). We are particularly interested in receiving comments regarding biological, cultural, or ecological issues, and we encourage the submission of scientific data, studies, or research to support your comments.

The EIS will consider a range of reasonable alternatives. APHIS is considering including a “no action” and “approve the petition request” alternatives. Under the “no action” alternative, in accordance with 7 CFR part 340, FTE would continue to be regulated and the environmental release and interstate movement of FTE lines 427 and 435 would require permits issued or notifications acknowledged by APHIS. APHIS might choose this alternative if there was insufficient evidence to demonstrate that the regulated eucalyptus events were not plant pests or the lack of plant pest risk from the unconfined cultivation of FTE lines 427 and 435. Under the “approve the petition request” alternative, FTE lines 427 and 435 would no longer be regulated articles under the regulations at 7 CFR part 340.

Environmental Issues for Consideration

We have also identified the following potential environmental issues for consideration in the EIS:

- Alteration in susceptibility to disease or insects—Potential of FTE lines 427 and 435 to harbor plant pests or diseases and the impacts of these pests or diseases on natural resources,

forestry, or agriculture within the range of FTE lines 427 and 435.

- Alteration in weediness characteristics—Potential of FTE lines 427 and 435 to be invasive in certain environments and the impacts to natural resources and sociocultural resources if it is invasive.

- Potential impacts of growing FTE lines 427 and 435 on soil hydrology and water resources and how potential changes in soil hydrology or water use may affect natural resources and sociocultural resources.

- Potential impacts of FTE lines 427 and 435 on fire incidence and ecology and how this may affect natural resources and sociocultural resources.

- Potential impacts of allelopathy of FTE lines 427 and 435 on forestry practices or land use.

- Potential direct or indirect effects of FTE lines 427 and 435 on human health.

- Potential direct or indirect effects of FTE lines 427 and 435 on wildlife and their habitats.

In considering reasonable alternatives, the EIS will also study whether these potential environmental issues pose any potential plant pest risks that FTE may exhibit. In addition to plant pest risks that may be posed by characteristics of an individual GE eucalyptus, like allelopathy (suppression of growth of nearby plants due to toxin release), the EIS will also examine potential plant pest risks associated with environmental issues arising from the potential scale of nonregulated GE eucalyptus plantings. Plantings under the earlier permits were of small scale and limited duration. A decision to approve the petition would allow for larger sized plantings, closer together, over a longer period of time.

Additionally, it is the first time APHIS has received a petition for deregulation for a GE tree like eucalyptus, where the species tends to be the dominant species in many forest areas, and the engineered change will increase the range of the species. These changes in scope from the small trials require analysis of the potential environmental and plant pest risk effects of large-scale FTE planting of local hydrology, fire ecology, and other potential issues discussed above.

While the EIS will consider a comprehensive range of potential environmental impacts that FTE eucalyptus may cause, impacts that are not plant pest risks will not affect APHIS' decision as to whether or not to make a determination of nonregulated status of FTE. As explained above, under the PPA, APHIS must make a determination of nonregulated status based on the GE organism's potential to pose a plant pest risk and nothing more.

Comments that identify other issues or alternatives that should be considered for examination in the EIS would be especially helpful. All comments received during the comment period will be carefully considered in developing the final scope of the EIS. Upon completion of the draft EIS and the plant pest risk assessment for FTE lines 427 and 435, a notice announcing their availability and an opportunity to comment on them will be published in the **Federal Register**.

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 22nd day of February 2013.

Michael Gregoire,

Deputy Administrator, Biotechnology Regulatory Services, Animal and Plant Health Inspection Service.

[FR Doc. 2013–04519 Filed 2–26–13; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2012–0026]

Pioneer Hi-Bred International, Inc.; Availability of Petition, Plant Pest Risk Assessment, and Environmental Assessment for Determination of Nonregulated Status of Maize Genetically Engineered for Herbicide Tolerance and Insect Resistance

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 received a petition from Pioneer Hi-Bred International, Inc., (Pioneer) seeking a determination of nonregulated status of maize designated as maize event DP–ØØ4114–3, which has been genetically engineered to be resistant to certain lepidopteran and coleopteran pests and tolerant to the herbicide glufosinate. The petition has been submitted in accordance with our regulations concerning the introduction of certain genetically engineered organisms and products. We are soliciting comments on whether this genetically engineered maize is likely to pose a plant pest risk. We are making available for public comment the Pioneer petition, our plant pest risk assessment, and our draft environmental assessment for the proposed determination of nonregulated status.

DATES: We will consider all comments that we receive on or before April 29, 2013.

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

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/#!documentDetail;D=APHIS-2012-0026-0001>.

- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2012–0026, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0026> or in our reading room, which 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) 799–7039 before coming.

The petition, draft environmental assessment, and plant pest risk assessment are also available on the APHIS Web site at http://www.aphis.usda.gov/brs/aphisdocs/11_24401p.pdf, http://www.aphis.usda.gov/brs/aphisdocs/11_24401p_dea.pdf, and http://www.aphis.usda.gov/brs/aphisdocs/11_24401p_dpra.pdf.

FOR FURTHER INFORMATION CONTACT: Dr. John Turner, Director, Environmental Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737–1236; (301) 851–3954, email: john.t.turner@aphis.usda.gov. To obtain copies of the petition, draft environmental assessment, or plant pest risk assessment, contact Ms. Cindy Eck at (301) 851–3892, email: cynthia.a.eck@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

Under the authority of the plant pest provisions of the Plant Protection Act (7 U.S.C. 7701 *et seq.*), the regulations in 7 CFR part 340, “Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests,” regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that

there is reason to believe are plant pests. Such genetically engineered organisms and products are considered “regulated articles.”

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. Paragraphs (b) and (c) of § 340.6 describe the form that a petition for a determination of nonregulated status must take and the information that must be included in the petition.

APHIS has received a petition (APHIS Petition Number 11–244–01p) from Pioneer Hi-Bred International, Inc., (Pioneer) of Johnston, IA, seeking a determination of nonregulated status of maize (*Zea mays*) designated as maize event DP–ØØ4114–3 (event 4114). Event 4114 has been genetically engineered to be resistant to certain lepidopteran pests, including European corn borer (*Ostrinia nubilalis*), and certain coleopteran pests, including western corn rootworm (*Diabrotica virgifera virgifera*), and tolerant to the herbicide glufosinate. The petition states that this maize is unlikely to pose a plant pest risk and, therefore, should not be a regulated article under APHIS’ regulations in 7 CFR part 340.

As described in the petition, event 4114 has been genetically engineered to produce the Cry proteins Cry1F, Cry34Ab1, and Cry35Ab1, as well as the herbicide tolerance protein phosphinothricin acetyltransferase (PAT). The Cry1F protein confers resistance to certain lepidopteran pests, including European corn borer; the Cry34Ab1 and Cry35Ab1 proteins confers resistance to certain coleopteran pests, including the western corn rootworm; and the PAT protein confers tolerance to the herbicidal active ingredient glufosinate-ammonium at current labeled rates. Event 4114 is currently regulated under 7 CFR part 340. Interstate movements and field tests of event 4114 have been conducted under permits issued or notifications acknowledged by APHIS.

Field tests conducted under APHIS oversight allowed for evaluation in a natural agricultural setting while imposing measures to minimize the risk of persistence in the environment after completion of the test. Data are gathered on multiple parameters and used by the applicant to evaluate agronomic characteristics and product performance. These and other data are used by APHIS to determine if the new variety poses a plant pest risk.

In section 403 of the Plant Protection Act, “plant pest” is defined as any

living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product: A protozoan, a nonhuman animal, a parasitic plant, a bacterium, a fungus, a virus or viroid, an infectious agent or other pathogen, or any article similar to or allied with any of the foregoing. APHIS has prepared a plant pest risk assessment to determine if event 4114 is unlikely to pose a plant pest risk.

APHIS has also prepared a draft environmental assessment (EA) in which it presents two alternatives based on its analyses of data submitted by Pioneer, a review of other scientific data, and field tests conducted under APHIS oversight. APHIS is considering the following alternatives: (1) Take no action, i.e., APHIS would not change the regulatory status of maize event 4114 and it would continue to be a regulated article, or (2) make a determination of nonregulated status of event 4114.

The draft EA has been prepared to provide the APHIS decisionmaker with a review and analysis of any potential environmental impacts associated with the proposed determination of nonregulated status of event 4114. The draft EA was 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 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Paragraph (d) of § 340.6 provides that APHIS will publish a notice in the **Federal Register** providing 60 days for public comment for petitions for a determination of nonregulated status. In accordance with § 340.6(d) of the regulations, we are publishing this notice to inform the public that APHIS will accept written comments regarding the petition for a determination of nonregulated status from interested or affected persons for a period of 60 days from the date of this notice. We are also soliciting written comments from interested or affected persons on the plant pest risk assessment and the draft EA prepared to examine any potential environmental impacts of the proposed determination of nonregulated status of the subject maize line. The petition, draft EA, and plant pest risk assessment are available for public review, and copies of the petition, draft EA, and plant pest risk assessment are available as indicated under **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT** above.

After the comment period closes, APHIS will review all written comments received during the comment period and any other relevant information. All comments received regarding the petition, draft EA, and plant pest risk assessment will be available for public review. After reviewing and evaluating the comments on the petition, the draft EA, plant pest risk assessment, and other data, APHIS will furnish a response to the petitioner, either approving or denying the petition. APHIS will also publish a notice in the **Federal Register** announcing the regulatory status of event 4114 and the availability of APHIS' written environmental decision and regulatory determination.

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 21 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 22nd day of February 2013.

Michael Gregoire,

Deputy Administrator, Biotechnology Regulatory Services, Animal and Plant Health Inspection Service.

[FR Doc. 2013–04518 Filed 2–26–13; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS–2013–0011]

Codex Alimentarius Commission: Meeting of the Codex Committee on Contaminants in Foods

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, are sponsoring a public meeting on March 12, 2013. The objective of the public meeting is to provide information and receive public comments on agenda items and draft U.S. positions that will be discussed at the 7th Session of the Codex Committee on Contaminants in Foods (CCCF) of the Codex Alimentarius Commission (Codex), which will be held in Moscow, Russian Federation, April 8–12, 2013. The Under Secretary for Food Safety and FDA recognize the importance of providing interested parties the opportunity to obtain background information on the 7th Session of the CCCF and to address items on the agenda.

DATES: The public meeting is scheduled for Tuesday, March 12, 2013, from 10:00 a.m. to 12:00 noon.

ADDRESSES: The public meeting will be held at the Harvey W. Wiley Federal Building, Room 1A–001, FDA, Center for Food Safety and Applied Nutrition (CFSAN), 5100 Paint Branch Parkway, College Park, MD 20740. Documents related to the 7th Session of the CCCF will be accessible via the World Wide Web at <http://www.codexalimentarius.org/meetings-reports/en/>.

Nega Beru, U.S. Delegate to the 7th Session of the CCCF invites interested U.S. parties to submit their comments electronically to the following email address henry.kim@fda.hhs.gov.

Registration: Attendees may register electronically at the same email address provided above by March 8, 2013. The meeting will be held in a Federal building; therefore, early registration is encouraged as it will expedite entry into the building and its parking area. You should also bring photo identification and plan for adequate time to pass through security screening systems. If you require parking, please include the vehicle make and tag number when you register. Attendees that are not able to attend the meeting in-person but wish to participate may do so by phone.

Call in Number: If you wish participate in the public meeting for the 7th Session of CCCF by telephone conference, please use the call in number and participant code listed below:

Call in Number: 1–888–858–2144.

Participant Code: 6208658.

FOR FURTHER INFORMATION CONTACT: Henry Kim, Ph.D., Office of Food Safety, CFSAN/FDA, HFS–317, 5100 Paint Branch Parkway, College Park, MD 20740, Telephone: (240) 402–2023, Fax: (301) 436–2632, email: henry.kim@fda.hhs.gov or Barbara McNiff, U.S. Codex Office, 1400 Independence Avenue, Washington, DC; Telephone (202) 690–4719, email: Barbara.McNiff@fsis.usda.gov.

FOR FURTHER INFORMATION ABOUT THE PUBLIC MEETING CONTACT: Henry Kim, Ph.D., Office of Food Safety, CFSAN/FDA, HFS–317, 5100 Paint Branch Parkway, College Park, MD 20740, Telephone: (240) 402–2023, Fax: (301) 436–2632, email: henry.kim@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

Background

Codex was established in 1963 by two United Nations organizations, the Food and Agriculture Organization (FAO) and the World Health Organization (WHO).

Through adoption of food standards, codes of practice, and other guidelines developed by its committees, and by promoting adoption and implementation by governments, Codex seeks to protect the health of consumers and ensure that fair practices are used in the food trade.

The CCCF is responsible for:

(a) Establishing or endorsing permitted maximum levels, and where necessary revising existing guideline levels for contaminants and naturally occurring toxicants in food and feed;

(b) Preparing priority lists of contaminants and naturally occurring toxicants for risk assessment by the Joint FAO/WHO Expert Committee on Food Additives (JECFA);

(c) Considering and elaborating methods of analysis and sampling for the determination of contaminants and naturally occurring toxicants in food and feed;

(d) Considering and elaborating standards or codes of practice for related subjects; and

(e) Considering other matters assigned to it by Codex in relation to contaminants and naturally occurring toxicants in food and feed.

The Committee is chaired by The Netherlands.

Issues To Be Discussed at the Public Meeting

The following items on the Agenda for the 7th Session of the CCCF will be discussed during the public meeting:

- Matters Referred to the CCCF by the Codex Alimentarius Commission or its subsidiary bodies
- Matters of Interest Arising from FAO and WHO (including JECFA)
- Matters of Interest Arising from other International Organizations
- Proposed Draft Maximum Levels for Deoxynivalenol (DON) in Cereals and Cereal-based Products and Associated Sampling Plans
- Editorial Amendments to the General Standard for Contaminants and Toxins in Foods and Feeds (GSCTFF)
- Proposed Draft Code of Practice for Weed Control to Prevent and Reduce Pyrrolizidine Alkaloid Contamination in Food and Feed
- Proposed Draft Revision of Maximum Levels for Lead in selected commodities in the General Standard for Contaminants and Toxins in Food and Feed
- Proposed Draft Annex for Prevention and Reduction of Aflatoxins and Ochratoxin A Contamination in Sorghum to the Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals

- Proposed Draft Code of Practice for the Prevention and Reduction of Ochratoxin A contamination in Cocoa
 - Proposed Draft Code of Practice to Reduce the Presence of Hydrocyanic Acid in Cassava and Cassava Products
 - Proposed Draft Maximum Levels for Hydrocyanic Acid in Cassava and Cassava Products
 - Proposed Draft revision of the guideline levels for radionuclides in food
 - Discussion paper on the development of a code of practice for the prevention and reduction of arsenic contamination in Rice
 - Discussion paper on control measures for fumonisations in maize and maize products
 - Discussion paper on management practices to reduce exposure of food-producing animals (livestock and bees) to pyrrolizidine alkaloids; and to reduce presence of Pyrrolizidine alkaloids in commodities (raw and processed)
 - Discussion paper on the review of the guideline level for methylmercury in fish and predatory fish
 - Discussion paper on aflatoxins in cereals
 - Priority List of Contaminants and Naturally Occurring Toxicants proposed for evaluation by JECFA
- 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 or request copies of these documents (see **ADDRESSES**).

Public Meeting

At the March 12, 2013 public meeting, draft U.S. positions on the 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 Dr. Henry Kim for the 7th Session of the CCCF (see **ADDRESSES**). Written comments should state that they relate to activities of the 7th Session of the CCCF.

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/2006_Notices_Index/. FSIS also will 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, recalls, 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 and farm groups, consumer interest groups, allied health professionals, and other individuals who have asked to be included. The update is 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 email 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 have the option to password protect their account.

USDA Nondiscrimination Statement

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Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's Target Center at 202-720-2600 (voice and TTY).

To file a written complaint of discrimination, write USDA Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW., Washington, DC 20250-9410 or call 202-720-5964 (voice and TTY). USDA is an equal opportunity provider and employer.

Done at Washington, DC, on February 20, 2013.

Mary Frances Lowe,

U.S. Manager for Codex Alimentarius.

[FR Doc. 2013-04471 Filed 2-26-13; 8:45 am]

BILLING CODE 3410-DM-P

DEPARTMENT OF AGRICULTURE**Forest Service****Bridger-Teton National Forest;
Wyoming; Teton to Snake Fuels
Management Project****AGENCY:** Forest Service, USDA.**ACTION:** Notice of intent to prepare an environmental impact statement.

SUMMARY: The Forest Service is preparing an environmental impact statement (EIS) to document the potential effects of the Teton to Snake Fuels Management Project. The analysis will evaluate and disclose the effects of treating National Forest land to reduce the potential fire behavior within the wildland-urban interface to better protect threatened values, to improve firefighter safety, and to allow fire to play a more natural role in the ecosystem. Treatments include understory thinning and prescribed fire some of which are located within the Palisades Wilderness Study Area (WSA) and Inventoried Roadless Areas (IRAs). Connected actions necessary to implement the proposed treatments include road maintenance, reconstruction, temporary road and landing construction and obliteration, and construction of fire control lines where needed to contain prescribed fire treatments. No road work or commercial vegetation treatments would occur within the WSA. Road maintenance would occur in a small portion of the Phillips Ridge IRA but no reconstruction would occur. The project is located in Teton and Lincoln Counties, Wyoming, west of the Jackson Hole valley and Snake River corridor, and east of the Caribou-Targhee National Forest.

The Teton to Snake Fuels Management Project was previously scoped and analyzed through an environmental assessment (EA) process. The EIS alternatives developed to date are the same as those in the EA. Public comments received on the original Proposed Action, Alternative 2, included support of the project as proposed, but also concerns that the proposed treatments constitute human manipulation in the WSA which could adversely affect wildlife, wilderness character, and eligibility for future designation in the National Wilderness Preservation System. Concern about proposed thinning treatments in the IRAs was also expressed. Requested modifications included reducing the amount of prescribed burning and eliminating all thinning treatments in the WSA and IRAs. Additionally

concern was expressed that the proposed action could have adverse effects to habitat for boreal owls and goshawks, as well as reduce old growth habitat. The Forest Service responded to these concerns by developing a new alternative (Alternative 3—Reduce Potential Impacts to Special Areas and Wildlife Habitat), which reduces activities in the WSA and IRAs and avoids goshawk habitat, whitebark pine, boreal forest, and old growth habitat. Changes include dropping, reconfiguring, and reducing the size of units, and changing treatment prescriptions. In addition to the above resource concerns, units were modified or dropped if they also had potential impacts to visual quality, implementation difficulty, or topography that could slow an advancing wildfire. Also considered was the proximity of hazardous fuels to homes and to other fuel reduction projects that could contribute to reducing fire behavior in the project area. The Jackson Ranger District may be contacted for specific treatment unit revisions made in developing Alternative 3.

DATES: Comments submitted during the scoping period for the environmental assessment (EA) beginning in 2010 will be brought forward into the EIS analysis so there is no need to re-submit them. New comments would be most useful if they present new information or describe specific unwanted effects of implementing Alternative 3. Comments concerning the scope of the analysis must be received by April 1st, 2013. The draft environmental impact statement is expected in July 2013 and the final environmental impact statement is expected September 2013.

ADDRESSES: Send written comments to Dale Deiter, District Ranger, USDA Forest Service, Bridger-Teton National Forest, 25 Rosencrans Lane, P.O. Box 1689, Jackson, WY 83001. Comments may also be sent via email to comments-intermtn-bridger-teton-jackson@fs.fed.us or via facsimile to (307) 739-5450. Verbal comments must be received in person at the Jackson Ranger Station, 25 Rosencrans Lane, Jackson, WY, or by telephone at (307) 739-5431 during normal business hours (8:00 a.m.–4:30 p.m.).

FOR FURTHER INFORMATION CONTACT: Visit our projects Web site at <http://www.fs.usda.gov/goto/btnf/projects> or contact Jason Lawhon, North Zone Fuels Assistant Fire Management Officer, phone (307) 739-5431 or email jlalawhon@fs.fed.us.

Individuals who use 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:**Purpose and Need for Action**

The purpose of this project is to (1) reduce wildland fire threat to residential areas, (2) allow Forest managers to transition from suppressing most fires to a more natural fire regime, and (3) improve firefighter and public safety.

The project area lies within the wildland-urban interface (WUI) as identified by Teton County's Community Wildfire Protection Plan. As per the National Fire Plan, the National Cohesive Wildland Fire Management Strategy, and the Healthy Forests Restoration Act, the Forest Service has made the commitment to protect human communities from wildfires originating on public lands by implementing hazardous fuel reduction projects on Federal lands within the WUI. A fire behavior assessment conducted in 2010 revealed that 42 percent of the area within one-quarter mile of residential areas and the Bonneville Power Administration powerline could produce flame lengths over 4 feet, and 25 percent of this same area could produce crown fires and potential spotting up to a mile ahead of the fire. Wildfires are difficult to suppress under these conditions, particularly with the prevailing winds pushing fire toward the residential areas bordering the project area on the east. Additionally, there is a need to remove some snags in close proximity to homes, where firefighters would be located, to promote safety during firefighting activities.

Wilderness policy dictates that the Forest Service shall "reduce, to an acceptable level, the risks and consequences of wildfire within wilderness or escaping from wilderness." Most of the project area is located within the Palisades Wilderness Study. There is a need to reduce potential fire behavior along the National Forest boundary to reduce the threat of wildfire spreading to residential areas, and to provide the opportunity for wildfire to play a more natural role in the ecosystem. The Wyoming Wilderness Act requires that the Palisades WSA be managed to preserve wilderness character, which includes allowing natural processes of ecological change, such as fire, to operate freely to the extent possible. However, this can only occur if fire managers feel they have a reasonable chance of keeping the fire from escaping off of National Forest System lands.

Proposed Action

Alternative 3 proposes to treat 35 units totalling 14,281 acres through thinning (1,757 acres) and prescribed burning (12,524 acres). Thinning would favor large tree retention using the general priority order of whitebark and limber pine, aspen, Douglas-fir, lodgepole pine, Engelmann spruce, and subalpine fir. Thinning would leave 70 to 200 trees per acre in the non-commercial units, and 60 to 140 trees per acre in the commercial units. Conifers in and around aspen clones would be thinned to release suppressed aspen. Residual branches, logs, and other resulting debris would be hand- or machine-piled and burned in the units or on the landings, or scattered to further reduce fuel concentrations in the project area. Ladder fuels would be pruned in some units. Snags would be removed as needed for firefighter safety in portions of 27 units located in close proximity to residential areas. Road reconstruction would occur on 1.3 miles of National Forest roads and a total of 1 mile of temporary road would be constructed and then obliterated after use. Routine maintenance would occur on 11.7 miles of roads. Approximately 27 landings would be used.

Prescribed fire would reduce fire potential while creating a mosaic of burned and unburned areas. Ground and aerial ignition techniques would adhere to site-specific burn plans that identify parameters for weather, air quality, contingency resources, other resource concerns, equipment needs, and responses for potential escapes. Fire managers would use, and subsequently rehabilitate, up to seven miles of low-impact fire control lines if needed to contain prescribed fire. Natural barriers to fire spread would be used where possible.

Alternative 3 includes extensive project design features and best practices to avoid or reduce impacts to cultural resources, water resources, range, recreation, scenery, sensitive plants, air quality, soils, special areas, and wildlife.

Possible Alternatives

At this time it is planned that the EIS will examine Alternative 1 (No Action), Alternative 2 (Proposed Action originally scoped in December 2010 and modified after further analysis), and Alternative 3—Reduce Potential Impacts to Special Areas and Wildlife Habitat (developed to address public concerns after original scoping period).

Preliminary Issues

Key issues identified during the original public scoping include effects

to the WSA, IRAs, and wildlife habitat. Additional public concerns addressed in the analysis include potential effects related to unauthorized motorized use, standing trees, spread of noxious weeds, road use, smoke, heavy equipment, and biodiversity.

In March 2012, the Palisades WSA map used by the Forest Service for analysis of the Teton to Snake Fuels Management Project was questioned. In July 2012, Jackson District Ranger Dale Deiter put the project on hold until more clarity was obtained regarding the WSA boundary. Since then extensive record searches have occurred uncovering many valuable maps and memos. In addition, two public meetings were held with people interested in the boundary issue. Based on the best information available at this time, the Forest Service is proceeding with the RARE II map from 1977 (Roadless Area and Review Evaluation process). The map package is expected to be assembled in March 2013 and will be submitted to the Regional and Washington Offices of the Forest Service for review and approval. Upon approval, a certified boundary and legal description will be prepared by the Forest Service lands office with final approval from the Regional Forester. A decision on the Teton to Snake Fuels Management Project would only be made after the Palisades WSA boundary is approved.

Responsible Official

Dale Deiter, District Ranger, Jackson Ranger District, Bridger-Teton National Forest

Nature of Decision To Be Made

The District Ranger will decide whether to implement one of the alternatives designed to meet the purpose and need for the project, or take no action.

Permits or Licenses Required

A permit would be required from the State of Wyoming prior to any prescribed burning. The appropriate regulatory agencies will be consulted regarding national or state required permits associated with roads used in project implementation, and required permits obtained prior to implementation.

Scoping Process

This notice of intent initiates the scoping process, which guides the development of the environmental impact statement. As noted above, comments submitted during the scoping period beginning in 2010 will be brought forward in the EIS so there is no

need to re-submit them. New information and concerns describing site-specific unwanted effects related to Alternative 3 would be useful.

It is important that reviewers provide their comments at such times and in such manner that they are useful to the agency's preparation of the environmental impact statement. Therefore, comments should be provided prior to the close of the comment period and should clearly articulate the reviewer's concerns and contentions.

Include the following information with your comments: Your name, address, email (optional), and telephone number; the project name: Teton to Snake Fuels Management Project; and site-specific comments, along with supporting information you believe will help identify issues, develop alternatives, or predict environmental effects of this proposal. The most useful comments provide new information or describe unwanted environmental effects potentially caused by the proposed action. If you reference scientific literature in your comments, you must provide a copy of the entire reference you have cited and include the predicted site-specific effects supported by the literature.

Comments received in response to this solicitation, including names and addresses of those who comment, will be part of the public record for this proposed action. Comments submitted anonymously will be accepted and considered; however anonymous comments will not provide the agency with the ability to provide you with project updates.

Dated: February 21, 2013.

Dale Deiter

Jackson District Ranger.

[FR Doc. 2013-04498 Filed 2-26-13; 8:45 am]

BILLING CODE 3410-11-P

DEPARTMENT OF AGRICULTURE

Forest Service

RIN 0596-AD06

National Forest System Land Management Planning Directives

AGENCY: Forest Service, USDA.

ACTION: Notice of issuance of agency proposed directives; request for comment.

SUMMARY: The Forest Service has issued proposed directives to Forest Service Handbook (FSH 1909.12) and Manual (FSM 1920) establishing procedures and responsibilities for implementing the

National Forest System (NFS) land management planning regulation. Issuance of these proposed directives will provide consistent overall guidance to Forest Service Line Officers and Agency employees in developing, amending, or revising land management plans for units of the NFS. Public comment is invited and will be considered in developing the final directives.

DATES: Comments must be received in writing by April 29, 2013.

ADDRESSES: Submit comments concerning the proposed directives through one of the following methods:

1. *Public participation portal:* <https://cara.ecosystem-management.org/Public/CommentInput?Project=30641>.

Comments may also be provided through the Federal rulemaking portal: <http://www.regulations.gov>.

2. *Facsimile:* Fax to: 503.224.1851.

Please identify your comments by

including "RIN 0596-AD06" or "planning directives" on the cover sheet or the first page.

3. *U.S. Postal Service:* The mailing address is: USDA Forest Service Planning Directives Comments, P.O. Box 40088, Portland, OR 97240.

FOR FURTHER INFORMATION CONTACT: Annie Eberhart Goode, Planning Specialist, Ecosystem Management Coordination Staff, 202-205-1056 or 703-605-4478.

SUPPLEMENTARY INFORMATION: The Forest Service has issued proposed directives to Forest Service Handbook (FSH) 1909.12) and Manual (FSM 1920) establishing procedures and responsibilities for implementing the National Forest System (NFS) land management planning regulation set out at 36 CFR part 219. This promulgated rule was published in the **Federal Register** on April 9, 2012 (77 FR 21161).

Public Participation

Please note that the Forest Service will not be able to receive hand-delivered comments. In addition, please note that all comments, including names and addresses when provided, will be placed in the record and available for public inspection and copying. The Agency cannot confirm receipt of comments. Individuals wishing to inspect comments should call Jody Sutton at 801-517-1020 to schedule an appointment.

These proposed directives are a revision of Forest Service Handbook (FSH) 1919.12 and Forest Service Manual (FSM) 1920. Copies of the proposed directives are available on the World Wide Web/Internet at <http://www.fs.usda.gov/goto/planningrule/directives>. Copies may be obtained by contacting one of the following Regional Offices:

Region	Phone No.	Address
Northern Region—R1	406-329-3511	<i>Street Address:</i> 200 E. Broadway, Missoula, MT 59802. <i>Mailing address:</i> P.O. Box 7669, Missoula, MT 59807-7669.
Rocky Mountain Region—R2	303-275-5350	<i>Street Address:</i> 740 Simms St., Golden, CO 80401. <i>Mailing address:</i> P.O. Box 25127, Lakewood, CO 80225-0127.
Southwestern Region—R3	505-842-3292	333 Broadway SE., Albuquerque, NM 87102.
Intermountain Region—R4	801-625-5605	324 25th Street, Ogden, UT 84401.
Pacific Southwest Region—R5	707-562-8737	1323 Club Drive, Vallejo, CA 94592.
Pacific Northwest Region—R6	503-808-2468	<i>Street Address:</i> 333 SW. First Avenue, Portland, Oregon 97204. <i>Mailing address:</i> P.O. Box 3623, Portland, OR 97208-3623.
Southern Region—R8	404-347-4095	1720 Peachtree Rd. NW., Atlanta, GA 30309.
Eastern Region—R9	414-297-3600	626 East Wisconsin Ave. Milwaukee, WI 53202.
Alaska Region—R10	907-586-8806	P.O. Box 21628, Juneau, AK 99802-1628.

Readers are encouraged to obtain a copy of the proposed directives to formulate their comments and provide input for the development of the final planning directives.

Background

On April 9, 2012, the U. S. Department of Agriculture (Department or USDA) adopted final planning regulations for the NFS at 36 CFR part 219 (77 FR 21161). These regulations, known collectively as the 2012 Planning Rule, provide broad programmatic direction in developing and carrying out land management planning. The rule explicitly directs the Chief of the Forest Service to establish planning procedures in the Forest Service Directives System (36 CFR 219.1(c)).

The Forest Service is implementing the 2012 Planning Rule. Those responsible officials that are implementing the 2012 Planning Rule must follow the regulations at 36 CFR 219 and applicable existing Forest Service Directives until they are superseded.

The Forest Service Directives System consist of the Forest Service Manual (FSM) and the Forest Service Handbook (FSH), which contain the Agency's policies, practices, and procedures, and serves as the primary basis for the internal management and control of programs and administrative direction to Forest Service employees. The directives for all Agency programs are set out on the World Wide Web/Internet at <http://www.fs.fed.us/im/directives>.

Specifically, the FSM contains legal authorities, objectives, policies, responsibilities, instructions, and guidance needed on a continuing basis by Forest Service Line Officers and primary staff to plan and execute programs and activities. The FSH is the principal source of specialized guidance and instruction for carrying out the policies, objectives, and responsibilities contained in the FSM.

For these proposed directives, both the FSM and the FSH provide policy direction, objectives, instructions, and guidance for Forest Service Line Officers and primary staff to plan and

execute the process of developing, revising, amending, and making administrative changes to plans.

Content of Proposed Directives

The following is an overview of the contents of the proposed directives.

FSM 1920—Land Management Planning Manual

This Forest Service Manual describes a process for developing, revising, amending, and making administrative changes to land management plans for the National Forest System (NFS). It includes authorities and responsibilities. It should be used in conjunction with the FSH.

FSH 1909.12—Land Management Planning Handbook

This FSH provides policy direction, objectives, instructions and guidance for the process of developing, revising, amending, and making administrative changes to plans for the NFS. It includes authorities and responsibilities.

Zero Code

The section known as the zero code contains authorities, responsibilities, and select definitions applicable to subsequent chapters.

Chapter 10—The Assessment

This chapter describes the procedures for writing an assessment for development, amendment, or revision of land management plans.

Chapter 20—Land Management Plan

This chapter describes the land management plan under the 2012 Planning Rule and explains the procedures for developing, amending, and revising land management plans.

Chapter 30—Monitoring

This chapter describes the plan monitoring program, broader-scale monitoring strategy, and biennial evaluation of the monitoring information for land management planning.

Chapter 40—Key Processes Supporting Land Management Planning

This chapter describes the adaptive management framework, use of best available scientific information, public participation and the role of collaboration, and tribal consultation as it relates to land management plans.

Chapter 50—Objection Process

This chapter describes the process for the public to seek administrative review of plans, plan revisions, and plan amendments before their approval. This process is referred to as the objection process.

Chapter 60—Forest Vegetation Resource Planning

This chapter provides procedures for developing plan components and other plan content to meet National Forest Management Act (NFMA) and planning rule requirements for identifying lands that are not suitable for timber production, plan components for timber harvest for timber production or other purposes, limitations on timber harvest, and display of the planned timber sale program.

Chapter 70—Wilderness Evaluation

This chapter describes the process for identifying and evaluating lands that may be suitable for inclusion in the National Wilderness Preservation System and determining whether to recommend any such lands for wilderness designation.

Chapter 80—Wild and Scenic River Evaluation

This chapter describes the process for identifying and evaluating potential additions to the National Wild and Scenic Rivers System. This chapter also addresses interim management of river segments determined to be eligible and suitable, documentation of study results, as well as the process for notifying Congress of agency wild and scenic river recommendations.

Chapter 90—References

This chapter contains exhibits or references not easily found electronically.

Regulatory Certifications*Regulatory Impact*

This notice has been reviewed under USDA procedures and Executive Order (E.O.) 12866, Regulatory Planning and Review. The Office of Management and Budget (OMB) has reviewed this notice and has determined that it is a significant action. The proposed directives would not have an annual effect of \$100 million or more on the economy nor adversely affect productivity, competition, jobs, the environment, public health or safety, nor State or local governments. The proposed directives would not interfere with an action taken or planned by another agency nor raise new legal or policy issues. Finally, the proposed directives would not alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients of such programs.

Moreover, the proposed directives have been considered in light of E.O. 13272 regarding proper consideration of small entities and the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), which amended the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). No direct or indirect financial impact on small businesses or other entities has been identified. Therefore, it is hereby certified that these proposed directives will not have a significant economic impact on a substantial number of small entities as defined by the act.

Environmental Impact

These proposed directives provide the detailed direction to agency employees necessary to carry out the provisions of the final 2012 Planning Rule adopted at 36 CFR part 219 governing land management planning. Forest Service Handbook 1909.15, section 31.12 (57 FR 43208; September 18, 1992) excludes from documentation in an

environmental assessment or impact statement “rules, regulations, or policies to establish Service-wide administrative procedures, program processes, or instructions.” The Agency’s conclusion is that these proposed directives fall within this category of actions and that no extraordinary circumstances exist as currently defined that require preparation of an environmental assessment or an environmental impact statement.

No Takings Implications

These proposed directives have been analyzed in accordance with the principles and criteria contained in E.O. 12360, Governmental Actions and Interference with Constitutionally Protected Property Rights, and it has been determined that they would not pose the risk of a taking of private property as they are limited to the establishment of administrative procedures.

Energy Effects

These proposed directives have been analyzed under E.O. 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. It has been determined that they do not constitute a significant energy action as defined in the Executive Order.

Civil Justice Reform

These proposed directives have been reviewed under E.O. 12988, Civil Justice Reform. These proposed directives will direct the work of Forest Service employees and are not intended to preempt any State and local laws and regulations that might be in conflict or that would impede full implementation of these directives. The directives would not retroactively affect existing permits, contracts, or other instruments authorizing the occupancy and use of NFS lands and would not require the institution of administrative proceedings before parties may file suit in court challenging their provisions

Unfunded Mandates

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538), which the President signed into law on March 22, 1995, the effects of these proposed directives on State, local, and Tribal governments, and on the private sector have been assessed and do not compel the expenditure of \$100 million or more by any State, local, or Tribal government, or anyone in the private sector. Therefore, a statement under section 202 of the act is not required.

Federalism

The Agency has considered these proposed directives under the requirements of E.O. 13132, Federalism. The Agency has made a preliminary assessment that they conform with the federalism principles set out in this Executive Order; would not impose any significant compliance costs on the States; and would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Moreover, these proposed directives address the land management planning process on National Forests, Grasslands or other units of the NFS, which do not directly affect the States. Based on comments received on these proposed directives, the Agency will consider if any additional consultation will be needed with State and local governments prior to adopting final directives.

Consultation and Coordination With Indian Tribal Governments

The Forest Service will conduct government-to-government consultation on the planning directives. The Forest Service considers tribal consultation as an ongoing, iterative process that encompasses development of the proposed directives through the issuance of final directives. During development of the 2012 Planning Rule, between September 23, 2010, and publication of the final rule on April 9, 2012, the Agency held 16 consultation meetings across the Country. In addition, Forest Service leaders held one-on-one meetings, as requested, with tribal leaders throughout the time period of development of the rule.

The Agency will contact all federally recognized Tribes and Alaska Native Corporations by mail to formally initiate consultation on the proposed directives and seek comments within 120 days.

Controlling Paperwork Burdens on the Public

These proposed directives do not contain any record keeping or reporting requirements or other information collection requirements as defined in 5 CFR part 1320 and, therefore, impose no paperwork burden on the public. Accordingly, the review provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) and implementing regulations at 5 CFR part 1320 do not apply.

Chapter 50 of these proposed directives contains information collection requirements as defined in 5

CFR part 1320. The information collection requirements have been approved by the Office of Management and Budget and assigned control number 0596-0158.

Conclusion

The Forest Service has developed these planning directives to set forth the legal authorities, objectives, policy, responsibilities, direction, and overall guidance for Forest Service Line Officers, agency employees, and others to use the 2012 Planning Rule. The proposed directives provide consistent interpretation of the 2012 Planning Rule for Line and Staff Officers, and interdisciplinary teams.

The 2012 Planning Rule and the proposed FSM and FSH sections together provide requirements and guidance for the Agency to adaptively manage the NFS to maintain and restore NFS land and water ecosystems and protect species while providing for ecosystem services and multiple uses. The proposed directives are intended to guide the development, revision, and amendment of land management plans to provide for the sustainability of ecosystems and resources; meet the need for forest restoration and conservation, watershed protection, and species diversity and conservation; and assist the Agency in providing a sustainable flow of benefits, services, and uses of NFS lands that provide jobs and contribute to the economic and social sustainability of communities.

By seeking public notice and comment on these proposed directives, the Agency is continuing its commitment to improve public involvement and transparency in decisionmaking associated with developing, amending, or revising a land management plan.

When the Agency offers the opportunity for public notice and comment on a proposed revision of a Forest Service Manual or Handbook revision, the Agency publishes a notice of a proposed revision with a minimum 60-day comment period. The Agency then considers the comments, makes any changes, drafts, and publishes a final **Federal Register** notice explaining the final directive and the rationale for any changes made from the propose. At a minimum, this process takes 6 months but normally takes 9–12 months.

The Forest Service is committed to providing adequate opportunities for the public to comment on administrative directives that are of substantial public interest or controversy, as provided in the regulations at 36 CFR part 216. All comments on these proposed directives will be considered in the development

of the final directives. The full text of these proposed directives are available on the World Wide Web/Internet at <http://www.fs.usda.gov/goto/planningrule/directives>. Single paper copies are available upon request from the address and phone numbers listed earlier in this notice as well as from the nearest Regional Office, the locations of which are also available on the Washington Office headquarters homepage on the World Wide Web/Internet: www.fs.fed.us/.

Dated: February 21, 2013.

Thomas L. Tidwell,
Chief.

[FR Doc. 2013-04470 Filed 2-26-13; 8:45 am]

BILLING CODE 3410-11-P

DEPARTMENT OF AGRICULTURE

National Institute of Food and Agriculture

Notice of Intent To Request an Extension of a Currently Approved Information Collection

AGENCY: National Institute of Food and Agriculture, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 and Office of Management and Budget (OMB) regulations (5 CFR part 1320) which implement the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), this notice announces the intention of the National Institute of Food and Agriculture (NIFA) to request an extension for a currently approved information collection (OMB No. 0524-0026) for Form NIFA-666, "Organizational Information."

DATES: Submit comments on or before April 29, 2013.

ADDRESSES: You may submit comments, identified by NIFA-2013-0008, by any of the following methods:

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

Email: rmartin@NIFA.usda.gov. Include NIFA-2013-0008 in the subject line of the message.

Fax: 202-720-0857.

Mail: Written comments concerning this notice and requests for copies of the information collection may be submitted to Robert Martin, Records Officer, Information Policy, Planning and Training; Mail: NIFA/USDA; Mail Stop 2216; 1400 Independence Avenue SW.; Washington, DC 20250-2299; Hand Delivery/Courier: 800 9th Street

SW., Waterfront Centre, Room 4206, Washington, DC 20024.

Instructions: All submissions received must include the agency name and NIFA-2013-0008. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

FOR FURTHER INFORMATION CONTACT:

Robert Martin, Records Officer, Information Policy, Planning and Training; Office of Information Technology; NIFA; USDA; Email: rmartin@nifa.NIFA.usda.gov.

SUPPLEMENTARY INFORMATION:

Title: Organizational Information.

OMB Number: 0524-0026.

Expiration Date of Current Approval: April 30, 2013.

Type of Request: Intent to extend a currently approved information collection for three years.

Abstract: NIFA has primary responsibility for providing linkages between the Federal and State components of a broad-based, national agricultural research, extension, and education system. Focused on national issues, its purpose is to represent the Secretary of Agriculture and carry out the intent of Congress by administering formula and grant funds appropriated for agricultural research, extension, and education. Before awards can be made, certain information is required from applicants to effectively assess the potential recipient's capacity to manage Federal funds.

Need for the Information: Form NIFA-666 "Organizational Information": Enables NIFA to determine that applicants recommended for awards will be responsible recipients of Federal funds. The information pertains to organizational management and financial matters of the potential grantee. This form and the documents which the applicant attaches to it provide NIFA with information such as the legal name of grantee, certification that the organization has the legal authority to accept Federal funding, identification and signatures of the key officials of the organization, the organization's practices in regard to compensation rates and benefits of employees, insurance for equipment, subcontracting with other organizations, etc., as well as the financial condition of the organization and certification that the organization is not delinquent on Federal taxes. All of this information is considered by NIFA prior to award to determine whether the grantee is both managerially and fiscally responsible. This information is submitted to NIFA on a one-time basis and updated accordingly. If sufficient changes occur

within the organization, the grantee submits revised information.

Estimate of the Burden: NIFA estimates the number of responses for the Form NIFA-666 will be 150 with an estimated response time of 6.3 hours per form, representing a total annual burden of 945 hours for this form. These estimates are based on a survey of grantees that were approved for grant awards.

They were asked to give an estimate of the time it took them to complete each form. This estimate was to include such things as: (1) Reviewing the instructions; (2) searching existing data sources; (3) gathering and maintaining the data needed; and (4) actual completion of the forms. The average time it took each respondent was calculated from their responses.

Comments: 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 a practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection 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.

Done at Washington, DC, this 22nd day of February 2013.

Catherine E. Woteki,

Under Secretary, REE, Chief Scientist, USDA.

[FR Doc. 2013-04670 Filed 2-26-13; 8:45 am]

BILLING CODE 3410-22-P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Nevada Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA) that a planning meeting the Nevada Advisory Committee (Committee) to the Commission will be held on March 21, 2013, at the Department of Employment, Training and Rehabilitation, 2800 East St. Louis Ave., Las Vegas, Nevada 89104. The meeting is scheduled to begin at 3:00 p.m. and adjourn at approximately 4:30

p.m. The purpose of the meeting is to discuss the Committee's report on peer-to-peer bullying in public schools and discuss other Committee projects.

Members of the public are entitled to submit written comments. The comments must be received in the Western Regional Office of the Commission by April 21, 2013. The address is Western Regional Office, U.S. Commission on Civil Rights, 300 N. Los Angeles Street, Suite 2010, Los Angeles, CA 90012. Persons wishing to email their comments, or to present their comments verbally at the meeting, or who desire additional information should contact Angelica Trevino, Office Manager, Western Regional Office, at (213) 894-3437, (or for hearing impaired TDD 913-551-1414), or by email to atrevino@usccr.gov. Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Regional Office at least ten (10) working days before the scheduled date of the meeting.

Records generated from this meeting may be inspected and reproduced at the Western Regional Office, as they become available, both before and after the meeting. Persons interested in the work of this advisory committee are advised to go to the Commission's Web site, www.usccr.gov, or to contact the Western Regional Office at the above email or street address. The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission and FACA.

Dated in Washington, DC, February 21, 2013.

David Mussatt,

Acting Chief, Regional Programs Coordination Unit.

[FR Doc. 2013-04516 Filed 2-26-13; 8:45 am]

BILLING CODE 6335-01-P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B-16-2013]

Foreign-Trade Zone 124—Gramercy, LA; Application for Reorganization (Expansion of Service Area) Under Alternative Site Framework

An application has been submitted to the Foreign-Trade Zones (FTZ) Board (the Board) by the Port of South Louisiana, grantee of Foreign-Trade Zone 124, requesting authority to reorganize the zone to expand its service area under the alternative site framework (ASF) adopted by the Board (15 CFR 400.2(c)). The ASF is an option

for grantees for the establishment or reorganization of zones and can permit significantly greater flexibility in the designation of new subzones or “usage-driven” FTZ sites for operators/users located within a grantee’s “service area” in the context of the Board’s standard 2,000-acre activation limit for a zone. The application was submitted pursuant to the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u) and the regulations of the Board (15 CFR part 400). It was formally docketed on February 21, 2013.

FTZ 124 was approved by the Board on December 20, 1985 (Board Order 319, 50 FR 53351, December 31, 1985), and was reorganized under the ASF on January 31, 2012 (Board Order 1814, 77 FR 6059, February 7, 2012). The zone currently has a service area that includes St. Charles, St. John the Baptist, St. James, La Fourche and St. Mary Parishes, Louisiana.

The applicant is now requesting authority to expand the service area of the zone to include Tangipahoa Parish, as described in the application. If approved, the grantee would be able to serve sites throughout the expanded service area based on companies’ needs for FTZ designation. The proposed expanded service area is adjacent to the Gramercy Customs and Border Protection port of entry.

In accordance with the Board’s regulations, Camille Evans of the FTZ Staff is designated examiner to evaluate and analyze the facts and information presented in the application and case record and to report findings and recommendations to the Board.

Public comment is invited from interested parties. Submissions shall be addressed to the Board’s Executive Secretary at the address below. The closing period for their receipt is April 29, 2013. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to May 13, 2013.

A copy of the application will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230–0002, and in the “Reading Room” section of the Board’s Web site, which is accessible via www.trade.gov/ftz. For further information, contact Camille Evans at Camille.Evans@trade.gov or (202) 482–2350.

Dated: February 21, 2013.

Andrew McGilvray,
Executive Secretary.

[FR Doc. 2013–04560 Filed 2–26–13; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–806]

Silicon Metal From the People’s Republic of China: Preliminary Results of Antidumping Duty Administrative Review; 2011–2012

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* February 27, 2013.

SUMMARY: The Department of Commerce (“Department”) is conducting an administrative review of the antidumping duty order on silicon metal from the People’s Republic of China (“PRC”) for the period of review (“POR”) June 1, 2011, through May 31, 2012. This review covers one PRC company, Shanghai Jinneng International Trade Co., Ltd. (“Shanghai Jinneng”).¹ The Department preliminarily finds that Shanghai Jinneng did not have reviewable transactions during the POR. We intend to issue the final results no later than 120 days from the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the “Act”).

FOR FURTHER INFORMATION CONTACT: Lori Apodaca, AD/CVD Operations, Office 4, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–4551.

SUPPLEMENTARY INFORMATION:

Background

On June 1, 2012, the Department published a notice of an opportunity to request an administrative review of the antidumping duty order on silicon metal from the PRC.² On June 29, 2012, Globe Metallurgical Inc. (“Petitioner”) requested a review of Shanghai Jinneng.³ On July 31, 2012, the

¹ See *Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation in Part*, 77 FR 45338 (July 31, 2012) (“*Initiation Notice*”).

² See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request *Administrative Review*, 77 FR 32528 (June 1, 2012).

³ See Letter from Petitioner to the Department of Commerce, Re: Request for Administrative Review, dated June 29, 2012.

Department initiated the review of Shanghai Jinneng.⁴ Shanghai Jinneng certified that the company had no shipments of subject merchandise to the United States during the POR on August 9, 2012.⁵ On October 18, 2012, the Department notified U.S. Customs and Border Protection (“CBP”) of the company claiming no shipments and requested that if CBP has information contradicting the claim, it provide such information.⁶ On November 9, 2012, the Department notified parties that the results of the CBP query indicated that Shanghai Jinneng had not shipped subject merchandise during the POR.⁷

As explained in the memorandum from the Assistant Secretary for Import Administration, the Department has exercised its discretion to toll deadlines for the duration of the closure of the Federal Government from October 29 through October 30, 2012.⁸ Thus, all deadlines in this segment of the proceeding have been extended by two days. The revised deadline for the preliminary results of this review is now March 4, 2013.

Scope of the Order

Imports covered by the order are shipments of silicon metal containing at least 96.00 but less than 99.99 percent of silicon by weight. Also covered by the order is silicon metal from the PRC containing between 89.00 and 96.00 percent silicon by weight but which contain a higher aluminum content than the silicon metal containing at least 96.00 percent but less than 99.99 percent silicon by weight. Silicon metal is currently provided for under subheadings 2804.69.10 and 2804.69.50 of the Harmonized Tariff Schedule of the United States (“HTSUS”) as a chemical product, but is commonly referred to as a metal. Semiconductor-grade silicon (silicon metal containing by weight not less than 99.99 percent of silicon and provided for in subheading 2804.61.00 of the HTSUS) is not subject to the order. Although the HTSUS

⁴ See *Initiation Notice*.

⁵ See Letter from Shanghai Jinneng to the Department of Commerce, Re: No Sales Certification, dated August 9, 2012.

⁶ See Instructions from the Department to CBP, Re: No Shipments Inquiry for Silicon Metal from the People’s Republic of China Exported by Shanghai Jinneng International Trade Co., Ltd. (A–570–806), Message number 2292301, dated October 18, 2012 (“*CBP Inquiry*”).

⁷ See Memorandum to the File, Re: Antidumping Duty Administrative Review of Silicon Metal from the People’s Republic of China, dated November 9, 2012 (“*CBP Query*”).

⁸ See Memorandum to the Record from Paul Piquado, AS for Import Administration, regarding “Tolling of Administrative Deadlines As a Result of the Government Closure During Hurricane,” dated October 31, 2012.

subheadings are provided for convenience and for customs purposes, the written description of the merchandise is dispositive.

Preliminary Determination of No Shipments

As noted in the "Background" section above, Shanghai Jinneng has submitted a timely-filed certification indicating that it had no shipments of subject merchandise to the United States during the POR. In addition, in response to our no-shipments inquiry, CBP did not provide any evidence contradicting Shanghai Jinneng's claim of no shipments. Further, on November 9, 2012, the Department released to interested parties the results of the CBP query that it used for corroboration of Shanghai Jinneng's no-shipments claim.⁹ The Department received no comments from any interested parties concerning the results of the CBP query.

Based on the certification of Shanghai Jinneng and our analysis of CBP information, we preliminarily determine that Shanghai Jinneng did not have any reviewable transactions during the POR. In addition, consistent with the Department's recently announced refinement to its assessment practice in non-market economy ("NME") cases, the Department finds that it is appropriate not to rescind the review in these circumstances but rather, to complete the review with respect to Shanghai Jinneng and issue appropriate instructions to CBP based on the final results of the review.¹⁰

Comments

Interested parties are invited to comment on the preliminary results and may submit case briefs and/or written comments within 30 days of the date of publication of this notice, pursuant to 19 CFR 351.309(c)(1)(ii). Rebuttal briefs, limited to issues raised in the case briefs, will be due five days after the due date for case briefs, pursuant to 19 CFR 351.309(d). Written argument should be filed electronically using Import Administration's Antidumping and Countervailing Duty Centralized Electronic Service System ("IA ACCESS").¹¹ Parties who submit case or rebuttal briefs in this proceeding are requested to submit with each argument a statement of the issue, a summary of the argument not to exceed five pages, and a table of statutes, regulations, and

cases cited, in accordance with 19 CFR 351.309(c)(2).

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Import Administration, U.S. Department of Commerce. The request must be filed electronically using IA ACCESS. An electronically filed document must be received successfully in its entirety by the Department's electronic records system, IA ACCESS, by 5:00 p.m. Eastern Standard Time, within 30 days after the date of publication of this notice.¹² Requests should contain: (1) The party's name, address and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs.

The Department intends to issue the final results of this administrative review, including the results of its analysis of the issues raised in any written briefs, not later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act.

Assessment Rates

Upon issuance of the final results, the Department will determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review. The Department intends to issue assessment instructions to CBP within 15 days after the publication date of the final results of this review. Pursuant to the recently announced refinement to its assessment practice in NME cases, if the Department continues to determine that an exporter under review had no shipments of the subject merchandise, any suspended entries that entered under that exporter's case number (*i.e.*, at that exporter's rate) will be liquidated at the PRC-wide rate. For a full discussion of this practice, *see Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties*, 76 FR 65694 (October 24, 2011).

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) For Shanghai Jinneng, which claimed no shipments,

the cash deposit rate will remain unchanged from the rate assigned to the company in the most recently completed review of the company; (2) for previously investigated or reviewed PRC and non-PRC exporters who are not under review in this segment of the proceeding but who have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recent period; (3) for all PRC exporters of subject merchandise that have not been found to be entitled to a separate rate the cash deposit rate will be the PRC-wide rate of 139.49 percent;¹³ and (4) for all non-PRC exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporter(s) that supplied that non-PRC exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

These preliminary results are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(4).

Dated: February 20, 2013.

Paul Piquado,

Assistant Secretary for Import Administration.

[FR Doc. 2013-04512 Filed 2-26-13; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-890]

Wooden Bedroom Furniture From the People's Republic of China: Initiation of Antidumping Duty New Shipper Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

¹³ For an explanation of the calculation of the PRC-wide rate, *see Final Determination of Sales at Less Than Fair Value: Silicon Metal from the People's Republic of China*, 56 FR 18570, 18571-2 (April 23, 1991).

⁹ See CBP Query.

¹⁰ See *Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties*, 76 FR 65694 (Oct. 24, 2011) and the "Assessment Rates" section, below.

¹¹ See, generally, 19 CFR 351.303.

¹² See 19 CFR 351.310(c).

DATES: *Effective Date:* February 27, 2013.

SUMMARY: The Department of Commerce (“Department”) has determined that a request for a new shipper review of the antidumping duty order on wooden bedroom furniture from the People’s Republic of China (“PRC”) meets the statutory and regulatory requirements for initiation. The period of review (“POR”) for the new shipper review is January 1, 2012 through December 31, 2012.

FOR FURTHER INFORMATION CONTACT: Lori Apodaca, AD/CVD Operations, Office 4, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–4551.

SUPPLEMENTARY INFORMATION:

Background

The antidumping duty order on wooden bedroom furniture from the PRC was published on January 4, 2005. *See Notice of Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Wooden Bedroom Furniture From the People’s Republic of China*, 70 FR 329 (January 4, 2005). On January 23, 2013, pursuant to section 751(a)(2)(B)(i) of the Tariff Act of 1930, as amended (the “Act”), and 19 CFR 351.214(c), the Department received a timely request for a new shipper review from Dongguan Chengcheng Furniture Co., Ltd. (“Dongguan Chengcheng”). On February 6, 2013, the Department placed entry data received from U.S. Customs and Border Protection (“CBP”) on the record of this proceeding and provided interested parties with an opportunity to comment on the data. No parties, other than Dongguan Chengcheng, commented on the CBP data. On February 6, 2013, the Department issued a supplemental questionnaire to Dongguan Chengcheng. On February 12, 2013, Dongguan Chengcheng submitted its supplemental questionnaire response. In its supplemental questionnaire response, Dongguan Chengcheng provided comments regarding the entry data received from CBP. We have also requested entry documents from CBP in order to confirm certain information reported by Dongguan Chengcheng. The continuation of the new shipper review will be contingent upon confirmation of this information. *See*, Memorandum to the File through Abdelali Elouaradia, Director, AD/CVD Operations, Office 4: Initiation of Antidumping New Shipper Review of Wooden Bedroom Furniture from the People’s Republic of China:

Dongguan Chengcheng Furniture Co. Ltd.: (“Initiation Checklist”), dated concurrently with this notice at item 18.

Dongguan Chengcheng stated that it is both the exporter and producer of the subject merchandise upon which its request for a new shipper review is based. Pursuant to section 751(a)(2)(B)(i)(I) of the Act and 19 CFR 351.214(b)(2)(i), Dongguan Chengcheng certified that it did not export wooden bedroom furniture to the United States during the period of investigation (“POI”). In addition, pursuant to section 751(a)(2)(B)(i)(II) of the Act and 19 CFR 351.214(b)(2)(iii)(A), Dongguan Chengcheng certified that, since the initiation of the investigation, it has never been affiliated with any PRC exporter or producer who exported wooden bedroom furniture to the United States during the POI, including those not individually examined during the investigation. As required by 19 CFR 351.214(b)(2)(iii)(B), Dongguan Chengcheng also certified that its export activities were not controlled by the central government of the PRC. *See generally*, Initiation Checklist.

In addition to the certifications described above, pursuant to 19 CFR 351.214(b)(2)(iv), Dongguan Chengcheng submitted documentation establishing the following: (1) the date on which it first shipped wooden bedroom furniture for export to the United States and the date on which the wooden bedroom furniture was first entered, or withdrawn from warehouse, for consumption; (2) the volume of its first shipment; and (3) the date of its first sale to an unaffiliated customer in the United States. *See generally*, Initiation Checklist.

The Department conducted a CBP database query and confirmed by examining the results of the CBP data query that Dongguan Chengcheng’s subject merchandise entered the United States during the POR specified by the Department’s regulations. *See* 19 CFR 351.214(g)(1)(i)(A). Pursuant to 19 CFR 351.221(c)(1)(i), the Department will publish the notice of initiation of a new shipper review no later than the last day of the month following the anniversary or semiannual anniversary month of the order.

Initiation of New Shipper Review

Pursuant to section 751(a)(2)(B) of the Act, 19 CFR 351.214(b), and based on the information on the record, the Department finds that Dongguan Chengcheng meets the threshold requirements for initiation of a new shipper review of its shipment(s) of wooden bedroom furniture from the PRC. *See generally*, Initiation Checklist.

The POR for the new shipper review of Dongguan Chengcheng is January 1, 2012, through December 31, 2012. *See* 19 CFR 351.214(g)(1)(i)(A). The Department intends to issue the preliminary results of this review no later than 180 days from the date of initiation, and the final results of this review no later than 270 days from the date of initiation. *See* section 751(a)(2)(B)(iv) of the Act.

It is the Department’s usual practice, in cases involving non-market economies, to require that a company seeking to establish eligibility for an antidumping duty rate separate from the country-wide rate provide evidence of *de jure* and *de facto* absence of government control over the company’s export activities. Accordingly, we will issue a questionnaire to Dongguan Chengcheng which will include a separate rate section. The review of the exporter will proceed if the response provides sufficient indication that the exporter is not subject to either *de jure* or *de facto* government control with respect to its exports of wooden bedroom furniture.

We will instruct CBP to allow, at the option of the importer, the posting, until the completion of the review, of a bond or security in lieu of a cash deposit for certain entries of the subject merchandise from Dongguan Chengcheng in accordance with section 751(a)(2)(B)(iii) of the Act and 19 CFR 351.214(e). Because Dongguan Chengcheng stated that it both produces and exports the subject merchandise, the sales of which form the basis for its new shipper review request, we will instruct CBP to permit the use of a bond only for entries of subject merchandise which the respondent both produced and exported.

Interested parties requiring access to proprietary information in this new shipper review should submit applications for disclosure under administrative protective order in accordance with 19 CFR 351.305 and 351.306.

This initiation and notice are published in accordance with section 751(a)(2)(B) of the Act and 19 CFR 351.214 and 351.221(c)(1)(i).

Dated: February 21, 2013.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2013–04575 Filed 2–26–13; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE**International Trade Administration**

[A-570-893]

Certain Frozen Warmwater Shrimp From the People's Republic of China: Notice of Preliminary Reconsideration of Changed Circumstances Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce ("Department") has received information sufficient to warrant reconsideration of a completed changed circumstances review ("CCR") of the antidumping duty order on certain frozen warmwater shrimp from the People's Republic of China ("PRC") originally conducted in 2007.¹ Based on evidence uncovered in the sixth administrative review ("AR6") of this proceeding,² we find the information submitted by Hilltop International ("Hilltop")³ in this CCR contains material misrepresentations and, consequently, is unusable for any purposes. Accordingly, our original determination that Hilltop is the successor-in-interest to Yelin Enterprise Co. Hong Kong ("Yelin") is preliminarily reversed such that Hilltop should properly be considered part of the PRC-wide entity, absent a determination of its own rate, separate from the PRC-wide entity.⁴

¹ See *Certain Frozen Warmwater Shrimp from the People's Republic of China: Notice of Final Results of Changed Circumstances Review*, 72 FR 33447 (June 18, 2007).

² See *Administrative Review of Certain Frozen Warmwater Shrimp From the People's Republic of China: Final Results, Partial Rescission of Sixth Antidumping Duty Administrative Review and Determination Not To Revoke in Part*, 77 FR 53856, and accompanying Issues and Decision Memorandum.

³ Hilltop is affiliated with Yangjiang City Yelin Haitat Quick Frozen Seafood Co., Ltd., Fuqing Yihua Aquatic Food Co., Ltd., Yelin Enterprise Co., Ltd., Ocean Beauty Corporation, Ever Hope International Co., Ltd., Ocean Duke Corporation and Kingston Foods Corporation. Further, the Department has found Hilltop, Yelin Enterprise Co., Ltd., Ocean Beauty Corporation, and Ever Hope International Co., Ltd. to be a single entity. See *Certain Frozen Warmwater Shrimp From the People's Republic of China: Preliminary Results, Partial Rescission, Extension of Time Limits for the Final Results, and Intent To Revoke, in Part, of the Sixth Antidumping Duty Administrative Review*, 77 FR 12801, 12804 (March 2, 2012); unchanged in *Administrative Review of Certain Frozen Warmwater Shrimp From the People's Republic of China: Final Results and Partial Rescission of Antidumping Duty Administrative Review*, 76 FR 51940 (August 19, 2011).

⁴ See, e.g., *Certain New Pneumatic Off-the-Road Tires From the People's Republic of China: Final Results of Changed Circumstances Review*, 75 FR 46914, 46916 (August 4, 2010); *Frozen Warmwater Shrimp from Vietnam: Notice of Final Results of*

DATES: Effective February 27, 2013.

FOR FURTHER INFORMATION CONTACT: Kabir Archuletta, AD/CVD Operations, Office 9, Import Administration, International Trade Administration, Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482-2593.

SUPPLEMENTARY INFORMATION:**Background**

Yelin was formally dissolved on December 12, 2006.⁵ On March 16, 2007, Hilltop filed a submission requesting that the Department conduct a CCR of the antidumping duty order on certain frozen warmwater shrimp from the PRC to confirm that Hilltop is the successor-in-interest to Yelin.⁶ On May 2, 2007, the Department published a combined initiation and preliminary results finding that Hilltop was the successor-in-interest to Yelin.⁷ On June 18, 2007, this finding was confirmed in the final results of this CCR.⁸

On December 5, 2012, we determined that we would reconsider this CCR determination in light of certain evidence discovered in AR6.⁹ On December 13, 2012, the Department placed public documents submitted in AR6 on the record of this proceeding.¹⁰ On December 17, 2012, the Department placed documents containing business proprietary information obtained during the first administrative review and AR6 on the record of this proceeding.¹¹

On December 31, 2012, the Department received comments from Petitioner on the documents placed on the record of this CCR.¹² On January 7,

Antidumping Duty Changed Circumstances Reviews, 74 FR 42050, 42051 (August 20, 2009).

⁵ See Letter from Hilltop to the Secretary of Commerce "Request for Expedited Changed Circumstances Determination" (March 16, 2007).

⁶ See *id.*

⁷ *Certain Frozen Warmwater Shrimp from the People's Republic of China: Notice of Initiation and Preliminary Results of Changed Circumstances Review*, 72 FR 24273 (May 2, 2007).

⁸ See *Certain Frozen Warmwater Shrimp from the People's Republic of China: Notice of Final Results of Changed Circumstances Review*, 72 FR 33447 (June 18, 2007).

⁹ See Letter to All Interested Parties from Catherine Bertrand, Program Manager, Office 9, "Certain Frozen Warmwater Shrimp from the People's Republic of China: Reopening the Record of Changed Circumstance Review" (December 5, 2012).

¹⁰ See Memo to the File from Kabir Archuletta, International Trade Analyst, Office 9, "Placing Documents on the Record of Changed Circumstances Review" (December 13, 2012).

¹¹ See Memo to the File from Kabir Archuletta, International Trade Analyst, Office 9, "Placing Documents on the Record of Changed Circumstances Review" (December 17, 2012).

¹² See Letter from the Ad Hoc Shrimp Trade Action Committee to the Secretary of Commerce

2013, the Department received rebuttal comments from Hilltop.¹³

Scope of Order

The merchandise that is subject to the order is certain frozen warmwater shrimp from the PRC. The products subject to the order at the time of this CCR was originally conducted¹⁴ were classified under U.S. Harmonized Tariff Schedule ("HTSUS") subheadings 0306.13.00.03, 0306.13.00.06, 0306.13.00.09, 0306.13.00.12, 0306.13.00.15, 0306.13.00.18, 0306.13.00.21, 0306.13.00.24, 0306.13.00.27, 0306.13.00.40, 1605.20.10.10, and 1605.20.10.30. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise remains dispositive.¹⁵

Preliminary Reconsideration

For a full description of our findings in this preliminary reconsideration, please see the Preliminary Reconsideration Memorandum.¹⁶ The Preliminary Reconsideration Memorandum is a public document on file electronically via Import Administration's Antidumping and Countervailing Duty Centralized Electronic Service System ("IA ACCESS"). IA ACCESS is available to registered users at <http://iaaccess.trade.gov> and in the Central Records Unit, room 7046 of the main

"Comments on Record Evidence" (December 31, 2012).

¹³ See Letter from Hilltop to the Secretary of Commerce "Hilltop Rebuttal Comments: Certain Frozen Warmwater Shrimp from the PRC: Reopening the Record of Changed Circumstances Review" (January 7, 2013).

¹⁴ We note that on April 26, 2011, the Department amended the antidumping duty order to include dusted shrimp, pursuant to the U.S. Court of International Trade ("CIT") decision in *Ad Hoc Shrimp Trade Action Committee v. United States*, 703 F. Supp. 2d 1330 (CIT 2010) and the U.S. International Trade Commission determination, which found the domestic like product to include dusted shrimp. See *Certain Frozen Warmwater Shrimp From Brazil, India, the People's Republic of China, Thailand, and the Socialist Republic of Vietnam: Amended Antidumping Duty Orders in Accordance with Final Court Decision*, 76 FR 23277 (April 26, 2011). The scope referenced here is the scope that was in effect when the Department conducted this original CCR proceeding.

¹⁵ See *Notice of Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Certain Frozen Warmwater Shrimp From the People's Republic of China*, 70 FR 5149 (February 1, 2005).

¹⁶ See "Decision Memorandum for Preliminary Reconsideration of Changed Circumstances Review: Certain Frozen Warmwater Shrimp from the People's Republic of China," ("Preliminary Reconsideration Memorandum") from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Import Administration, dated concurrently with these results and hereby adopted by this notice.

Department of Commerce building. In addition, a complete version of the Preliminary Reconsideration Memorandum can be accessed directly on the Internet at <http://www.trade.gov/ia/>. The signed Preliminary Reconsideration Memorandum and the electronic versions of the Preliminary Reconsideration Memorandum are identical in content.

For the reasons detailed in the Preliminary Reconsideration Memorandum, we preliminarily determine that Hilltop is not the successor-in-interest to Yelin and is considered part of the PRC-wide entity. In making this determination we have relied on adverse facts available, in accordance with section 776(a) and (b) of the Tariff Act of 1930, as amended (“the Act”).

Public Comment

Any interested party may request a hearing within 14 days of publication of this notice in accordance with 19 CFR 351.310(c). Interested parties may submit case briefs no later than 14 days after the date of publication of this notice, in accordance with 19 CFR 351.309(c)(1)(ii). Rebuttal briefs, which must be limited to issues raised in the case briefs, may be filed no later than five days after the case briefs, in accordance with 19 CFR 351.309(d)(1). Any hearing, if requested, will normally be held two days after rebuttal briefs are due, in accordance with 19 CFR 351.310(d)(1).

The Department will issue its final results of review within 270 days after the date on which the preliminary reconsideration of this CCR is published in the **Federal Register**, or within 45 days if all parties to the proceeding agree to the outcome of the review, in accordance with 19 CFR 351.216(e), and will publish these results in the **Federal Register**.

The current requirement for a cash deposit of estimated antidumping duties on all subject merchandise will continue unless and until it is modified pursuant to the final results of this CCR. We note that Hilltop was determined to be part of the PRC-wide entity in AR6 and is currently subject to the cash deposit requirements applicable to the PRC-wide entity.

This notice is published in accordance with sections 751(b) and 777(i) of the Act and 19 CFR 351.216.

Dated: February 21, 2013.

Paul Piquado,
Assistant Secretary for Import
Administration.

[FR Doc. 2013-04550 Filed 2-22-13; 4:15 pm]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C-570-989, C-331-803, C-533-854, C-560-825, C-557-814, C-549-828, and C-552-815]

Certain Frozen Warmwater Shrimp From the People's Republic of China, Ecuador, India, Indonesia, Malaysia, Thailand, and the Socialist Republic of Vietnam: Postponement of Preliminary Determinations in the Countervailing Duty Investigations

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* February 27, 2013.

FOR FURTHER INFORMATION CONTACT: Eric Greynolds or Christopher Hargett, AD/CVD Operations, Office 8, Import Administration, U.S. Department of Commerce, Room C-100, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: 202-482-6071 and 202-482-4161, respectively.

SUPPLEMENTARY INFORMATION:

Background

On January 17, 2013, the Department of Commerce (the Department) initiated countervailing duty investigations of certain frozen warmwater shrimp from the People's Republic of China, Ecuador, India, Indonesia, Malaysia, Thailand, and the Socialist Republic of Vietnam.¹ Currently, the preliminary determinations are due no later than March 23, 2013. In the *Initiation Notice*, the Department incorrectly listed the case number for *Certain Frozen Warmwater Shrimp From the People's Republic of China* as C-570-988; however, the case number should read C-570-989.

Postponement of Due Date for Preliminary Determinations

Section 703(b)(1) of the Tariff Act of 1930, as amended (the Act), requires the Department to issue the preliminary determination in a countervailing duty investigation within 65 days after the date on which the Department initiated the investigation. However, if the petitioner makes a timely request for an extension, section 703(c)(1)(A) of the Act allows the Department to postpone making the preliminary determination

¹ See *Certain Frozen Warmwater Shrimp From the People's Republic of China, Ecuador, India, Indonesia, Malaysia, Thailand, and the Socialist Republic of Vietnam: Initiation of Countervailing Duty Investigations*, 78 FR 5416 (January 25, 2013) (*Initiation Notice*).

until no later than 130 days after the date on which the administering authority initiated the investigation.

On February 8, 2013, the Coalition of Gulf Shrimp Industries, the petitioner in these investigations, requested that the deadline for the preliminary determination in each of these cases be extended to 130 days from the date of initiation in accordance with 19 CFR § 351.205(b)(2). Therefore, in accordance with section 703(c)(1)(A) of the Act, we are fully extending the due date for the preliminary determinations to no later than 130 days after the day on which the investigations were initiated. However, as that date falls on a federal holiday (*i.e.*, May 27, 2013), the deadline for completion of the preliminary determinations is now May 28, 2013, the next business day.

This notice is issued and published pursuant to section 703(c)(2) of the Act.

Dated: February 21, 2013.

Paul Piquado,

Assistant Secretary for Import
Administration.

[FR Doc. 2013-04577 Filed 2-26-13; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Proposed Information Collection; Comment Request; Research on Evacuating Persons With Mobility Impairments

AGENCY: National Institute of Standards and Technology (NIST), Commerce.

ACTION: Notice.

SUMMARY: 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 take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before April 29, 2013.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at jjessup@doc.gov).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Kathryn Butler, 100 Bureau Drive, Mailstop 8662, Gaithersburg, MD

20899–8662, *kathryn.butler@nist.gov*, 301–975–6673.

SUPPLEMENTARY INFORMATION:

I. Abstract

NIST's research on elevators has primarily focused on the technical aspects of ensuring safe and reliable evacuation for the occupants of tall buildings. In addition, the International Code Council and the National Fire Protection Association provide requirements for the use of elevators for both occupant evacuation and fire fighter access into the building. However, there still is little understanding of how occupants use elevator systems during fire emergencies.

The focus of this research effort is two-fold: (1) To gain an understanding of how building occupants with mobility impairments currently evacuate multi-story buildings in the United States during fire emergencies, and (2) to learn about the concerns of persons with mobility impairments on using elevators during fire evacuations. This research aims to provide guidance to designers and building managers on aspects of fire evacuation that concern occupants with mobility impairments and on how to improve elevator design and usage during fire emergencies. The research includes four opportunities for participation:

(a) Building managers and designated safety personnel from a sample of four to ten existing and new federal high-rise buildings in the United States will be contacted to fill out a questionnaire requesting information on the emergency plans and procedures for the building, including how the buildings' evacuation plans incorporate the use of the existing elevator system to evacuate occupants with mobility impairments during fire emergencies. The building emergency plan will be requested from either the General Services Administration (GSA) or from the building manager.

(b) Occupants with mobility impairments in the buildings identified in part (a) will be asked for basic information on their mobility with regard to evacuation, previous evacuation experiences, and preferences on how to evacuate during a fire emergency. At the end of the questionnaire, they will be invited to participate in a one-on-one interview to discuss these issues in more detail.

(c) Occupants with mobility impairments identified in part (b) will participate in a one-on-one interview requesting more detailed information on previous evacuation experiences, awareness of emergency procedures,

and views and preferences on using an elevator to evacuate during a fire emergency.

(d) Professionals involved with emergency planning (e.g., GSA, USDA, DHS, building emergency managers, researchers) and building occupants with mobility impairments, if willing, will be invited to participate in one of two focus groups. A preliminary analysis of the data resulting from parts (a) through (c) will be summarized in the form of two sets of potential plans for the use of elevators during fire evacuation by occupants with mobility impairments: One for existing buildings and one for new buildings. Members of the focus groups will review both of these potential plans. They will then participate in a discussion that will lead to guidance for designers and building managers on aspects of fire evacuation that concern occupants with mobility impairments and on how to improve elevator design and usage during fire emergencies. The order of the discussion of plans for existing and new buildings will be switched for the two focus groups to ensure that each plan receives the same amount of attention overall.

II. Method of Collection

The data from questionnaire (a) will be collected electronically. The questionnaire will be made available on a secured Web site and the link to this Web site will be distributed by NIST staff to building property managers and designated safety personnel.

The data from questionnaire (b) will be collected electronically. The questionnaire will be made available on a secured Web site and the link to this Web site will be distributed by NIST staff to occupants with mobility impairments in the buildings identified in part (a).

The data from the one-on-one interviews will be audiotaped if permission is granted or recorded in written notes if not. Participants will identify their interest in the questionnaire from part (b). Each interview will be conducted by a member of the NIST research team at the participant's workplace or by phone.

The data from the focus groups will be audio taped and recorded in written notes. Professionals involved with emergency planning (e.g., GSA, USDA, DHS, building emergency managers, researchers) and building occupants with mobility impairments, if willing, will be invited to participate.

III. Data

OMB Control Number: None.
Form Number: None.

Type of Review: Regular submission (new information collection).

Affected Public: Collections (a) and (d): Selected individuals, such as building managers and designated safety personnel, who are familiar with or in charge of developing emergency procedures for multi-story buildings in the United States, including both federal and private sector buildings; Collections (b) and (c): Selected high-rise building occupants with mobility impairments.

Estimated Number of Respondents: 180.

Estimated Time per Response: Surveys, 15 minutes; Interviews, 2 hours; and Focus groups, 2 hours.

Estimated Total Annual Burden Hours: 168.

Estimated Total Annual Cost to Public: \$0.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: February 21, 2013.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2013–04491 Filed 2–26–13; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC520

New England Fishery Management Council; Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Habitat Committee to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Tuesday, March 19, 2013 at 9 a.m.

ADDRESSES: The meeting will be held at the Hawthorne Hotel, 18 Washington Square, Salem, MA 01970; telephone: (978) 744-4080; fax: (978) 745-9842.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Paul J. Howard, Executive Director, New England Fishery Management Council; telephone: (978) 465-0492.

SUPPLEMENTARY INFORMATION: The Habitat Committee will continue development of management alternatives for Omnibus EFH Amendment 2. Regarding Dedicated Habitat Research Areas, the Committee will review PDT recommendations about: (1) Implementing dedicated habitat research areas (e.g. defining “use” in relation to sunset provisions), (2) goals and objectives for specific research areas, and (3) boundaries for Eastern Maine and Georges Bank DHRAs. Regarding gear modifications, the Committee will (1) review PDT information about gear modifications for scallop dredges, (2) discuss other gear modification options as needed, and (3) discuss a gear modification research agenda and data collection program. The Committee will also review recommended boundaries for a single Habitat Management Area in the Great South Channel. Other business may be discussed as necessary.

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

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Paul J. Howard, Executive Director, at (978)

465-0492, at least 5 days prior to the meeting date.

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

Dated: February 22, 2013.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.
[FR Doc. 2013-04509 Filed 2-26-13; 8:45 am]

BILLING CODE 3510-22-P

BUREAU OF CONSUMER FINANCIAL PROTECTION

[Docket No. CFPB-2013-0004]

Request for Information Regarding an Initiative To Promote Student Loan Affordability

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice and request for information.

SUMMARY: This notice requests information from the public to determine options that would increase the availability of affordable payment plans for borrowers with existing private student loans. Section 1035 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) establishes an ombudsman for student loans (Ombudsman) within the Consumer Financial Protection Bureau (Bureau). Among other things, the Ombudsman is responsible for making “appropriate recommendations” to the Director of the Bureau, the Secretary of the Treasury, the Secretary of Education, and Congress.

In October 2012, the Ombudsman presented a report, which recommended that policymakers identify opportunities to spur refinance and modification activity in the private student loan market. This notice seeks information from market participants, consumers, and other stakeholders in order to provide more detailed information on ways to encourage the development of more affordable loan repayment mechanisms for private student loan borrowers.

DATES: Comments must be received on or before April 8, 2013.

ADDRESSES: You may submit responsive information and other comments, identified by Docket No. CFPB-2013-0004, by any of the following methods:

- *Electronic:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Mail/Hand Delivery/Courier:* Monica Jackson, Office of the Executive Secretary, Consumer Financial Protection Bureau, 1700 G Street NW., Washington, DC 20552.

Instructions: The Bureau encourages the early submission of comments. All submissions must include the document title and docket number. Because paper mail in the Washington, DC area and at the Bureau is subject to delay, commenters are encouraged to submit comments electronically. Please note the number associated with any question to which you are responding at the top of each response (you are not required to answer all questions to receive consideration of your comments). In general, all comments received will be posted without change to <http://www.regulations.gov>. In addition, comments will be available for public inspection and copying at 1700 G Street NW., Washington, DC 20552, on official business days between the hours of 10 a.m. and 5 p.m. Eastern Time. You can make an appointment to inspect the documents by telephoning 202-435-7275.

All submissions, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. Sensitive personal information, such as account numbers or Social Security numbers, should not be included. Submissions will not be edited to remove any identifying or contact information.

FOR FURTHER INFORMATION CONTACT: For general inquiries, submission process questions or any additional information, please contact Monica Jackson, Office of the Executive Secretary, at 202-435-7275.

Authority: 12 U.S.C. 5511(c).

SUPPLEMENTARY INFORMATION: There are more than 38 million student loan borrowers with over \$1.1 trillion in outstanding debt. The majority of the market consists of loans originated under Title IV of the Higher Education Act. The remainder of the market consists of private student loans. In July 2012, the Director of the Bureau and the Secretary of Education submitted a report to Congress detailing the private student loan market. The report¹ found that, as of the end of 2011, there were more than \$8 billion in defaulted private student loan balances, with even more in delinquency. Federal student loans frequently provide for income-based repayment options for borrowers with partial financial hardship, as well as rehabilitation options for borrowers in default. In general, private student

¹ Consumer Financial Protection Bureau and Department of Education: Report on Private Student Loans (2012).

loans do not offer similar modified repayment options.

The Dodd-Frank Act requires the Secretary of the Treasury to designate an Ombudsman within the Bureau. The Dodd-Frank Act requires that the Ombudsman present an annual report describing the activities of the Ombudsman during the prior year, compile and analyze data on borrower complaints regarding private educational loans, and make appropriate recommendations to policymakers. In October 2012, the Ombudsman released an annual report.² The report, among other things, analyzed complaints and other input from private student loan borrowers, and noted that many consumers reported difficulties negotiating repayment plans with their lenders and servicers in times of financial difficulty, as well as challenges finding refinance options. Included in the report was a recommendation that policymakers identify options to spur the availability of loan modification and refinance options for student loan borrowers.

Some policymakers have sought changes to the treatment of private student loans in the bankruptcy code. This policy option is not the primary subject of this Request for Information. Rather, this request seeks information on options to increase the level of affordable repayment options for both pre-default and post-default borrowers in distress who wish to repay their loans but may be lacking near-term ability to service their obligations.

Loan Modifications

For the purposes of this request, a loan modification refers to a restructuring of a debt obligation agreed to by the creditor and debtor where the creditor agrees to a concession. In recent years, many homeowners have sought more affordable repayment options for mortgage obligations to avoid foreclosure. In such situations, some creditors may have an economic incentive to modify the loan, as the net present value (NPV) of the restructured debt may be greater in value than the value of the collateral after foreclosure costs. However, in other situations, with respect to securitized debt obligations secured by residential real estate, subordinated note holders might be unwilling to approve a change in terms. Given the potential impact foreclosures can have on the financial system and local economies, many policymakers pursued policies designed to encourage

alternative repayment options for mortgage borrowers.

The private student loan market might also benefit from further loan modification activity. Even with concessions, creditors might increase the NPV of distressed loans through such modifications. However, the market for private student loans differs from the market for residential mortgages. Private student loans are not secured by collateral and have generally lower outstanding balances relative to mortgages. These differences might fundamentally impact creditors' economic calculus for determining whether to offer a change in repayment terms.

There are also some important similarities between the two markets. As with mortgage origination, student loan originators often access funding through the asset-backed securities (ABS) market. In 2012, public filings reveal that more than \$4 billion of private student loan asset-backed securities were issued. Like in the mortgage market, private student loan underwriting practices have significantly improved since the economic downturn, which may limit the level of distress for future borrowers. Another notable similarity is the employment of third-party loan servicers unaffiliated with the original lender, though this practice is less prevalent in the private student loan market than in the mortgage market.

Borrowers of federal student loans have a number of options to modify the terms of their obligations to ensure an affordable payment plan. For example, borrowers with a partial financial hardship can elect the Income-Based Repayment plan, which caps payments on eligible student loans as a percentage of income above 150% of the poverty line. Borrowers in default can rehabilitate many federal student loans by making "reasonable and affordable" payments in a consistent, timely fashion for a specified period. There are also provisions to adjust the status of a rehabilitated federal student loan on a consumer's credit report.

Available data indicate that, in recent years, there has been limited modification activity in the private student loan market. There are a number of potential impediments to offering alternative repayment options. Some of these may include: (a) Accounting guidelines that add complexity when offering alternative repayment options without charging off the loan;³ (b)

operational and information technology limitations among loan servicers; and (c) incentive mismatch among trustees, administrators, and/or noteholders in ABS trusts and loan servicers.

Impacts on Individual Borrowers and the Public

Policymakers have employed various measures to prevent foreclosures among American homeowners and to mitigate resulting risks to the public and the broader economy. Examples of these risks include increased stress on insured depository institutions and decreased home values of properties proximate to foreclosed homes—both of which can lead to further distress. Given the relative size of the private student loan market and the nature of the product, private student borrower distress is unlikely to contribute to similar, significant systemic risk. However, distress among borrowers with all types of student loans may cause other negative effects in the broader economy. For example, the Department of Treasury's Office of Financial Research described in its recent annual report that student loan debt might dampen consumption.⁴ Changes in the household headship rates, automobile sales, and homeownership by younger Americans might also be impacted by student debt levels. Should these risks be significant, policymakers may wish to consider partnerships between the federal government and the private sector to increase the availability of alternative repayment options and reduce the levels of delinquency and default.

The Ombudsman seeks information in order to provide policymakers with further details on potential ways to increase payment affordability for private student loan borrowers in distress and on the risks of failing to do so. The deadline for submission of comments is April 8, 2013.

The Bureau encourages comments from the public, including:

- Consumers;
- Financial institutions, including lenders and loan servicers;
- Nationally recognized statistical rating organizations (NRSROs);
- Private student loan asset-backed trust administrators;
- Institutions of higher education;
- Credit reporting agencies;
- Debt collectors;
- Housing finance professionals;
- Manufacturers of automobiles and other financed goods;
- Brokers and service providers in the residential real estate industry;

² Consumer Financial Protection Bureau: Annual Report of the CFPB Student Loan Ombudsman (2012).

³ See, for example, CNBE Policy Guidance 2010–02, issued by the Office of the Comptroller of the Currency in August 2010.

⁴ Department of the Treasury, Office of Financial Research: Annual Report to Congress (2012).

- Professional associations, such as those representing health professionals and teachers;

- Providers of financial counseling; and

- Other interested parties.

The Bureau is interested in responses in the following general areas, as well as specific questions below. Please feel free to respond to any of the questions outlined below.

Scope of Borrower Hardship

1 What are the primary drivers of private student loan borrower distress?

a What characteristics might predict distress at loan origination?

b What characteristics might predict distress for borrowers who complete a program of study?

c What characteristics might predict distress during repayment?

d What are typical debt-to-income ratios of borrowers in distress?

2 How do borrowers in distress typically stay current with their private student loans? To what extent do borrowers reduce consumption or adjust living arrangements to meet obligations?

a Do borrowers seek to reduce payments on federal student loans in order to make payments on private student loans?

b To what extent do borrowers in distress accrue other debt (credit cards, family loans) to meet private student loan obligations?

c To what extent do borrowers in distress forego "other nonessential expenses" to meet private student loan obligations?

Current Options for Borrowers with Hardship

3 What options currently exist for borrowers to permanently or temporarily lower monthly payments on private student loan obligations? To what extent have these affordable repayment options cured delinquencies?

4 How do lenders typically evaluate whether or not a borrower qualifies for these affordable repayment options? If lenders make use of financial models, what are the key drivers of these models?

5 Do lenders work directly with co-signers to modify terms? If so, how?

6 What is the incidence or expectation of re-default rates among restructured private student loans?

Past and Existing Loan Modification Programs for Other Types of Debt

7 What are some examples of loan modification programs sponsored by a public entity or the private sector that have been successful? Which features of these programs might be applicable to a

student loan affordability program? Which features of these programs might not be appropriate for a student loan affordability program?

Servicing Infrastructure

8 Is the servicing infrastructure utilized by major lenders flexible enough to process loan modifications at scale? What are the limitations of these servicing platforms? Are those limitations capable of being overcome? What are the estimated costs of overcoming those limitations?

9 What are the key differences between servicing of student loans compared to servicing of residential mortgages that must be considered when crafting an affordability program?

Consumer Reporting and Credit Scoring

10 How are payments plans for defaulted private and federal student loans currently reported to consumer reporting agencies? How are rehabilitated federal student loans reported by consumer reporting agencies, and how does that reporting affect credit scores?

Lender Participation

11 How might an affordability program sponsored by a public entity mitigate moral hazard and selection bias?

Borrower Awareness

12 What are some examples of modification or refinance initiatives that successfully made borrowers aware of a new program? Which features of these programs are applicable in the private student loan market?

13 What are the most effective communication mechanisms to reach borrowers in distress?

Spillovers

14 How do student loan payments impact access to mortgage credit? How does student debt impact a consumer's ability to accumulate a down payment? How does student debt impact a consumer's ability to meet debt-to-income requirements for FHA-insured and private sector mortgages?

15 To what extent does student loan debt impact the market for automobiles? How does student loan debt impact a consumer's ability to secure an auto loan?

16 What evidence exists about the impact of student loan debt on consumption, savings, homeownership, household formation, entrepreneurship, and other indicators of economic health?

Dated: February 20, 2013.

Garry Reeder,

Chief of Staff, Bureau of Consumer Financial Protection.

[FR Doc. 2013-04419 Filed 2-26-13; 8:45 am]

BILLING CODE 4810-AM-P

DEPARTMENT OF DEFENSE

Department of the Air Force

U.S. Air Force Academy Board of Visitors Notice of Meeting

AGENCY: U.S. Air Force Academy Board of Visitors.

ACTION: Meeting notice.

SUMMARY: In accordance with 10 U.S.C. 9355, the U.S. Air Force Academy (USAFA) Board of Visitors (BoV) will hold a meeting in Harmon Hall at the United States Air Force Academy in Colorado Springs, Colorado on March 15–16, 2013. The meeting will begin at 2:30 p.m. on March 15 and 9:00 a.m. on March 16. The purpose of this meeting is to review morale and discipline, social climate, curriculum, instruction, infrastructure, fiscal affairs, academic methods, and other matters relating to the Academy. Specific topics for this meeting include a Forthclassmen Cadet Focus Group, an Upperclassmen Cadet Focus Group, an Athletic Department Update, a Superintendent's Update, a Character Update, an Impact of NDAA Requirements brief and the Subcommittee Chair Updates. In accordance with 5 U.S.C. 552b, as amended, and 41 CFR 102–3.155, three sessions of this meeting shall be closed to the public because they involve matters covered by subsection (c)(6) of 5 U.S.C. 552b. Public attendance at the open portions of this USAFA BoV meeting shall be accommodated on a first-come, first-served basis up to the reasonable and safe capacity of the meeting room. In addition, any member of the public wishing to provide input to the USAFA BoV should submit a written statement in accordance with 41 CFR 102–3.140(c) and section 10(a)(3) of the Federal Advisory Committee Act and the procedures described in this paragraph. Written statements must address the following details: The issue, discussion, and a recommended course of action. Supporting documentation may also be included as needed to establish the appropriate historical context and provide any necessary background information. Written statements can be submitted to the Designated Federal Officer (DFO) at the Air Force address detailed below at any time. However, if a written statement is

not received at least 10 calendar days before the first day of the meeting which is the subject of this notice, then it may not be provided to or considered by the BoV until its next open meeting. The DFO will review all timely submissions with the BoV Chairman and ensure they are provided to members of the BoV before the meeting that is the subject of this notice. For the benefit of the public, rosters that list the names of BoV members and any releasable materials presented during the open portions of this BoV meeting shall be made available upon request.

If after review of timely submitted written comments and the BoV Chairman and DFO deem appropriate, they may choose to invite the submitter of the written comments to orally present the issue during an open portion of the BoV meeting that is the subject of this notice. Members of the BoV may also petition the Chairman to allow specific personnel to make oral presentations before the BoV. In accordance with 41 CFR 102-3.140(d), any oral presentations before the BoV shall be in accordance with agency guidelines provided pursuant to a written invitation and this paragraph. Direct questioning of BoV members or meeting participants by the public is not permitted except with the approval of the DFO and Chairman.

FOR FURTHER INFORMATION CONTACT: For additional information or to attend this BoV meeting, contact Capt Bobby Hale, Accessions and Training Division, AF/A1PT, 1040 Air Force Pentagon, Washington, DC 20330, (703) 695-4066.

Henry Williams Jr.,

Acting Air Force Federal Register Liaison Officer.

[FR Doc. 2013-04501 Filed 2-26-13; 8:45 am]

BILLING CODE 5001-10-P

DEPARTMENT OF EDUCATION

[Docket No.: ED-2012-ICCD-0074]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Part 601 Preferred Lender Arrangements

AGENCY: Department of Education (ED), Federal Student Aid (FSA).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing an extension of an existing information collection of a previously approved information collection.

DATES: Interested persons are invited to submit comments on or before March 29, 2013.

ADDRESSES: Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at <http://www.regulations.gov> by selecting Docket ID number ED-2012-ICCD-0074 or via postal mail, commercial delivery, or hand delivery. Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted. Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 2E103, Washington, DC 20202-4537.

FOR FURTHER INFORMATION CONTACT: Electronically mail ICDocketMgr@ed.gov. Please do not send comments here.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Part 601 Preferred Lender Arrangements

OMB Control Number: 1845-0101

Type of Review: Extension of an existing collection of information

Respondents/Affected Public: Individual or households

Total Estimated Number of Annual Responses: 13,674,883

Total Estimated Number of Annual Burden Hours: 3,197,761

Abstract: Part 601—Institution and Lender Requirements Relating to Education Loans is a new section of the regulations governing private education loans offered at covered institutions by lenders also participating in the FFEL program. These regulations assure the Secretary that the integrity of the program is protected from fraud and misuse of program funds and places requirements on institutions and lenders to insure that borrowers receive additional disclosures about Title IV, HEA program assistance prior to obtaining a private education loan. These regulations require covered institutions to provide a variety of new loan disclosures, disclosures on private loans, for institutions to prepare and submit an annual report on the use of private loans, and to establish and adopt a code of conduct for institutions participation in a preferred lender arrangement. The Department, in conjunction with outside entities are submitting the Private Education Loan Applicant Self-Certification form for OMB's approval. While information about the applicant's cost of attendance and estimated financial assistance must be provided to the student, if available, the student will provide the data to the private loan lender who must collect and maintain the self-certification form prior to disbursement of a Private Education Loan. The Department will not receive the Private Education Loan Applicant Self-Certification form and therefore will not be collecting and maintaining the form or its data.

Dated: February 21, 2013.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management.

[FR Doc. 2013-04436 Filed 2-26-13; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF ENERGY

[FE Docket No. 12-184-LNG]

Pangea LNG (North America) Holdings, LLC; Application for Long-Term Authorization To Export Liquefied Natural Gas Produced From Domestic Natural Gas Resources to Non-Free Trade Agreement Countries for a 25-Year Period

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of application.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy (DOE) gives notice of receipt of an application (Application) filed on December 19, 2012, by Pangea LNG (North America) Holdings, LLC (Pangea), requesting long-term, multi-contract authorization to export domestically produced liquefied natural gas (LNG) in an amount up to the equivalent of 398.5 billion cubic feet (Bcf) per year (Bcf/y) of natural gas (equal to 1.09 Bcf/day of natural gas), the equivalent of 8 million metric tons per annum (mtpa), from its proposed South Texas LNG Export Project (ST LNG Project) located at the Port of Corpus Christi in Ingleside, Texas. Pangea requests this authorization for a 25-year term commencing on the earlier of the date of first export or seven years from the date the requested authorization is granted. The LNG would be exported to any country (1) with which the United States does not have a free trade agreement (FTA) requiring national treatment for trade in natural gas, (2) that has developed or in the future develops the capacity to import LNG via ocean-going carrier, and (3) with which trade is not prohibited by U.S. law or policy. Pangea is requesting this authorization to export LNG both on its own behalf and as agent for other parties who hold title to the LNG at the point of export. The Application was filed under section 3 of the Natural Gas Act (NGA). Protests, motions to intervene, notices of intervention, and written comments are invited.

DATES: Protests, motions to intervene or notices of intervention, as applicable, requests for additional procedures, and written comments are to be filed using procedures detailed in the Public Comment Procedures section no later than 4:30 p.m., eastern time, April 29, 2013.

ADDRESSES:

Electronic Filing by email:
fergas@hq.doe.gov.

Regular Mail: U.S. Department of Energy (FE-34), Office of Natural Gas Regulatory Activities, Office of Fossil Energy, P.O. Box 44375, Washington, DC 20026-4375.

Hand Delivery or Private Delivery Services (e.g., FedEx, UPS, etc.): U.S. Department of Energy (FE-34), Office of Natural Gas Regulatory Activities, Office of Fossil Energy, Forrestal Building, Room 3E-042, 1000 Independence Avenue SW., Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT:

Larine Moore or Marc Talbert, U.S. Department of Energy (FE-34), Office of Natural Gas Regulatory Activities, Office of Fossil Energy, Forrestal

Building, Room 3E-042, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586-9478; (202) 586-7991.

Edward Myers, U.S. Department of Energy, Office of the Assistant General Counsel for Electricity and Fossil Energy, Forrestal Building, Room 6B-256, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586-3397.

SUPPLEMENTARY INFORMATION:

Background

Pangea is a Delaware limited liability company with its principal place of business in The Woodlands, Texas. Pangea is a wholly owned subsidiary of Pangea LNG B.V. (Pangea LNG), a Netherlands-based company that is developing floating LNG liquefaction and storage solutions around the globe. Pangea LNG's ordinary shares are owned by Daewoo Shipbuilding & Marine Engineering Co., Ltd. (DSME) (70%), D&H Solutions AS (20%), and NextDecade International Coöperatief U.A. (NextDecade International) (10%).

DSME is a South Korea-based company whose major shareholders consist of Korea Development Bank (31.27%) and Korea Asset Management Corporation (19.11%), with the remaining shares being widely-held (with no individual entities holding five (5) percent or more of DSME's shares).¹ D&H Solutions AS is a Norwegian-based joint venture company that is owned by Hemla II AS (50%) and DSME (50%). NextDecade International is a Netherlands-based cooperative and has six (6) individual investors from the United States, Spain, and The Netherlands.

Pangea states that consistent with an executed Letter of Intent, it is working with Statoil North America, Inc. on the development of the ST LNG Project. Statoil North America, Inc. is a subsidiary of Statoil ASA (Statoil), a Norwegian upstream oil and gas company listed on the Oslo and New York stock exchanges. Pangea states that headquartered in Stavanger, Norway, Statoil is an international energy company with 40 years of offshore oil and gas production experience on the Norwegian Continental Shelf and currently has operations in 36 countries. Pangea states that Statoil's LNG activities include being the operator of the Sønøhvit, and LNG export facility in Norway; exercising its capacity holder rights with respect to the Cove Point import and regasification terminal (in the U.S.); and producing, transporting

and marketing LNG worldwide. Pangea states that Statoil has been active in the U.S. oil and gas industry for 25 years. Pangea states that over the past decade, Statoil has increased its North American business substantially through upstream positions in the Gulf of Mexico, acreages in the Marcellus shale gas play, the Eagle Ford shale gas play, the Bakken shale oil play and oil sands acreages in Alberta, Canada. Pangea further states that it and Statoil are in active negotiations with respect to Statoil procuring up to a 50% equity stake in the ST LNG Project and utilizing up to 50% of the liquefaction and export capacity of the ST LNG Project.²

Current Application

In the instant Application, Pangea seeks long-term, multi-contract authorization to export domestically produced LNG in an amount up to the equivalent of 398.5 billion cubic feet (Bcf) per year (Bcf/y) of natural gas (equal to 1.09 Bcf/day of natural gas), the equivalent of 8 million metric tons per annum (mtpa), for a period of 25 years beginning on the earlier of the date of first export or seven years from the date the authorization is granted by DOE/FE. Pangea seeks to export this LNG to any nation with which the United States does not have an FTA requiring national treatment for trade in natural gas or LNG with which trade is not prohibited by United States law or policy. Pangea is seeking this export authorization in conjunction with its proposal to construct, own, and operate the ST LNG Project.³ Pangea states that the ST LNG Project will consist of both land-based and floating components and will include natural gas treatment, compression, liquefaction and storage

² Should a change in control occur prior to DOE/FE's issuance of an order in this proceeding, Pangea will file a supplement to the instant Application to update the relevant applicant information. Pangea acknowledges that in any order granting the authorization requested in the Application, DOE/FE may require that Pangea request approval from the Assistant Secretary for Fossil Energy prior to a change in control of the authorization holder, whether by asset sale, stock transfer or other means.

³ Pangea states: (i) Regulatory approval also must be obtained from the Federal Energy Regulatory Commission (FERC) under Section 3 of the NGA for the siting, construction, and operation of the ST LNG Project and under Section 7 of the NGA for the siting, construction, and operation of an affiliated natural gas pipeline that will bring feed gas and fuel gas to the ST LNG Project; (ii) Pangea will initiate the process to obtain such authorizations in Spring 2013 by requesting authorization from the Director of the Office of Energy Projects to commence the FERC's mandatory National Environmental Policy Act pre-filing review process for the ST LNG Project and associated pipeline; (iii) the potential environmental impacts of the ST LNG Project, as well as the affiliated pipeline, will be reviewed by FERC in conjunction with that proceeding.

¹ Pangea LNG states that Treasury shares comprise 1.2% of the total shares of DSME.

facilities, as well as ancillary facilities required to receive and liquefy natural gas, and to store and deliver LNG. Pangea states that the ST LNG Project will be capable of processing an average of approximately 398.5 Bcf/y, approximately 1.09 Bcf/d, of pipeline-quality natural gas. Pangea states that such gas will be delivered to the ST LNG Project through an approximately 27-mile-long pipeline, South Texas Pipeline, to be developed by a Pangea affiliate. Pangea intends to interconnect the ST LNG Project with nine interstate and intrastate pipeline systems⁴ via the South Texas Pipeline, thereby allowing natural gas to be supplied through displacement or direct access from a wide variety of supply sources.

Public Interest Considerations

Pangea states that the ST LNG Project has been proposed, in part, due to the markedly improved outlook for domestic natural gas reserves and production. Pangea states that improved drilling techniques and extraction technologies have contributed to the rapid growth in new supplies from unconventional gas-bearing formations across the U.S. and have been utilized to enhance production in some conventional fields. Pangea states that such developments have completely changed the complexion of the U.S. natural gas industry and radically expanded the resource base.

Pangea states that LNG exports via the ST LNG Project represents a market-driven path toward deploying the country's vast energy reserves in a manner that will meaningfully contribute to the public interest through a variety of benefits, including: (1) More jobs⁵ and personal income, greater tax

revenues, and increased economic activity; (2) Improved U.S. balance of payments (by between \$3.7 billion and \$6 billion annually) through the exportation of natural gas and the displacement of imports of other petroleum liquids; (3) Enhanced national security, as a result of the U.S.'s larger role in international energy markets, assistance provided to our allies, and reduced U.S. dependency on foreign oil and natural gas production;⁶ (4) Better opportunities to market U.S. products and services abroad, as a result of new competitively priced gas supplies introduced into world markets leading to improved economies among the U.S.'s trading partners; (5) Increased economic trade and closer ties with foreign trading partners and hemispheric allies, while displacing environmentally damaging fuels in those countries; (6) Increased production capacity able to better adjust to varying domestic demand scenarios; and (7) Dampened volatility in domestic natural gas prices.

Pangea submits that these benefits, and others discussed in this Application, demonstrate that Pangea's export proposal is not inconsistent with the public interest. Pangea states that this stance is now buttressed by the independent NERA Report, which key findings related to the macroeconomic impacts of LNG exports are overwhelmingly positive.

Further discussion of the public interest and analysis of the impact of LNG exports is included in the Application and Appendix A of the Application.

Environmental Impact

Pangea states that it will request NGA Section 3 authorization from FERC so that it may site, construct, and operate the ST LNG Project. Pangea states that it intends to commence the FERC's mandatory pre-filing process in Spring 2013 and then file its final application to obtain Section 3 authorization in the Fall 2013. Pangea states that its affiliate developing the ST Pipeline will file an application for NGA Section 7(c) authorization to construct, own, and operate the South Texas Pipeline.

Pangea states that the potential environmental impacts of the ST LNG Project will be reviewed by FERC under the National Environmental Policy Act (NEPA). Pangea further states that

model to assess shifts in employment, which were found to be within industry norms. *Id.* at 2.

⁶ John Deutch, *The U.S. Natural-Gas Boom Will Transform the World*, Wall Street Journal (August 14, 2012), <http://online.wsj.com/article/SB10001424052702303343404577514622469426012.html>.

consistent with the NEPA scheme applicable to applications for authorizations under NGA Section 3 delineated by Congress in the Energy Policy Act of 2005,⁷ it expects that FERC shall act as the lead agency, with DOE/FE acting as a cooperating agency, in connection with the ST LNG Project.

DOE/FE Evaluation

The Application will be reviewed pursuant to section 3 of the NGA, as amended, and the authority contained in DOE Delegation Order No. 00-002.00L (April 29, 2011) and DOE Redesignation Order No. 00-002.04E (April 29, 2011). In reviewing this LNG export Application, DOE will consider any issues required by law or policy. To the extent determined to be relevant or appropriate, these issues will include the impact of LNG exports associated with this Application, and the cumulative impact of any other application(s) previously approved, on domestic need for the gas proposed for export, adequacy of domestic natural gas supply, U.S. energy security, and any other issues, including the impact on the U.S. economy (GDP), consumers, and industry, job creation, U.S. balance of trade, international considerations, and whether the arrangement is consistent with DOE's policy of promoting competition in the marketplace by allowing commercial parties to freely negotiate their own trade arrangements. Parties that may oppose this Application should comment in their responses on these issues, as well as any other issues deemed relevant to the Application.

NEPA requires DOE to give appropriate consideration to the environmental effects of its proposed decisions. No final decision will be issued in this proceeding until DOE has met its environmental responsibilities.

Due to the complexity of the issues raised by the Applicants, interested persons will be provided 60 days from the date of publication of this Notice in which to submit comments, protests, motions to intervene, notices of intervention, or motions for additional procedures.

Public Comment Procedures

In response to this notice, any person may file a protest, comments, or a motion to intervene or notice of intervention, as applicable. Any person wishing to become a party to the proceeding must file a motion to intervene or notice of intervention, as applicable. The filing of comments or a protest with respect to the Application

⁷ Public Law 109-58, 119 Stat. 594.

⁴ Pangea states these nine pipelines are: Texas Eastern Transmission Corporation, Kinder Morgan Tejas Pipeline, LLC, Natural Gas Pipeline Company of America, Transcontinental Gas Pipeline Corporation, Tennessee Gas Pipeline Company, Gulf South Pipeline Company, LP, Crosstex Energy, L.P., GulfTerra Texas Pipeline, LP, and Channel Industries Gas Company. Their total estimated combined throughput is approximately 4.4 Bcf/d. The South Texas Pipeline's actual interconnects and delivery/receipt points ultimately will be determined in accordance with the needs of the users of the South Texas Pipeline. Significantly, there are various other natural gas pipelines crossed by, or in proximity to, the South Texas Pipeline's proposed route that may provide additional transportation options if needed.

⁵ As discussed in the Perryman Report supporting this Application, Pangea asserts that the ST LNG Project will spur substantial job creation. The statement found at page 2 of the NERA Report ("LNG exports are not likely to affect the overall level of employment in the U.S.") should not be read to contradict this. http://www.fe.doe.gov/programs/gasregulation/reports/nera_lng_report.pdf. NERA had as a base assumption "full employment" within the U.S. economy. NERA Report at 103. Therefore, NERA could only use its

will not serve to make the commenter or protestant a party to the proceeding, although protests and comments received from persons who are not parties will be considered in determining the appropriate action to be taken on the Application. All protests, comments, motions to intervene or notices of intervention must meet the requirements specified by the regulations in 10 CFR part 590.

Filings may be submitted using one of the following methods: (1) EMail the filing to fergas@hq.doe.gov with FE Docket No. 12-184-LNG in the title line; (2) mailing an original and three paper copies of the filing to the Office of Natural Gas Regulatory Activities at the address listed in **ADDRESSES**. The filing must include a reference to FE Docket No. 12-184-LNG; or (3) hand delivering an original and three paper copies of the filing to the Office of Natural Gas Regulatory Activities at the address listed in **ADDRESSES**. The filing must include a reference to FE Docket No. 12-184-LNG.

A decisional record on the Application will be developed through responses to this notice by parties, including the parties' written comments and replies thereto. Additional procedures will be used as necessary to achieve a complete understanding of the facts and issues. A party seeking intervention may request that additional procedures be provided, such as additional written comments, an oral presentation, a conference, or trial-type hearing. Any request to file additional written comments should explain why they are necessary. Any request for an oral presentation should identify the substantial question of fact, law, or policy at issue, show that it is material and relevant to a decision in the proceeding, and demonstrate why an oral presentation is needed. Any request for a conference should demonstrate why the conference would materially advance the proceeding. Any request for a trial-type hearing must show that there are factual issues genuinely in dispute that are relevant and material to a decision and that a trial-type hearing is necessary for a full and true disclosure of the facts.

If an additional procedure is scheduled, notice will be provided to all parties. If no party requests additional procedures, a final Opinion and Order may be issued based on the official record, including the Application and responses filed by parties pursuant to this notice, in accordance with 10 CFR 590.316.

The Application filed by Pangea is available for inspection and copying in the Office of Natural Gas Regulatory

Activities docket room, Room 3E-042, 1000 Independence Avenue SW., Washington, DC 20585. The docket room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays. The Application and any filed protests, motions to intervene or notice of interventions, and comments will also be available electronically by going to the following DOE/FE Web address: <http://www.fe.doe.gov/programs/gasregulation/index.html>.

Issued in Washington, DC, on February 21, 2013.

John A. Anderson,

Manager, Natural Gas Regulatory Activities, Office of Oil and Gas Global Security and Supply, Office of Fossil Energy.

[FR Doc. 2013-04540 Filed 2-26-13; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

U.S. Energy Information Administration

Agency Information Collection Extension

AGENCY: U.S. Energy Information Administration (EIA), Department of Energy (DOE).

ACTION: Agency Information Collection Activities: Information Collection Extension; Notice and Request for Comments.

SUMMARY: The EIA, pursuant to the Paperwork Reduction Act of 1995, intends to extend for three years with the Office of Management and Budget (OMB), Form FE-746R, "Natural Gas Imports and Exports." Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, 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 automated collection techniques or other forms of information technology.

DATES: Comments regarding this proposed information collection must be received on or before April 29, 2013. If you anticipate difficulty in submitting comments within that period, contact

the person listed in **ADDRESSES** as soon as possible.

ADDRESSES: Send comments to Lisa Tracy. To ensure receipt of the comments by the due date, submission by email (lisa.tracy@hq.doe.gov) is recommended. The mailing address is U.S. Department of Energy (FE-34), Office of Natural Gas Regulatory Activities, Office of Fossil Energy, P.O. Box 44375, Washington, DC 20026-4375, Attn: Lisa Tracy. Alternatively, Ms. Tracy may be contacted by telephone at (202) 586-4523 or by fax at (202) 586-6050.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of the information collection instrument and instructions should be directed to Lisa Tracy at the contact information given above. Forms and instructions are also available on the Internet at: http://www.fe.doe.gov/programs/gasregulation/report_guidelines.html.

SUPPLEMENTARY INFORMATION: This information collection request contains:

- (1) OMB No.: 1901-0294;
- (2) Information Collection Request Title: Natural Gas Imports and Exports;
- (3) Type of Request: Three-year extension;

(4) Purpose: The Federal Energy Administration Act of 1974 (15 U.S.C. 761 et seq.) and the DOE Organization Act (42 U.S.C. 7101 et seq.) require the EIA to carry out a centralized, comprehensive, and unified energy information program. This program collects, evaluates, assembles, analyzes, and disseminates information on energy resource reserves, production, demand, technology, and related economic and statistical information. This information is used to assess the adequacy of energy resources to meet near and longer term domestic demands.

The EIA, as part of its effort to comply with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), provides the general public and other Federal agencies with opportunities to comment on collections of energy information conducted by or in conjunction with the EIA. Also, the EIA will later seek approval by the Office of Management and Budget (OMB) under Section 3507(a) of the Paperwork Reduction Act of 1995.

DOE's Office of Fossil Energy (FE) is delegated the authority to regulate natural gas imports and exports under section 3 of the Natural Gas Act of 1938, 15 U.S.C. 717b. In order to carry out its delegated responsibility, FE requires those persons seeking to import or export natural gas to file an application providing basic information on the

scope and nature of the proposed import/export activity. Once an importer or exporter receives authorization from FE, they are required to submit monthly reports of all import and export transactions. Form FE-746R collects critical information on U.S. natural gas trade including: name of importer/exporter; country of origin/destination; international point of entry/exit; name of supplier; volume; price; transporters; U.S. geographic market(s) served; and duration of supply contract on a monthly basis. The data, published in *Natural Gas Imports and Exports*, are used to ensure compliance with the terms and conditions of the authorizations. In addition, the data are used to monitor North American gas trade, which, in turn, enables the Federal government to perform market and regulatory analyses; improve the capability of industry and the government to respond to any future energy-related supply problems; and keep the general public informed of international natural gas trade;

(4a) Proposed Changes to Information Collection:

FE proposes to include two additional reporting sections for the collection and identification of new types of natural gas transactions related to:

(a) Exports of compressed natural gas by truck; and

(b) Exports of liquefied natural gas by vessel in ISO containers;

(5) *Annual Estimated Number of Respondents:* 326;

(6) *Annual Estimated Number of Total Responses:* 4,099;

(7) *Annual Estimated Number of Burden Hours:* 12,978; and

(8) *Annual Estimated Reporting and Recordkeeping Cost Burden:* \$0; FE estimates that there are no additional costs to respondents associated with the surveys other than the costs associated with the burden hours.

Statutory Authority: Section 13(b) of the Federal Energy Administration Act of 1974, Public Law 93-275, codified at 15 U.S.C. 772(b) and Section 3 of the Natural Gas Act of 1938, codified at 15 U.S.C. 717b.

Issued in Washington, DC, on February 21, 2013.

Stephanie Brown,

Director, Office of Survey Development and Statistical Integration, U.S. Energy Information Administration.

[FR Doc. 2013-04546 Filed 2-26-13; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER12-1179-003.
Applicants: Southwest Power Pool, Inc.

Description: Integrated Marketplace Compliance Filing to be effective 3/1/2014.

Filed Date: 2/15/13.

Accession Number: 20130215-5167.

Comments Due: 5 p.m. ET 3/8/13.

Docket Numbers: ER13-940-000.

Applicants: Midwest Independent Transmission System Operator, Inc.

Description: Midwest Independent Transmission System Operator, Inc. submits Notice of Termination of Generator Interconnection Agreement No. 1983 for Project G590.

Filed Date: 2/15/13.

Accession Number: 20130215-5091.

Comments Due: 5 p.m. ET 3/8/13.

Docket Numbers: ER13-941-000.

Applicants: San Diego Gas & Electric Company.

Description: SDGE Transmission Owner Tariff TO4 Formula to be effective 9/1/2013.

Filed Date: 2/15/13.

Accession Number: 20130215-5156.

Comments Due: 5 p.m. ET 3/8/13.

Docket Numbers: ER13-942-000.

Applicants: Pacific Gas and Electric Company.

Description: Amendment to Lathrop Irrigation District IA and WDT SA No. 23 to be effective 2/18/2013.

Filed Date: 2/15/13.

Accession Number: 20130215-5159.

Comments Due: 5 p.m. ET 3/8/13.

Docket Numbers: ER13-943-000.

Applicants: Pacific Gas and Electric Company.

Description: CCSF IA—2013 Annual Adjustment to Traffic Light Costs to be effective 2/1/2013.

Filed Date: 2/15/13.

Accession Number: 20130215-5162.

Comments Due: 5 p.m. ET 3/8/13.

Docket Numbers: ER13-944-000.

Applicants: Ohio Valley Electric Corporation.

Description: Pro Forma SGIP (Attachment O) and SGIA (Attachment P) to be effective 9/3/2010.

Filed Date: 2/15/13.

Accession Number: 20130215-5163.

Comments Due: 5 p.m. ET 3/8/13.

Docket Numbers: ER13-945-000.

Applicants: Midwest Independent Transmission System Operator, Inc., Entergy Services, Inc.

Description: 02-15-13 Entergy Attachment P to be effective 12/19/2013.

Filed Date: 2/15/13.

Accession Number: 20130215-5166.

Comments Due: 5 p.m. ET 3/8/13.

Docket Numbers: ER13-946-000.

Applicants: Avista Corporation.

Description: Avista Corp Cancellation of KEC Unsigned SA to be effective 2/19/2013.

Filed Date: 2/19/13.

Accession Number: 20130219-5004.

Comments Due: 5 p.m. ET 3/12/13.

Docket Numbers: ER13-947-000.

Applicants: Alabama Power Company.

Description: Mobile Energy (Hog Bayou) Interconnection Agreement Amendment Filing to be effective 1/18/2013.

Filed Date: 2/19/13.

Accession Number: 20130219-5006.

Comments Due: 5 p.m. ET 3/12/13.

Docket Numbers: ER13-948-000.

Applicants: Entergy Services, Inc., Midwest Independent Transmission System Operator, Inc.

Description: Entergy Services, Inc., et al. submits Attachment O Templates to MISO Open Access Transmission, Energy and Operating Reserve Markets Tariff on behalf of Entergy Arkansas, Inc., et al.

Filed Date: 2/15/13.

Accession Number: 20130215-5187.

Comments Due: 5 p.m. ET 3/8/13.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Dated: February 19, 2013.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2013-04431 Filed 2-26-13; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission****Combined Notice of Filings #2**

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER13–895–001.
Applicants: ISO New England Inc.
Description: Amendment to MR Chges to Modify DA Energy Market Sch. to be effective 12/31/9998.

Filed Date: 2/19/13.

Accession Number: 20130219–5168.

Comments Due: 5 p.m. ET 2/28/13.

Docket Numbers: ER13–949–000.

Applicants: Southern California Edison Company.

Description: Revised Added Facilities Rate for Agmts under WDAT 1 of 4 to be effective 1/1/2013.

Filed Date: 2/19/13.

Accession Number: 20130219–5109.

Comments Due: 5 p.m. ET 3/12/13.

Docket Numbers: ER13–950–000.

Applicants: Southern California Edison Company.

Description: Revised Added Facilities Rate for Agmts under WDAT 2 of 4 to be effective 1/1/2013.

Filed Date: 2/19/13.

Accession Number: 20130219–5116.

Comments Due: 5 p.m. ET 3/12/13.

Docket Numbers: ER13–951–000.

Applicants: Southern California Edison Company.

Description: Revised Added Facilities Rate for Agmts under WDAT 3 of 4 to be effective 1/1/2013.

Filed Date: 2/19/13.

Accession Number: 20130219–5122.

Comments Due: 5 p.m. ET 3/12/13.

Docket Numbers: ER13–952–000.

Applicants: Southern California Edison Company.

Description: Revised Added Facilities Rate for Agmts under WDAT 4 of 4 to be effective 1/1/2013.

Filed Date: 2/19/13.

Accession Number: 20130219–5134.

Comments Due: 5 p.m. ET 3/12/13.

Docket Numbers: ER13–953–000.

Applicants: Mesquite Solar 1, LLC.
Description: Mesquite Solar 1 LLC Joinder Agreement and Amendment to be effective 2/22/2013.

Filed Date: 2/19/13.

Accession Number: 20130219–5139.

Comments Due: 5 p.m. ET 3/12/13.

Docket Numbers: ER13–954–000.

Applicants: Northern States Power Company, a Minnesota corporation, Northern States Power Company, a Wisconsin corporation.

Description: 2013 Interchange Agreement to be effective 1/1/2013.

Filed Date: 2/19/13.

Accession Number: 20130219–5140.

Comments Due: 5 p.m. ET 3/12/13.

Docket Numbers: ER13–955–000.

Applicants: Mesquite Power, LLC.

Description: Mesquite Power, LLC Concurrence to Joinder Agreement and Amendment to be effective 2/22/2013.

Filed Date: 2/19/13.

Accession Number: 20130219–5151.

Comments Due: 5 p.m. ET 3/12/13.

Docket Numbers: ER13–956–000.

Applicants: Arizona Public Service Company.

Description: Arizona Public Service files three Mead Phoenix Project Service Agreements to be effective 4/22/2013.

Filed Date: 2/19/13.

Accession Number: 20130219–5155.

Comments Due: 5 p.m. ET 3/12/13.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Filed Date: 2/19/13.

Accession Number: 20130219–5155.

Comments Due: 5 p.m. ET 3/12/13.

Dated: February 19, 2013.
Nathaniel J. Davis, Sr.,
Deputy Secretary.
[FR Doc. 2013–04432 Filed 2–26–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER11–2970–004.

Applicants: Peetz Logan Interconnect, LLC.

Description: Peetz Logan Interconnect, LLC to be effective 11/1/2011.

Filed Date: 2/19/13.

Accession Number: 20130219–5184.

Comments Due: 5 p.m. ET 3/12/13.

Docket Numbers: ER13–957–000.

Applicants: California Independent System Operator Corporation.

Description: 2013–02–19 Price Consistency to be effective 5/1/2013.

Filed Date: 2/19/13.

Accession Number: 20130219–5175.

Comments Due: 5 p.m. ET 3/12/13.

Docket Numbers: ER13–958–000.

Applicants: Sunpower Corporation.

Description: Petition by SunPower Corporation for Limited Waiver of certain California Independent System Operator Corporation L.L.C. Open Access Transmission Tariff provisions of Appendix GG.

Filed Date: 2/19/13.

Accession Number: 20130219–5185.

Comments Due: 5 p.m. ET 3/12/13.

Docket Numbers: ER13–959–000.

Applicants: Duke Energy Carolinas, LLC.

Description: Formula Rate Filing (Various Corrections) to be effective 7/2/2012.

Filed Date: 2/20/13.

Accession Number: 20130220–5025.

Comments Due: 5 p.m. ET 3/13/13.

Docket Numbers: ER13–960–000.

Applicants: PJM Interconnection, L.L.C.

Description: Notice of Cancellation of First Revised SA No. 2925 in Docket No. ER12–520–000 to be effective 9/26/2012.

Filed Date: 2/20/13.

Accession Number: 20130220–5026.

Comments Due: 5 p.m. ET 3/13/13.

Docket Numbers: ER13–961–000.

Applicants: PJM Interconnection, L.L.C.

Description: Notice of Cancellation of Second Revised SA No. 2789 in Docket No. ER12–521–000 to be effective 9/26/2012.

Filed Date: 2/20/13.

Accession Number: 20130220–5027.

Comments Due: 5 p.m. ET 3/13/13.

Take notice that the Commission received the following electric reliability filings:

Docket Numbers: RR12–8–001.

Applicants: North American Electric Reliability Corp.

Description: Compliance Filing of the North American Electric Reliability Corporation in Response to December 20, 2012 Commission Order.

Filed Date: 2/19/13.

Accession Number: 20130219–5190.

Comments Due: 5 p.m. ET 3/21/13.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211

and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Dated: February 20, 2013.

Nathaniel J. Davis, Sr.,
Deputy Secretary.

[FR Doc. 2013-04493 Filed 2-26-13; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP13-577-000.
Applicants: Natural Gas Pipeline Company of America.
Description: Natural Gas Pipeline Company of America LLC submits tariff filing per 154.204: JP Morgan Neg Rate to be effective 4/1/2013.
Filed Date: 2/21/13.
Accession Number: 20130221-5053.
Comments Due: 5 p.m. ET 3/5/13.

Docket Numbers: RP13-578-000.
Applicants: Natural Gas Pipeline Company of America.
Description: Natural Gas Pipeline Company of America LLC submits tariff filing per 154.204: Wisconsin Electric Neg Rates to be effective 4/1/2013.
Filed Date: 2/21/13.
Accession Number: 20130221-5054.
Comments Due: 5 p.m. ET 3/5/13.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Dated: February 21, 2013.

Nathaniel J. Davis, Sr.,
Deputy Secretary.

[FR Doc. 2013-04494 Filed 2-26-13; 8:45 am]

BILLING CODE 6717-01-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2013-0092; FRL-9379-2]

Diflubenzuron; Receipt of Application for Emergency Exemption; Solicitation of Public Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received a specific exemption request from the Wyoming Department of Agriculture to use the pesticide diflubenzuron (CAS No. 35367-38-5) to treat up to 26,000 acres of alfalfa to control grasshoppers and Mormon crickets. The applicant proposes a use which is supported by the Interregional (IR)-4 program and has been requested in 5 or more previous years, and a petition for tolerance has not yet been submitted to the Agency. EPA is soliciting public comment before making the decision whether or not to grant the exemption.

DATES: Comments must be received on or before March 14, 2013.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2013-0092, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Andrea Conrath, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (703) 308-9356; fax number: (703) 605-0781; email address: conrath.andrea@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. What should I consider as I prepare my comments for EPA?

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

2. *Tips for preparing your comments.* When submitting comments, remember to:

- Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticide(s) discussed in this document, compared to the general population.

II. What action is the agency taking?

Under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136p), at the discretion of the EPA Administrator, a Federal or State agency may be exempted from any provision of FIFRA if the EPA Administrator determines that emergency conditions exist which require the exemption. The Wyoming Department of Agriculture has requested the EPA Administrator to issue a specific exemption for the use of diflufenuron on alfalfa to control grasshoppers and Mormon crickets. Information in accordance with 40 CFR part 166 was submitted as part of this request.

As part of this request, the applicant asserts that projected population levels for these damaging insect pests are higher than normal for the 2013 season. The applicant claims that registered alternatives will not provide adequate control to avert significant economic losses from occurring.

The Applicant proposes to make no more than two applications of diflufenuron, at a rate of 0.032 lbs. active ingredient (a.i.) (equivalent to 2 fl. oz. of product containing 2 lbs. a.i. per gallon). Application could be made on up to 26,000 acres of alfalfa, from the date of approval, if granted, until October 31, 2013, in the state of Wyoming. If the maximum proposed acreage were treated at the maximum rate, a total of 814 lbs. active ingredient (407 gallons formulated product) could be applied.

This notice does not constitute a decision by EPA on the application itself. The regulations governing FIFRA

section 18 require publication of a notice of receipt of an application for a specific exemption proposing use which is supported by the Inter-Regional Project Number 4 (IR-4) program and has been requested in 5 or more previous years, and a petition for tolerance has not yet been submitted to the Agency. The notice provides an opportunity for public comment on the application.

The Agency will review and consider all comments received during the comment period in determining whether to issue the specific exemption requested by the Wyoming Department of Agriculture.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: February 15, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2013-04561 Filed 2-26-13; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2013-0010; FRL-9377-5]

Pesticide Experimental Use Permit; Receipt of Application; Comment Request

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's receipt of an application 71049-EUP-L from KIM-C1, LLC, requesting an experimental use permit (EUP) for the plant growth regulator, forchlorfenuron. The Agency has determined that the permit may be of regional and national significance. Therefore, because of the potential significance, EPA is seeking comments on this application.

DATES: Comments must be received on or before March 29, 2013.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2013-0010, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

Cynthia Giles-Parker, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (703) 305-7740; email address: giles-parker.cynthia@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. Although this action may be of particular interest to those persons who conduct or sponsor research on pesticides, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. What should I consider as I prepare my comments for EPA?

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

2. *Tips for preparing your comments.* When submitting comments, remember to:

- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
- ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticide(s) discussed in this document, compared to the general population.

II. What action is the agency taking?

Under section 5 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. 136c, EPA can allow manufacturers to field test pesticides under development. Manufacturers are required to obtain an EUP before testing new pesticides or new uses of pesticides if they conduct experimental field tests on 10 acres or more of land or one acre or more of water.

Pursuant to 40 CFR 172.11(a), the Agency has determined that the following EUP application may be of regional and national significance, and therefore is seeking public comment on the EUP application.

Submitter: KIM-C1, LLC, 2547 W. Shaw Avenue, Suite 116, Fresno, CA 93711.

EUP Number: 71049-EUP-L.

Pesticide Chemical: Forchlorfenuron.

Type of Chemical: Plant Growth Regulator.

Summary of Request: Crop Uses and Timing of Application (only one application permitted per crop per year): Almond from 80% petal fall to the time when nutlet length averages 4–6 millimeters (mm); cherry at shuck split or a later application at straw color to color break; fig when average fig is 12–

15 mm; pear at 15–25 days post-petal fall; pistachio at beginning of kernel formation when shells start to fill at approximately 5–7 weeks after bloom; plum/prune during bloom. The amount of chemical product to be used is 77,400 fluid ounces or 605 gallons on 1,935 acres. from 2013–2015.

A copy of the application and any information submitted is available for public review in the docket established for this EUP application.

Following the review of the application and any comments and data received in response to this solicitation, EPA will decide whether to issue or deny the EUP request, and if issued, the conditions under which it is to be conducted. Any issuance of an EUP will be announced in the **Federal Register**.

List of Subjects

Environmental protection, Experimental use permits.

Dated: February 15, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2013–04527 Filed 2–26–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2009–0879; FRL–9379–7]

Exposure Modeling Public Meeting; Notice of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: An Exposure Modeling Public Meeting (EMPM) will be held for one day on March 19, 2013. This notice announces the location and time for the meeting and sets forth the tentative agenda topics.

DATES: The meeting will be held on March 19, 2013 from 9:00 a.m. to 4:00 p.m. Requests to participate in the meeting must be received on or before March 11, 2013.

To request accommodation of a disability, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**, preferably at least 10 days prior to the meeting, to give EPA as much time as possible to process your request.

ADDRESSES: The meeting will be held at the Environmental Protection Agency, Office of Pesticide Programs (OPP), One Potomac Yard (North Building), Fourth Floor Conference Center (N–4830), 2777 S. Crystal Drive, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT:

Gabe Rothman, Environmental Fate and Effects Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 347–8011; fax number: (703) 305–6309; email address: rothman.gabe@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are required to conduct testing of chemical substances under the Toxic Substances Control Act (TSCA), the Federal Food, Drug, and Cosmetic Act (FFDCA), or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Agriculture, Forestry, Fishing and Hunting NAICS code 11
- Utilities NAICS code 22
- Professional, Scientific and Technical NAICS code 54

B. How can I get copies of this document and other related information?

The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2009–0879, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

II. Background

On a biannual interval, an Exposure Modeling Public Meeting will be held for presentation and discussion of current issues related to modeling pesticide fate, transport, and exposure of risk assessment in a regulatory

context. Meeting dates and abstract requests are announced through the "emplist" forum on the LYRIS list server at https://lists.epa.gov/read/all_forums/.

III. How can I request to participate in this meeting?

You may submit a request to participate in this meeting to the person listed under **FOR FURTHER INFORMATION CONTACT**. Do not submit any information in your request that is considered CBI. Requests to participate in the meeting, identified by docket ID number EPA-HQ-OPP-2009-0879, and must be received on or before March 11, 2013.

IV. Tentative Topics for the Meeting

Update on Development of the Spatial Aquatic Model (SAM).
Pesticide Root Zone Model for Ground Water Model (PRZM-GW) Implementation.
Pesticide Flooded Application Model (PFAM) Implementation.
Recent Developments for Drinking Water Intakes Percent Cropped Area (DWI PCA) Guidance.
Other topics related to environmental exposure modeling and monitoring of pesticides in surface water, ground water, soil, air, and biota.

List of Subjects

Environmental protection, pesticide exposure assessment, exposure modeling, pesticide monitoring, groundwater, PRZM-GW, SAM, PFAM, DWI PCA.

Dated: February 13, 2013.

Donald J. Brady,

Director, Environmental Fate and Effects Division, Office of Pesticide Programs.

[FR Doc. 2013-04407 Filed 2-26-13; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL 9785-7; CERCLA-04-2013-3755]

Florida Petroleum Reprocessors Site; Davie, Broward County, FL; Notice of Settlement

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Settlement.

SUMMARY: Under 122(h) of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), the United States Environmental Protection Agency has entered into a settlement with 2238 NW 86th Street Inc. concerning the Florida Petroleum Reprocessors Site located in Davie, Broward County, Florida. The

settlement addresses the PRP's Site-wide liability on an Ability-to-Pay basis.

DATES: The Agency will consider public comments on the settlement until March 29, 2013. The Agency will consider all comments received and may modify or withdraw its consent to the settlement if comments received disclose facts or considerations which indicate that the settlement is inappropriate, improper, or inadequate.

ADDRESSES: Copies of the settlement are available from Ms. Paula V. Painter. Submit your comments by Site name Florida Petroleum Reprocessors Site by one of the following methods:

- www.epa.gov/region4/superfund/programs/enforcement/enforcement.html.
- Email: Painter.Paula@epa.gov.
- U.S. Environmental Protection Agency, 61 Forsyth Street SW., Atlanta, Georgia 30303.

FOR FURTHER INFORMATION CONTACT: Paula V. Painter at 404/562-8887.

Dated: January 22, 2013.

Anita L. Davis,

Chief, Superfund Enforcement & Information Management Branch, Superfund Division.

[FR Doc. 2013-04610 Filed 2-26-13; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-9785-2; EPA-R01-OEP-FRL#: 13-007]

State Program Requirements; Approval of Maine's National Pollutant Discharge Elimination System (NPDES) Permitting Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice. Proposal To Approve Maine's National Pollutant Discharge Elimination System (NPDES) Permitting Program.

SUMMARY: In 1999 the State of Maine applied to implement its NPDES program under the Clean Water Act in the state, including the territories of the Aroostook Band of Micmacs and the Houlton Band of Maliseet Indians. Today, EPA is proposing to act on the state's application as it applies in those Indian territories and is inviting comment.

DATES: Interested persons may submit comments on the approval of Maine's NPDES Permitting Program in these territories as part of the administrative record to EPA—Region 1, at the address given below, no later than midnight through April 29, 2013.

ADDRESSES: Submit comments by one of the following methods:

- Email: velez.glenda@epa.gov.
- Mail: Glenda Vélez, USEPA-Region 1, 5 Post Office Square—OEP06-01, Boston, MA 02109-3912.
- No facsimiles (faxes) will be accepted.

FOR FURTHER INFORMATION: Additional information concerning the proposed approval of Maine's program in these territories may be obtained between the hours of 9 a.m. and 5 p.m. Monday through Friday excluding holidays from: Glenda Vélez, USEPA-Region 1, 5 Post Office Square—OEP06-01, Boston, MA 02109-3912, Telephone: 617-918-1677, Email: velez.glenda@epa.gov.

SUPPLEMENTARY INFORMATION:

2001 Approval of Maine's Base NPDES Permitting Program

On December 17, 1999, EPA determined that the State of Maine had submitted a complete application to administer the National Pollutant Discharge Elimination System (NPDES) permitting program in the state under the Clean Water Act (CWA). 33 U.S.C. 1251, *et seq.*, see 64 FR 73552 (Dec. 30, 1999). Maine's application included an assertion of authority to implement the program in the territories of the federally-recognized Indian tribes within the state, based on the jurisdictional provisions of the Maine Indian Claims Settlement Act (MICSA), which ratified the Maine Implementing Act (MIA). 25 U.S.C. 1721, *et seq.* and 30 M.R.S.A. § 6201, *et seq.*, respectively.

On January 12, 2001, EPA approved the State of Maine's application to administer the NPDES program for all areas of the state other than Indian country. At that point EPA did not take any action on Maine's application to administer the program within the territories of the federally-recognized Indian tribes in Maine. EPA published notice of its action on February 28, 2001. 56 FR 12791. As described in the **Federal Register**, EPA approved the state's application to administer both the NPDES permit program covering point source dischargers and the pretreatment program covering industrial dischargers into publicly owned treatment works (POTWs). EPA did not authorize the state to regulate cooling water intake structures under CWA section 316(b) (33 U.S.C. 1326(b)). 56 FR at 12792.

2003 Partial Approval of Maine's Program in Indian Territories

On October 31, 2003, EPA approved the State of Maine's application to administer the NPDES program in the

Indian territories of the Penobscot Indian Nation and the Passamaquoddy Tribe, with the exception of any discharges that qualified as “internal tribal matters” under MICSA and MIA. 68 FR 65052 (Nov. 18, 2003). This action generally authorized the state to administer the NPDES program in the territories of the two largest Indian tribes in the state, finding that the combination of MICSA and MIA created a unique jurisdictional arrangement that granted the state authority to issue permits to dischargers. EPA did not approve the state’s program to regulate two small tribally-owned and operated POTWs. EPA determined that permitting these POTWs qualified as an internal tribal matter and, therefore, fell within an enumerated exception to the grant of jurisdiction to the state in MICSA and MIA. EPA also did not take action on the state’s application as it applied to the territories of the two other federally-recognized tribes in the state, the Houlton Band of Maliseet Indians and the Aroostook Band of Micmacs. These two tribes are subject to jurisdictional provisions different from those that apply to the Penobscot and Passamaquoddy tribes.

2012 Approval of Maine’s Program as to Penobscot and Passamaquoddy Tribal Discharges

On March 26, 2012, EPA approved Maine’s NPDES program to apply to tribally owned and operated discharges in the territories of the Penobscot Nation and Passamaquoddy Tribe (the “southern tribes”), pursuant to the decision of the Federal Court of Appeals for the First Circuit. 77 FR 23481 (April 19, 2012). The court had found that such discharges did not qualify as internal tribal matters and were, therefore, subject to the laws of the state. *Maine v. Johnson*. 498 F.3d 37 (1st Cir. 2007). As a result, EPA approved the state to implement its program in the territories of the southern tribes without exception. Accordingly, the state assumed responsibility from EPA for issuing and administering the two permits EPA had previously withheld for the Penobscot Nation Indian Island treatment works (EPA NPDES Permit No. ME 0101311 and MEPDES License No. 2672) and the Passamaquoddy Tribal Council treatment works (EPA NPDES Permit No. 1011773 and MEPDES License No. 2561). In that action the EPA only approved the state’s program with respect to the two permits for the two tribal treatment works. EPA did not take action on Maine’s program application with respect to the Aroostook Band of Micmacs and

Houlton Band of Maliseet Indians (the “northern tribes”).

Intervening Legal Developments

In the process leading up to EPA’s 2003 partial approval of the state’s program in Indian country, EPA had invited comment on the state’s jurisdiction under MICSA to implement its program in the territories of all the Indian tribes in Maine, including the northern tribes. Since EPA’s initial decision to defer action on the state’s application as it applies to the northern tribes, the Federal Court of Appeals for the First Circuit has issued several opinions which clarify the operation of MICSA’s jurisdictional provisions as they apply to those tribes. Therefore, EPA is again inviting comment on Maine’s application to administer its program in the northern tribes’ territories so that interested parties can address those opinions and any other aspects of Maine’s NPDES program relevant to authorizing the state’s NPDES program in these tribes’ territories. In this way, EPA can respond to comments that more accurately reflect the current state of the law and program implementation, rather than comments from 2000 and 2001.

In brief, there are three decisions from the First Circuit that EPA expects will guide the Agency’s analysis of the jurisdictional issues in acting on Maine’s application as it applies to the northern tribes. The first is *Maine v. Johnson*. 498 F.3d 37. As described above, the court held that MICSA’s “internal tribal matters” exception to the state’s jurisdiction over the southern tribes did not include discharges of pollutants into navigable waters to be permitted under Maine’s program. *Id.* at 46. Therefore, Maine’s state permitting program applies without exception in the territories of the southern tribes, and the state has jurisdiction sufficient for EPA to approve the state’s program under the federal Clean Water Act.

Second, in *Aroostook Band of Micmacs v. Ryan*, 484 F.3d 41 (2007) the court held that MICSA made the Aroostook Band subject to the state’s jurisdiction without the exception for “internal tribal matters” that is available to the southern tribes. *Id.* at 50. Third, in *Houlton Band of Maliseet Indians v. Ryan* the court extended this analysis to the Maliseet tribe. 484 F.3d 73, 74–75 (1st Cir. 2007). In both these cases, each tribe sought to block enforcement of Maine’s antidiscrimination laws in connection with the tribes’ decision to terminate the employment of certain tribal government employees. The court held that the tribes were subject to state

regulation when making such employment decisions.

Proposed Action on Maine’s Program

Employment decisions by tribal governments qualify as an internal tribal matter with respect to the southern tribes and, therefore, are beyond the reach of state regulation under MICSA. *Penobscot Nation v. Fellecker*, 164 F.3d 706 (1st Cir. 1999). In its pair of decisions in 2007, the First Circuit clarified that the scope of Maine’s jurisdictional authority over the northern tribes reaches further than the state’s authority over the southern tribes, and the state can regulate matters of the northern tribes that would qualify as internal tribal matters of the southern tribes. The First Circuit has ruled that the state has adequate authority to implement its NPDES program in the territories of the southern tribes, even in the face of the internal tribal matters exception the southern tribes have from state regulation. It appears to follow, therefore, that Maine has an even stronger claim of authority to implement its NPDES program in the territories of the northern tribes.

Accordingly, EPA proposes to approve the state to implement its NPDES program in the territories of the Houlton Band of Maliseet Indians and the Aroostook Band of Micmacs, provided Maine submits and EPA approves a program addressing the requirements of CWA section 316(b) as described below. EPA invites comment on both the determination of the state’s jurisdiction to implement the program in these tribes’ territories and the respective roles of the state, tribes, and EPA in the context of a state implementing the NPDES program in the territories of federally recognized tribes in Maine.¹

Note that in 2001 when EPA first approved the state’s program, Maine did not have authority to regulate cooling water intake structures under CWA section 316(b). The state has since granted Maine DEP that authority, and EPA is working with DEP to develop the state regulations necessary for Maine to implement that program. Once Maine submits that program, EPA will publish a separate notice inviting comment on the adequacy of Maine’s section 316(b) program before taking final action to approve the state’s NPDES program, including the section 316(b) program, in these territories. The Agency is inviting comment now on the balance of the

¹ Neither tribe has applied to EPA to implement the NPDES permit program, so this proposed action does not invite comment on the question of whether either tribe has authority to implement the program.

state's permitting program and the jurisdictional issue.

Authority: This action is proposed to be taken under the authority of Section 402 of the Clean Water Act as amended, 42 U.S.C. 1342.

Dated: January 31, 2013.

H. Curtis Spalding,

Regional Administrator, Region 1.

[FR Doc. 2013-04531 Filed 2-26-13; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Submission for OMB Review; Comment Request; Purchaser Eligibility Certification

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, 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 revision of an existing information collection, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). On December 18, 2012 (77 FR 74847), the FDIC requested comment for 60 days on a proposal to revise its Purchaser Eligibility Certification information collection, which is currently approved under OMB Control No. 3064-0135. No comments were received on the proposal. The FDIC hereby gives notice of its plan to submit to OMB a request to approve revision of the collection.

DATES: Comments must be submitted on or before March 29, 2013.

ADDRESSES: Interested parties are invited to submit written comments to the FDIC by any of the following methods:

- *http://www.FDIC.gov/regulations/laws/federal/notices.html.*
- *Email: comments@fdic.gov.* Include the name of the collection in the subject line of the message.
- *Mail:* Leneta G. Gregorie (202-898-3719), Counsel, Room NY-5050, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429.
- *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 17th Street Building (located on F Street), on business days between 7:00 a.m. and 5:00 p.m.

All comments should refer to the relevant OMB control number. A copy of the comments may also be submitted to the OMB desk officer for the FDIC:

Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Leneta G. Gregorie, at the FDIC address above.

SUPPLEMENTARY INFORMATION: Proposal to revise the following currently approved collection of information:

Title: Asset Purchaser Eligibility Certification.

OMB Number: 3064-0135.

Form Number: FDIC 7300/06, "Purchaser Eligibility Certification"; 7300/07, "Pre-Qualification Request"; and 7300/08, "Contact Information Form".

Frequency of Response: On occasion.
Affected Public: Business or other financial institutions.

Estimated Number of Respondents: 600.

Estimated Time per Response: 1.0 hour (*Purchaser Eligibility Certification*, 30 minutes; *Pre-Qualification Request*, 20 minutes; and *Contact Information Form*, 10 minutes).

Total Annual Burden: 600 hours.

General Description of Collection: The FDIC uses the *Purchaser Eligibility Certification* form, FDIC Form No. 7300/06, to identify prospective bidders who are not eligible to purchase assets of failed institutions from the FDIC. Specifically, section 11(p) of the Federal Deposit Insurance Act prohibits the sale of assets of failed institutions to certain individuals or entities that profited or engaged in wrongdoing at the expense of those failed institutions, or seriously mismanaged those failed institutions. The FDIC is proposing to update the Privacy Act Statement in the *Purchaser Eligibility Certification* form. In addition, the FDIC is proposing to add two forms to the Purchaser Eligibility Certification information collection: the *Pre-Qualification Request* form, FDIC Form No. 7300/07, is designed to determine which prospective bidders are qualified to bid on particular types of assets offered by the FDIC (e.g., securities, mortgage servicing portfolios, shared national credits. Interests in structured transactions, credit card receivables) for which no further qualification criteria are required to be met and to ensure that prospective bidders understand the terms and conditions of asset sales; and the *Contact Information Form*, FDIC Form No. 7300/08, determines the type of assets a prospective bidder is interested in and facilitates communication with the prospective bidder. A link to copies of the forms can be found directly beneath this notice on the FDIC's

Federal Register Citations Web page at: <http://www.fdic.gov/regulations/laws/federal/notices.html>.

Request for Comment

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collection, 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 information collection on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Dated at Washington, DC, this 21st day of February 2013.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2013-04438 Filed 2-26-13; 8:45 am]

BILLING CODE 6714-01-P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments on the agreements to the Secretary, Federal Maritime Commission, Washington, DC 20573, within ten days of the date this notice appears in the **Federal Register**. Copies of the agreements are available through the Commission's Web site (www.fmc.gov) or by contacting the Office of Agreements at (202)-523-5793 or tradeanalysis@fmc.gov.

Agreement No.: 010979-052.

Title: Caribbean Shipowners Association.

Parties: CMA CGM, S.A.; Seaboard Marine, Ltd.; Seafreight Line, Ltd.; Tropical Shipping and Construction Company Limited; and Zim Integrated Shipping Services, Ltd.

Filing Party: Wayne R. Rohde, Esq.; Cozen O'Connor, 1627 I Street NW.; Washington, DC 20006.

Synopsis: The amendment would add the Cayman Islands to the geographic scope of the agreement.

Agreement No.: 012129.

Title: EUKOR/"K" Line Space Charter Agreement.

Parties: EUKOR Car Carriers, Inc. and Kawasaki Kisen Kaisha, Ltd.

Filing Party: John P. Meade, Esq.; Vice-President; K-Line America, Inc.; 6009 Bethlehem Road; Preston, MD 21655.

Synopsis: The amendment adds Korea to the geographic scope of the agreement and updates the address of Kawasaki Kisen Kaisha, Ltd.

By Order of the Federal Maritime Commission.

Dated: February 22, 2013.

Karen V. Gregory,
Secretary.

[FR Doc. 2013-04591 Filed 2-26-13; 8:45 am]

BILLING CODE 6730-01-P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Applicants

The Commission gives notice that the following applicants have filed an application for an Ocean Transportation Intermediary (OTI) license as a Non-Vessel-Operating Common Carrier (NVO) and/or Ocean Freight Forwarder (OFF) pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. 40101). Notice is also given of the filing of applications to amend an existing OTI license or the Qualifying Individual (QI) for a licensee.

Interested persons may contact the Office of Ocean Transportation Intermediaries, Federal Maritime Commission, Washington, DC 20573, by telephone at (202) 523-5843 or by email at OTI@fmc.gov.

AC Alliance USA LLC (NVO & OFF), 1350 Michael Drive, Suite D, Wood Dale, IL 60191. Officers: Matway Gurfinkel, Manager (QI), Andrew Shepin, Manager/Member. Application Type: New NVO & OFF License.

Aduana International Freight Forwarding Services, Inc. (NVO & OFF), #7 Aspac Warehouse Harmon Industrial Warehouse, Harmon, Guam 96921. Officers: Edgar Baterna, Corporate Secretary (QI), Maria Lourdes Austria, President. Application Type: New NVO & OFF License.

AFC LS, LLC (NVO & OFF), 975 Cobb Place Blvd., Suite 101, Kennesaw, GA 30144. Officers: Keith Phillips, Vice President (QI), Glenn Henderson, President. Application Type: New NVO & OFF License.

Air Sea Land Shipping & Moving Inc. (NVO & OFF), 211 East 43rd Street, Suite 1206, New York, NY 10017. Officers: Vajira P. Mendis, President (QI), Rienze D. Fernando, Vice President. Application Type: New NVO & OFF License.

Armada AVS Corp (NVO), 709 E. Walnut Street, Carson, CA 90746. Officers: Oksana Zharkova, Secretary (QI), Vadim Kornilov, President. Application Type: QI Change.

Auto Export Shipping, Inc. dba A.E.S. Inc. (NVO), One Slater Drive, Elizabeth, NJ 07206. Officers: Michael DeCandia, Assistant Secretary (QI), Andrea Amico, President. Application Type: QI Change.

Bright Star Logistics, Inc. (NVO & OFF), 11205 S. La Cienega Blvd., Los Angeles, CA 90045. Officers: Kirk Kim, Secretary (QI), Woo B. Lim, President. Application Type: QI Change.

Darya Globeship, LLC (NVO & OFF), 1252 Stonehaven Court, Lake Mary, FL 32746. Officer: Himjit Sikand, Managing Member (QI). Application Type: New NVO & OFF License.

Delmar International (N.Y.) Inc. dba Delmar International dba Delmar International (USA) (NVO & OFF), One Cross Island Plaza, Suite 115, Rosedale, NY 11422. Officers: Robert Tayler, Vice President (QI), Robert Cutler, President. Application Type: QI Change.

Dongbu Express U.S.A. Inc. (NVO & OFF), 19191 S. Vermont Avenue, Suite 610, Torrance, CA 90502. Officers: Mi Jung Yu, Vice President (QI), Joosup Jung, CEO. Application Type: New NVO & OFF License.

Efreightsolutions LLC (NVO), 5021 Statesman Drive, Suite 200, Irving, TX 75063. Officers: Frank M. Ramirez, Assistant Secretary (QI), William Askew, Member. Application Type: QI Change.

Emarat Shipping Inc. (NVO & OFF), 1150 N. Richfield Road, Suite 8, Anaheim, CA 92807. Officer: Tareq K. Elbarq, President (QI). Application Type: Add OFF Service.

Enter to USA LLC (NVO & OFF), 1553 NW 82 Avenue, Miami, FL 33126. Officers: Julio A. Aninat, Operating Manager (QI), Rodrigo A. Armijo, Manager. Application Type: New NVO & OFF License.

HLI Logistics, LLC (NVO & OFF), 1250 Liberty Avenue, Hillside, NJ 07205. Officers: Ute Bender, Managing Director (QI), Georg Fisher, Operations Director. Application Type: New NVO & OFF License.

Knight(USA), L.L.C. (NVO & OFF), 5 Wellington Court, Eastampton, NJ 08060. Officers: Louis Simone, Operating Manager (QI), Marcario Jack, Member. Application Type: Add OFF Service.

Milogix, Inc. (NVO & OFF), 14747 Artesia Blvd., Suite 5J, La Mirada, CA 90638. Officer: Susan Choe, President

(QI). Application Type: New NVO & OFF License.

Newtrans Worldwide, Inc. (NVO & OFF), 750 Arthur Avenue, Elk Grove Village, IL 60007. Officer: Kenny K. Kim, President (QI). Application Type: Add Trade Name S-Logibis (US), Inc.

Norman G. Jensen, Inc. dba Jensen Marine Services (NVO & OFF), 3050 Metro Drive, Suite 300, Minneapolis, MN 55425. Officers: Roxi Peiffer, Assistant Secretary (QI), Peter Luit, President. Application Type: QI Change.

Ocean Star International, Inc. dba O.S.I. dba International Van Lines (NVO), 3961 NW 126th Avenue, Coral Springs, FL 33065. Officer: Joshua S. Morales, President. Application Type: Removing Trade Name International Van Lines.

Piton Logistics, Inc (NVO & OFF), 1837 South State Road 7, Fort Lauderdale, FL 33317. Officers: Marlene Sookram-Sirju, President (QI), Narina Ramcharitar, Treasurer. Application Type: New NVO & OFF License.

Polmar Cargo, Inc. (NVO & OFF), 1225 NW 93rd Court, Doral, FL 33172. Officers: Handher Amador, Treasurer (QI), Jesus A. Kauam, President. Application Type: New NVO & OFF License.

Ri-Time Group, Inc (NVO), 19254 E. Walnut Drive, Suite 204, City of Industry, CA 91748. Officer: Biyu Gao, President (QI). Application Type: New NVO License.

Royal Shipping Inc. (NVO & OFF), 6846 Whitefield Street, Suite B, Dearborn Heights, MI 48127. Officers: Hussein M. Mazeh, Secretary (QI), Mariam Mazeh, President. Application Type: New NVO & OFF License.

Tapco International, Inc. (NVO & OFF), 990 West 15th Street, Riviera Beach, FL 33404. Officers: Paul Pellitieri, President (QI), Virginia Pellitieri, Vice President. Application Type: New NVO & OFF License.

Trans Atlantic Shipping L.L.C. (NVO & OFF), 25519 Hawks Run Lane, Sorrento, FL 32776. Officers: Timothy A. Voit, Vice President (QI), Stacey L. Wilson, Vice President. Application Type: Add NVO Service.

Weida Freight System, Inc. (NVO), 819 Arbor Vitae, Inglewood, CA 90301. Officers: Maria L. Trujillo, Vice President (QI), Victor Y. Wei, President. Application Type: QI Change & add Trade Name WFS Global Logistics, Inc.

By the Commission.

Dated: February 22, 2013.

Karen V. Gregory,
Secretary.

[FR Doc. 2013-04592 Filed 2-26-13; 8:45 am]

BILLING CODE 6730-01-P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Reissuances

The Commission gives notice that the following Ocean Transportation Intermediary licenses have been reissued pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. 40101) effective on the date shown.

License No.: 017697N.

Name: IREH Logistic Services Inc.
Address: 488 E. Ocean Blvd., Suite 702, Long Beach, CA 90802.

Date Reissued: December 27, 2012.

License No.: 017719NF.

Name: Sunjin Shipping (U.S.A.), Inc.
Address: 149-15 177th Street, Jamaica, NY 11434.

Date Reissued: January 6, 2013.

License No.: 018732N.

Name: Transways Logistics International Inc.

Address: 149-23 182nd Street, Suite 101, Jamaica, NY 11413.

Date Reissued: January 25, 2013.

License No.: 022246N.

Name: Pelham Services, Inc.
Address: 5413 NW. 72nd Avenue, Miami, FL 33166.

Date Reissued: December 23, 2012.

Vern W. Hill,

Director, Bureau of Certification and Licensing.

[FR Doc. 2013-04593 Filed 2-26-13; 8:45 am]

BILLING CODE 6730-01-P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Revocations

The Commission gives notice that the following Ocean Transportation Intermediary licenses have been revoked pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. 40101) effective on the date shown.

License No.: 1695F.

Name: Union Shipping Company.
Address: 7480 NW. 52nd Street, Miami, FL 33166.

Date Revoked: January 14, 2013.

Reason: Failed to maintain a valid bond.

License No.: 001945F.

Name: The I.C.E. Co., Inc.
Address: 1702 Minters Chapel Road, Suite 100, Grapevine, TX 76051.

Date Revoked: January 14, 2013.

Reason: Voluntary Surrender of License.

License No.: 2868F.

Name: Jarvis International Freight, Inc.

Address: 1950 South Starpoint Drive, Houston, TX 77032.

Date Revoked: December 11, 2012.

Reason: Voluntary Surrender of License.

License No.: 017269N.

Name: Fastmark Corporation.
Address: 7206 NW. 84th Avenue, Medley, FL 33166.

Date Revoked: January 22, 2013.

Reason: Failed to maintain a valid bond.

License No.: 017835N.

Name: Multi Link Container Line, LLC.

Address: 20 East Sunrise Highway, Suite 308, Valley Stream, NY 11581.

Date Revoked: January 18, 2013.

Reason: Failed to maintain a valid bond.

License No.: 018732F.

Name: Transways Logistics International Inc.

Address: 149-23 182nd Street, Suite 101, Jamaica, NY 11413.

Date Revoked: January 25, 2013.

Reason: Failed to maintain a valid bond.

License No.: 020829N.

Name: Yishun Logistics (USA) Inc.
Address: 167-43 148th Avenue, 2nd Floor, Jamaica, NY 11434.

Date Revoked: January 25, 2013.

Reason: Failed to maintain a valid bond.

License No.: 021023NF.

Name: Inma Export Corp.
Address: 1208 SW. 2nd Street, Miami, FL 33135.

Date Revoked: January 26, 2013.

Reason: Failed to maintain valid bonds.

License No.: 022332NF.

Name: FS Goodship, LLC.
Address: 699 Lively Blvd., Elk Grove Village, IL 60007.

Date Revoked: January 16, 2013.

Reason: Voluntary Surrender of License.

License No.: 022922N.

Name: Valueway Global Logistics Inc.
Address: 136-31 41st Avenue, Suite 7C, Flushing, NY 11355.

Date Revoked: January 18, 2013.

Reason: Voluntary Surrender of License.

License No.: 023744N.

Name: StarWin Logistics Inc.
Address: 160-51 Rockaway Blvd., Suite 200, Jamaica, NY 11434.

Date Revoked: January 28, 2013.

Reason: Voluntary Surrender of License.

License No.: 023835NF.

Name: Purely Global, Inc.

Address: 15050 SW. 23rd Street, Miami, FL 33185.

Date Revoked: January 30, 2013.

Reason: Voluntary Surrender of License.

Vern W. Hill,

Director, Bureau of Certification and Licensing.

[FR Doc. 2013-04596 Filed 2-26-13; 8:45 am]

BILLING CODE 6730-01-P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than March 14, 2013.

A. Federal Reserve Bank of Richmond (Adam M. Drimer, Assistant Vice President) 701 East Byrd Street, Richmond, Virginia 23261-4528:

1. *Betty J. Wright*, Mount Airy, North Carolina, to individually and together with the Hylton Wright Living Trust Agreement and ARMAT Foundation, as a group acting in concert; to acquire voting shares of Surrey Bancorp, and thereby indirectly acquire voting shares of Surrey Bank & Trust, both in Mount Airy, North Carolina.

Board of Governors of the Federal Reserve System, February 22, 2013.

Margaret McCloskey Shanks,
Deputy Secretary of the Board.

[FR Doc. 2013-04502 Filed 2-26-13; 8:45 am]

BILLING CODE 6210-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-13-0852]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call (404) 639-7570 or send an email to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Prevalence Survey of Healthcare-Associated Infections (HAIs) in Acute Care Hospitals in the United States—Extension—(0920-0852 exp.5/31/13)—National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Preventing healthcare-associated infections (HAIs) is a CDC priority. An essential step in reducing the occurrence of HAIs is to estimate accurately the burden of these infections in U.S. hospitals, and to describe the types of HAIs and causative organisms. The scope and magnitude of HAIs in the United States were last directly estimated in the 1970s by CDC's Study on the Efficacy of Nosocomial Infection Control (SENIC), in which comprehensive data were collected from a sample of 338 hospitals; 5% of hospitalized patients acquired an infection not present at the time of admission. Because of the substantial resources necessary to conduct hospital-wide surveillance in an ongoing

manner, most of the more than 4,500 hospitals now reporting to the CDC's current HAI surveillance system, the National Healthcare Safety Network (NHSN 0920-0666 expires 1/31/15), focus instead on device-associated and procedure-associated infections in a selected patient locations, and do not report data on all types of HAIs occurring hospital-wide. Periodic assessments of the magnitude and types of HAIs occurring in all patient populations within acute care hospitals are needed to inform decisions by local and national policy makers and by hospital infection control personnel regarding appropriate targets and strategies for HAI prevention. Such assessments can be obtained in periodic national prevalence surveys, such as those that have been conducted in several European countries.

In 2008-2009, CDC developed a pilot protocol for a HAI point prevalence survey, conducted over a 1-day period at each of 9 acute care hospitals in one U.S. city. This pilot phase was followed in 2010 by a phase 2, limited roll-out HAI and antimicrobial use prevalence survey, conducted during July and August in 22 hospitals across 10 Emerging Infections Program sites (in California, Colorado, Connecticut, Georgia, Maryland, Minnesota, New Mexico, New York, Oregon, and Tennessee). Experience gained in the phase 1 and phase 2 surveys was used to conduct a full-scale, phase 3 survey in 2011, involving 183 hospitals in the 10 EIP sites. Over 11,000 patients were surveyed, and analysis of HAI and antimicrobial use data is ongoing at this time. Preliminary HAI prevalence results were presented at the 52nd Interscience Conference on Antimicrobial Agents and Chemotherapy (San Francisco, CA, September 8-12, 2012) and preliminary antimicrobial use results were presented at the 2012 IDWeek conference (San Diego, CA, October 17-21, 2012).

An extension of the prevalence survey's existing OMB approval is

sought, to allow a repeat HAI and antimicrobial use prevalence survey to be performed in 2014. A repeat survey will allow further refinement of survey methodology and assessment of changes over time in prevalence, HAI distribution, and pathogen distribution. It will also allow for a re-assessment of the burden of antimicrobial use, at a time when antimicrobial stewardship is an area of active engagement in many acute care hospitals. The 2014 survey will be performed in a sample of up to 500 acute care hospitals, drawn from the acute care hospital populations in each of the 10 EIP sites (and including participation from many hospitals that participated in prior phases of the survey). Infection prevention personnel in participating hospitals and EIP site personnel will collect demographic and clinical data from the medical records of a sample of eligible patients in their hospitals on a single day in 2014, to identify CDC-defined HAIs. The surveys will provide data for CDC to make estimates of the prevalence of HAIs across this sample of U.S. hospitals as well as the distribution of infection types and causative organisms. These data can be used to work toward reducing and eliminating healthcare-associated infections—a DHHS Healthy People 2020 objective (<http://www.healthypeople.gov/2020/topicsobjectives2020/overview.aspx?topicid=17>). This survey project also supports the CDC Winnable Battle goal of improving national surveillance for healthcare-associated infections (<http://www.cdc.gov/winnablebattles/Goals.html>).

The total burden is 9,375 hours, which represents an increase of 250 hours over the previously approved burden. The increase is requested because the median number of responses per respondent in the 2011 phase 3 survey was 75. Previously, we had estimated 73 responses per respondent. There are no costs to respondents. The total estimated annualized burden is 9,375.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Number of responses per respondent	Average burden per response in hours
Infection Prevention Personnel in Participating Hospitals	500	75	15/60

* Assumptions: One respondent per hospital, collection of data on median of 75 patients per hospital, average data collection time of 15 minutes per patient.

Kimberly S. Lane,

Deputy Director, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2013-04508 Filed 2-26-13; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-13-0263]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-5960 or send an email to *omb@cdc.gov*. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Requirements for the Importation of Nonhuman Primates into the United States (formerly Requirements for a Special Permit to Import Cynomolgus, African Green, or Rhesus Monkeys into the United States) (OMB Control No. 0920-0263 Exp.6/30/2014)—Revision—National Center Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Since May 1990, CDC has monitored the arrival and/or uncrating of certain shipments of non-human primates

imported into the United States under a special permit program specific to Cynomolgus, African Green, or Rhesus Monkeys. CDC has monitored compliance with this special permit through the collection of information focused on determining whether or not importers conduct adequate disease control practices. Importers were required to renew their special permit every 180 days.

In February 2013, CDC promulgated two regulations pertaining to the importation of nonhuman primates. The first rule, Requirements for Importers of Nonhuman Primates (2/15/2013, Vol. 78, No. 32/p. 11522) consolidates into 42 CFR 71.53 the requirements previously found in 42 CFR part 71.53 with those found in the Special Permit to Import Cynomolgus, African Green, or Rhesus Monkeys into the United States. It also extended the time period for registration/permit renewal from 180 days to 2 years. The Special Permit has been withdrawn. The requirements found therein are now incorporated into the revised final rule for 42 CFR 71.53. The second rule, Establishment of User Fees for Filovirus Testing of Nonhuman Primate Liver Samples (2/12/2013, Vol.78, No. 29, p.9828), outlines a process by which importers can send liver tissues to CDC from primates that die during importation from reasons other than trauma. CDC performs these tests due to the absence of a private sector option. CDC feels these regulatory changes balance the public health risks posed by the importation of nonhuman primates with the burden imposed on regulating their importation.

These rule changes have prompted CDC to modify how it administers the information collected from the public in the enforcement of nonhuman primate regulations. CDC is requesting the following changes:

1. CDC requests that this information collection request be re-named “Requirements for the Importation of Nonhuman Primates into the United States” to more accurately reflect the type of information that is requested from respondents.

2. To streamline administration of this information collection request, CDC requests that CDC form 75.10A Application for Registration as an Importer of Nonhuman Primates and the Recordkeeping requirement currently approved under OMB Control Number 0920-0134 Foreign Quarantine Regulations, be moved and included in this revision to OMB Control Number 0920-0263. This action places all nonhuman primate information collection requirements and requests into one information collection request administered by CDC.

3. CDC is renaming the different portions of the information collected in this information collection to more accurately list the types of forms and documentation CDC collects from importers of nonhuman primates. Therefore, the former information categories of Businesses (limited permit), Businesses (extended permit), and Organizations (extended permit) are being renamed and reorganized. The information contained in these categories will now be accounted for in the Documentation sections of the burden table. This categorization will more accurately reflect CDC’s interaction with the importers.

4. CDC also requests additional burden hours to account for notification to CDC from importers of shipment arrivals and requests for release from quarantine.

5. CDC further requests the addition of the Filovirus Diagnostic Specimen Submission Form for Non-human Primate Materials, which will be used to collect all of the necessary information from nonhuman primate importers to test nonhuman primate liver samples for filovirus and communicate the results of this test. This action adds approximately 50 hours of burden to this information collection request.

This information collection involves minimal personally identifiable information and should have limited impact on an individual’s privacy. There are no costs to respondents other than their time.

The total burden requested for this information collection is 146.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name/CFR reference	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Nonhuman Primate Importer	71.53(g) New Importer Registration—Nonhuman Primates.	1	1	10/60
Nonhuman Primate Importer	71.53(g) Importer Re-Registration—Nonhuman Primates.	12	1	10/60

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name/CFR reference	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Nonhuman Primate Importer	71.53(h) Documentation (no form) (New Importer).	1	1	10
Nonhuman Primate Importer	71.53(h) Documentation (no form) (Registered Importer).	12	1	30/60
Nonhuman Primate Importer	Recordkeeping and reporting requirements for importing NHPs: Notification of shipment arrival 71.53(n) (no form).	25	6	15/60
Nonhuman Primate Importer	Quarantine release 71.53(l) (No form)	25	6	15/60
Nonhuman Primate Importer	71.53 (v) Form: Filovirus Diagnostic Specimen Submission Form for Non-human Primate Materials.	10	15	20/60

Kimberly S. Lane,

Deputy Director, Office of Scientific Integrity,
Office of the Associate Director for Science,
Office of the Director, Centers for Disease
Control and Prevention.

[FR Doc. 2013-04510 Filed 2-26-13; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1597-N2]

Medicare Program; Changes to the Semi-Annual Meeting of the Advisory Panel on Hospital Outpatient Payment (HOP Panel)—March 11 and March 12, 2013

AGENCY: Centers for Medicare &
Medicaid Services (CMS), HHS.

ACTION: Notice of meeting date and time,
location, and format change.

SUMMARY: This notice announces
changes to the meeting date and time,
location, and format of the first semi-
annual public meeting of 2013 that was
announced and published in the
Federal Register on November 26, 2012,
entitled “Medicare Program; Semi-
Annual Meeting of the Advisory Panel
on Hospital Outpatient Payment (HOP
Panel)—March 11 and 12, 2013.”

DATES: Monday, March 11, 2013, from 1
p.m. to 5 p.m. Eastern Daylight Time
(EDT).

FOR FURTHER INFORMATION CONTACT:
Chuck Braver, (410) 786-3985.

SUPPLEMENTARY INFORMATION:

I. Background

On November 26, 2012, we published
a notice in the **Federal Register** (77 FR
70447) announcing the first semi-annual
meeting of the Advisory Panel on

Hospital Outpatient Payment (HOP, the
Panel) for 2013. We note that the
November 26, 2012 notice provides
specific information on the purpose of
the meeting and the agenda. This
information remains the same and has
not changed with the exception of the
meeting date and time, location, and
format as specified in this notice. We
refer readers to that previously
published notice for general
information.

II. Provisions of the Notice

The November 26, 2012, notice
announced an in-person meeting to be
held over two days, March 11 through
12, 2013. Since the publication of that
notice, the date and time, location, and
format of the Panel meeting has
changed. Therefore, we are publishing
this notice to provide the public with
the necessary information related to this
upcoming public Panel meeting.

First, the November 26, 2012, notice
included the published date of the Panel
meeting as Monday, March 11, 2013,
from 1 p.m. to 5 p.m. EDT and Tuesday,
March 12, 2013, from 9 a.m. to 5 p.m.
EDT. The Panel meeting date and time
has been changed and will only take
place on March 11, 2013, from 1 p.m.
to 5 p.m. EDT.

Second, the November 26, 2012 notice
included, the published meeting
location as the CMS Central Office
Auditorium, 7500 Security Boulevard,
Woodlawn, Maryland 21244-1850. The
Panel meeting format has been changed
to Teleconference, Webcast, and
Webinar. Therefore, there will no longer
be an in-person meeting location for this
public Panel meeting. Participants
should view the CMS Web site at:
<http://cms.hhs.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html> for the most
current details regarding the meeting.

Participants who have registered to
attend the in-person meeting based on
the November 26, 2012 notice do not
have to re-register. The teleconference
dial-in instructions, and related webcast
and webinar details will be posted on
the CMS Web site approximately 1 week
prior to the meeting at: [http://
cms.hhs.gov/Regulations-and-
Guidance/Guidance/FACA/
AdvisoryPanelonAmbulatoryPayment
ClassificationGroups.html](http://cms.hhs.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html). Interested
participants who did not register will be
able to access the teleconference,
webcast, and webinar by following the
instructions on the above CMS Web site.

III. Collection of Information Requirements

This document does not impose
information collection and
recordkeeping requirements.
Consequently, it need not be reviewed
by the Office of Management and
Budget under the authority of the
Paperwork Reduction Act of 1995 (44
U.S.C. 35).

(Catalog of Federal Domestic Assistance
Program; No. 93.773 Medicare—Hospital
Insurance Program; and No. 93.774,
Medicare—Supplementary Medical
Insurance Program)

Dated: February 20, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare
& Medicaid Services.

[FR Doc. 2013-04524 Filed 2-22-13; 4:15 pm]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2013-N-0001]

Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 25 and 26, 2013, from 8 a.m. to 6 p.m.

Location: Holiday Inn, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD 20879. The hotel phone number is 301-948-8900.

Contact Person: Sara J. Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg 66, rm. 1611, Silver Spring, MD 20993-0002, Sara.Anderson@fda.hhs.gov, 301-796-7047, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On April 25, 2013, during session I, the committee will discuss and make recommendations on the appropriate regulatory classification for diagnostic devices known as methotrexate enzyme immunoassays. Methotrexate enzyme immunoassays are considered pre-Amendment devices since they were in commercial distribution prior to May 28, 1976 when the Medical Device Amendments

became effective. Methotrexate enzyme immunoassays are currently regulated under the heading of "Enzyme Immunoassay, Methotrexate," Product Code LAO, as unclassified under the 510(k) premarket notification authority. Methotrexate enzyme immunoassays are for the quantitative determination of methotrexate. The measurements obtained are used in monitoring levels of methotrexate to ensure appropriate drug therapy. FDA is seeking panel input on the safety and effectiveness of methotrexate enzyme immunoassays.

On April 25, 2013, during session II, the committee will discuss and make recommendations on the appropriate regulatory classification for diagnostic devices known as phencyclidine (PCP) enzyme immunoassays and PCP radioimmunoassays. PCP enzyme immunoassays and PCP radioimmunoassays are considered pre-Amendment devices since they were in commercial distribution prior to May 28, 1976 when the Medical Device Amendments became effective. PCP enzyme immunoassays are currently regulated under the heading of "Enzyme Immunoassay, Phencyclidine," Product Code LCM, and "Radioimmunoassay, Phencyclidine," Product Code LCL, as unclassified under the 510(k) premarket notification authority. FDA is seeking panel input on the safety and effectiveness of PCP enzyme immunoassays and PCP radioimmunoassays.

On April 26, 2013, the committee will discuss and make recommendations on the appropriate regulatory classification for diagnostic devices known as isoniazid test strips. Isoniazid test strips are considered pre-Amendment devices since they were in commercial distribution prior to May 28, 1976 when the Medical Device Amendments became effective. Isoniazid test strips are currently regulated under the heading of "Strip, Test Isoniazid," Product Code MIG, as unclassified under the 510(k) premarket notification authority. Isoniazid test strips are a qualitative assay used for detecting isonicotinic acid and its metabolites in urine to determine compliance of isoniazid (INH) medication. FDA is seeking panel input on the safety and effectiveness of isoniazid test strips.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after

the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before April 16, 2013. On April 25, 2013, oral presentations will be scheduled between approximately 9:30 a.m. and 10 a.m. for session I and between 2 p.m. and 2:30 p.m. for session II. Oral presentations from the public will be scheduled between 1 p.m. and 2 p.m. on April 26, 2013. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 8, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 9, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact James Clark, Conference Management Staff, at James.Clark@fda.hhs.gov or 301-796-5293, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm11462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 22, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013-04543 Filed 2-26-13; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Oncologic Drugs Advisory Committee.

General Function of the Committee:

To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 2, 2013, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Caleb Briggs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, email: ODAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting

link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: During the morning session, the committee will discuss new drug application (NDA) 204408, with the established name tivozanib capsules, submitted by AVEO Pharmaceuticals, Inc. The proposed indication (use) for this product is for the treatment of advanced renal (kidney) cell carcinoma.

During the afternoon session, the committee will discuss NDA 201848, a drug/device combination product with the proposed trade name Melblez Kit (Melblez (melphalan) for Injection for use with the Delcath Hepatic Delivery System), submitted by Delcath Systems, Inc. The proposed indication (use) for this product is for the treatment of patients with unresectable ocular melanoma that is metastatic to the liver.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before April 18, 2013. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11 a.m., and 3:30 p.m. to 4 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 10, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 11, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Caleb Briggs at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 22, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013-04542 Filed 2-26-13; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

Science Board to the Food and Drug Administration Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Science Board to the Food and Drug Administration. This meeting was announced in the **Federal Register** of January 30, 2013 (78 FR 6332). The amendment is being made to reflect changes in the *Date and Time*, *Agenda*, and *Procedures* portions of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Martha Monser, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4286, Silver Spring, MD 20993, 301-796-4627, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington DC area). Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 30, 2013, FDA announced that a meeting of the Science Board to the Food and Drug Administration would be held on February 27, 2013.

1. On page 6332, in the third column, the *Date and Time* portion of the document is changed to read as follows:

Date and Time: The meeting will be held on Wednesday, February 27, 2013, from approximately 8:30 a.m. to 3:45 p.m.

2. On page 6333, in the first column, the *Agenda* portion of the document is changed to read as follows:

Agenda: On February 27, 2013, the Science Board will be provided with updates and/or a draft report from the Center for Devices and Radiological Health Research Review subcommittee and the Global Health subcommittee. Progress updates will be presented regarding the Global Health subcommittee and the recently established Center for Biologics Evaluation and Research Review Postmarketing Safety Review subcommittee. Overviews of genomics activities at the Centers for Food Safety and Applied Nutrition and Veterinary Medicine will be presented, along with plans for an Agencywide working group to address crosscutting genomics activities. Finally, recipients of the fiscal year 2012 Scientific Achievement Awards (selected by the Science Board) will provide overviews of the activities for which the awards were given.

3. On page 6333, in the second column, in the *Procedures* section, the third sentence is changed to read as follows:

Procedures: Oral presentations from the public will be scheduled between approximately 3 p.m. and 3:30 p.m.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: February 20, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013-04535 Filed 2-26-13; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

Psychopharmacologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee:

Psychopharmacologic Drugs Advisory Committee.

General Function of the Committee:

To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 21, 2013, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Minh Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, Fax: 301-847-8533, PDAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On March 21, 2013, the committee will discuss new drug application (NDA) 204442, PROBUPHINE (buprenorphine hydrochloride and ethylene vinyl acetate) subdermal implant, submitted by Titan Pharmaceuticals, Inc., and its safety and efficacy for the proposed indication of maintenance treatment of opioid dependence.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background

material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before March 14, 2013. Oral presentations from the public will be scheduled between approximately 1:45 p.m. and 2:45 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before March 6, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 7, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Minh Doan at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 20, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013-04536 Filed 2-26-13; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

Ophthalmic Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Ophthalmic Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 8, 2013, from 8:30 a.m. to 6 p.m.

Location: Hilton Washington, DC North/Gaithersburg, Salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel telephone number is 301-977-8900.

Contact Person: Natasha Facey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1544, Silver Spring, MD 20993-0002, Natasha.Facey@fda.hhs.gov, 301-796-5290, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On April 8, 2013, the committee will discuss, make recommendations, and vote on information regarding the premarket

approval application for the Trulign Toric posterior chamber intraocular lens sponsored by Bausch and Lomb. The Trulign Toric posterior chamber intraocular lens is intended for primary implantation in the capsular bag of the eye for visual correction of aphakia and postoperative refractive astigmatism secondary to removal of a cataractous lens in adult patients with or without presbyopia, who desire improved uncorrected distance vision and reduction of residual refractive cylinder. Trulign Toric provides approximately one diopter of monocular accommodation, which allows for near, intermediate, and distance vision without spectacles.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before April 1, 2013. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before March 22, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 26, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee

meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams at Annmarie.Williams@fda.hhs.gov or 301-796-5966, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm11462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 20, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013-04534 Filed 2-26-13; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request Healthy Communities Study; How Communities Shape Children's Health (HCS)

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on November 30, 2012, Pages 71426-71427 allowed 60-days for public comment. Two (2) comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection

Title: Healthy Communities Study; How Communities Shape Children's Health (HCS). *Type of Information Collection Request:* Revision—OMB#

0925–0649. *Need and Use of Information Collection:* The HCS will address the need for a cross-cutting national study of community programs and policies and their relationship to childhood obesity. The HCS is an observational study of communities that aims to (1) determine the associations between community programs/policies and body mass index (BMI), diet, and physical activity for children; (2) identify the community, family, and child factors that modify or mediate the associations between community programs/policies and BMI, diet, and physical activity in children; and (3) assess the associations between programs/policies and BMI, diet and physical activity in children in communities that have a high proportion of African American, Latino,

and/or low-income residents. A total of 264 communities and over 21,000 elementary and middle school children and their parents will be part of this study. A HCS community is defined as a high school catchment area. The study examines quantitative and qualitative information obtained from community-based initiatives; community characteristics (e.g., school environment); measurements of children’s physical activity levels and dietary practices; and children’s and parents’ BMIs. Results from the Healthy Communities Study may influence the future development and funding of policies and programs to reduce childhood obesity. Furthermore, HCS results will be published in scientific journals and will be used for the development of future research

initiatives targeting childhood obesity. *Frequency of Response:* One time. *Affected Public:* Families or households; businesses, other for-profit, and non-profit. *Type of Respondents:* Parents, children, community key informants (who have knowledge about community programs/policies related to nutrition, physical activity, and weight of children), food service personnel, physical education instructors, school liaisons, and physicians or medical secretaries. The annual reporting burden is as follows: *Estimated number of respondents:* 69,010; *Estimated Number of Responses per Respondent:* 1; and *Estimated Total Burden Hours Requested:* 29,657. The annualized cost to respondents is estimated at \$381,841. There are no capital, operating, or maintenance costs to report.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden per response (in hours)	Estimated total annual burden hours requested
Parents (screening)	39,600	1	10/60	6,732
Parents/Caregivers	7,128	1	1.56	11,120
Second Parents	3,564	1	7/60	428
Parents who refuse to participate	880	1	10/60	150
Children	7,128	1	1.04	7,413
Key Informants (screening)	3,520	1	5/60	282
Key Informants	1,056	1	2.25	2,376
Food Service Personnel	352	1	5/60	28
District Food Service Administrator/Manager	88	1	30/60	44
Physical Education Instructors	352	1	15/60	88
School Liaisons	352	1	25/60	148
Physicians/medical secretaries	4,990	1	10/60	848
Total	69,010	29,657

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and

instruments contact: Dr. Sonia Arteaga, NIH, NHLBI, 6701 Rockledge Drive, MSC 7936, Bethesda, MD 20892–7936, or call non-toll free number (301) 435–0377 or Email your request, including your address to: hcs@nhlbi.nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: February 19, 2013.

Lynn Susulske,
NHLBI Project Clearance Liaison, National Institutes of Health.
Michael S. Lauer,
Director, DCVS, National Institutes of Health.
 [FR Doc. 2013–04528 Filed 2–26–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request: Clinical Myttheries: A Video Game About Clinical Trials

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on June 13, 2012, page 35407 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended,

revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Clinical Mytheries: A Video Game About Clinical Trials. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* New England Research Institutes as a contractor for the National Heart Lung and Blood Institute is planning to create an engaging, informational “serious video game” for adolescents about clinical studies which: (1) Incorporates core learning objectives; and (2) dispels misconceptions. Two types of information collection are planned:

- Usability testing to understand game-play/usability. This information will be collected by focus group and will be digitally recorded 90 minute groups.
- A pre/post randomized trial to measure change in knowledge. This information will be collected electronically through on-line questionnaire.

The game will be incorporated with a larger initiative to provide information about clinical research (<http://www.nhlbi.nih.gov/childrenandclinicalstudies/index.php>). *Frequency of Response:* Once. *Affected Public: Individuals. Type of Respondents:* Adolescents—aged 8–14.

The annual reporting burden is as follows: *Estimated Number of Respondents:* 280; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours per Response: Wave 1—90/60 (1.5 hours), Wave 2—80/60 (1.33 hours); and Estimated Total Annual Burden Hours Requested:* 378. The annualized cost to respondents is estimated at: \$3,783. There are no Capital Costs to report. The Operating Costs to collect this information is estimated at \$42,425.00.

Note: *The following table is acceptable for the Respondent and Burden Estimate information, if appropriate, instead of the text as shown above.*

Form name	Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Qualitative Focus Group Discussion Guide and screener.	Adolescents—Wave one	30	1	90/60 (1.5 hours) ..	45
Screen pre post eval	Adolescents—Wave two	250	1	80/60 (1.33 hours)	333
Total	280	378

Request For Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202–395–6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Victoria Pemberton, RNC, MS, CCRC, National Heart, Lung and Blood Institute, 6701

Rockledge Drive, Rm. 8109, Bethesda, MD 20892, or call non-toll-free number (301) 435–0510 or Email your request, including your address to: pembertonv@mail.nih.gov

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: February 8, 2013.
Michael Lauer,
Director, Division of Cardiovascular Diseases, National Heart, Lung, and Blood Institute, NIH.

Dated: February 12, 2013.
Lynn Susulske,
NHLBI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2013–04547 Filed 2–26–13; 8:45 am]
BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious

commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Java Software for Investigational Drug Clinical Research

Description of Technology: A Java based software application available for academic use and on a royalty-bearing basis for commercial licensing. The Investigational Drug Management System (IDMS) supports the operational needs of the investigation drug section of a pharmacy providing inventory management functions which fulfill the recordkeeping requirements defined in the Code of Federal Regulations related to the storage, labeling, handling, and dispensing of investigational drugs. The internet/browser based application interfaces with the Computerized Provider Order Entry (CPOE) system for

tracking patients and prescriptions for investigational drugs. The IDMS supports the prescription filling process by capturing real-time data during the dispensing activity where automated safety checks are performed, ensuring the “five rights” of medication use are satisfied. The system supports randomized double-blind clinical trials by generating complex, multi-tiered randomization schemes that produce patient-specific treatment assignments along with industry standard labels containing barcodes. IDMS serves as the book of record providing end-to-end traceability for the receipt of raw materials from their source to the dispensing of finished pharmaceutical dosage forms to patients.

Potential Commercial Applications:

- Clinical data management
- Clinical Trials
- Investigational new drug trials

Competitive Advantages:

- Web based
- User friendly
- Data portability
- Randomization tables

Development Stage:

- Prototype
- Clinical

Inventors: Richard O. DeCederfelt, George J. Grimes, Stephen M. Bergstrom, Jon W. McKeeby (all of NIH-CC).

Intellectual Property: HHS Reference No. E-063-2013/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Contact: Michael Shmilovich; 301-435-5019; shmilovm@mail.nih.gov.

Software To Improve the Quality of Microscopy Images

Description of Technology: Available for licensing and commercial use is software based on an iterative deconvolution procedure that recovers images that have been blurred by a known point spread function. The software provides superior results when multiple independent observations of the same specimen are obtained. An example of such observations might be the multiple views of a specimen collected by a selective illumination plane microscope (SPIM). By using the blurring function and observations (raw images) corresponding to each view in sequential order through the iteration loop, the resulting output contains higher resolution, contrast, and signal than would result if any single observation alone was used, or if the output from single deconvolution operations on each image are combined, e.g. by averaging. In its current form, the software has been tested on the

Richardson-Lucy deconvolution (RLD) procedure. Preliminary data indicate that the algorithm provides an isotropic resolution of 350 nm, greatly improving the raw data (lateral resolution 0.5 microns, axial resolution 1.5 microns) on nematode embryos. In vivo data illustrating the power of the algorithm are available upon request.

Potential Commercial Applications:

- Image Resolution
 - Sub-micron microscopy
- Competitive Advantages:*
- Enables isotopic resolution
 - Iterative deconvolution algorithm that can readily be applied to SPIM datasets

Development Stage:

- Prototype
- In vitro data available
- In vivo data available (animal)

Inventors: Hari Shroff, Andrew York, Yicong Wu (all of NIBIB).

Publications:

1. Swoger J, et al. Multi-view image fusion improves resolution in three-dimensional microscopy. *Opt Express*. 2007 Jun 25;15(13):8029–42. [PMID 19547131]
2. Verveer PJ, et al. High-resolution three-dimensional imaging of large specimens with light sheet-based microscopy. *Nat Methods*. 2007 Apr;4(4):311–3. [PMID 17339847]

Intellectual Property: HHS Reference No. E-062-2013/0—Software Tool. Patent protection is not being pursued for this technology.

Licensing Contact: Michael Shmilovich; 301-435-5019; shmilovm@mail.nih.gov.

Collaborative Research Opportunity: The NIBIB Section on High Resolution Optical Imaging is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize our algorithm, especially with respect to multiview microscopes. For collaboration opportunities, please contact Hari Shroff at hari.schroff@nih.gov.

Background-Free Fluorescent Nanodiamond Imaging

Description of Technology: Available for licensing and commercial development are intellectual property rights covering a method of imaging a biological specimen (e.g., human tissue) using fluorescent nanodiamonds implanted into the subject of interest, applying a magnetic field to said subject and producing a resultant image by a net juxtaposition of a second acquired image. This process suppresses the background and permits selective imaging of the nanodiamonds in the

presence of background fluorescence that exceeds the signal from the nanodiamonds. Another aspect of the invention provides an imaging method in which the resulting image is acquired by applying time-varying magnetic fields using one or more secondary image averaged against the first. The technique relies on imposing a small (~100 Gauss) magnetic field on the sample of interest during optical imaging combined with post-processing of the acquired images to remove the background. This technology can readily be added onto any commercial optical imaging platform to achieve background-free images of the nanodiamonds in a biological specimen.

Potential Commercial Applications:

- In vitro and in vivo optical imaging and diagnostics
- MRI imaging

Competitive Advantages:

- Improved resolution through composite imagery
- Background elimination
- Indefinite tracking due to the exceptional stability of the fluorescent nanodiamonds
- Wide excitation band (~500–600 nm)
- Broad-band Near IR emission (600–700 nm)
- Nanodiamonds are stable in aqueous solution
- In related technologies we have developed a method to specifically coat and functionalize nanodiamonds for targeting and labeling applications

Development Stage:

- Prototype
- In vitro data available
- In vivo data available (animal)

Inventors: Susanta Sarkar, Ambika Bumb, Keir Neuman (all of NHLBI).

Intellectual Property: HHS Reference No. E-261-2012/0—US Provisional Application No. 61/711,702 filed 09 Oct 2012.

Related Technology: HHS Reference No. E-175-2012/0—US Provisional Application No. 61/672,996 filed 18 Jul 2012, “Method of Preparing Silica-coated Nanodiamonds.”

Licensing Contact: Michael Shmilovich; 301-435-5019; shmilovm@mail.nih.gov.

Collaborative Research Opportunity: The NHLBI Laboratory of Single Molecule Biophysics is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize background-free imaging of fluorescent nanodiamonds for in vivo and in vitro applications. For collaboration opportunities, please contact Keir C. Neuman, Ph.D. at neumankc@mail.nih.gov or 301-496-3376.

Silica-Coated Nanodiamonds for Imaging and the Delivery of Therapeutic Agents

Description of Technology: NIH investigators invented a robust and easily implemented method of synthesizing silica-coated nanodiamonds for imaging and therapeutic applications. A patent estate covering these methods is offered for licensing to commercial entities. The method generally includes coating nanodiamonds with a silica precursor, e.g., tetraethylorthosilicate (TEOS), inside liposomes. The liposomes are then removed to yield a final product that is stable, monodisperse, and easy to functionalize.

Potential Commercial Applications:

- Imaging
- Drug delivery

Competitive Advantages:

- Small size
- Physiologically inert carrier
- Monodisperse
- Stable in aqueous solution
- Readily functionalized

Development Stage: Prototype.

Inventors: Ambika Bumb (NHLBI), Susanta Kumar Sarkar (NHLBI), Keir Neuman (NHLBI), Martin Brechbiel (NCI).

Publications:

1. Yu SJ, et al. Bright fluorescent nanodiamonds: no photobleaching and low cytotoxicity. *J Am Chem Soc.* 2005 Dec 21;127(50):17604–5. [PMID 16351080]
2. Wilson RM. Nanodiamonds are promising quantum probes of living cells. *Phys Today* 2011 Aug;64(8):17. [doi 10.1063/PT.3.1204]
3. Chow EK, et al. Nanodiamond therapeutic delivery agents mediate enhanced chemoresistant tumor treatment. *Sci Transl Med.* 2011 Mar 9;3(73):73ra21. [PMID 21389265]
4. Krueger A. New carbon materials: biological applications of functionalized nanodiamond materials. *Chemistry* 2008;14(5):1382–90. [PMID 18033700]

Intellectual Property: HHS Reference No. E-175-2012/0—US Provisional Application No. 61/672,996 filed 18 Jul 2012.

Related Technology: HHS Reference No. E-261-2012/0—US Provisional Application No. 61/711,702 filed 09 Oct 2012, “Imaging Methods and Computer-Readable Media for Background-Free imaging of Fluorescent Nanodiamonds.”

Licensing Contact: Michael Shmilovich; 301-435-5019; shmilovm@mail.nih.gov.

Collaborative Research Opportunity: The NHLBI Laboratory of Single Molecule Biophysics is seeking statements of capability or interest from

parties interested in collaborative research to further develop, evaluate or commercialize fluorescent nanodiamonds for use as in vivo and in vitro optical tracking probes. For collaboration opportunities, please contact Keir C. Neuman, Ph.D. at neumankc@mail.nih.gov or 301-496-3376.

Dated February 20, 2013.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2013-04443 Filed 2-26-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301-496-7057; fax: 301-402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Chimeric Antigen Receptors to CD22 for Treating Hematological Cancers

Description of Technology: Chimeric antigen receptors (CARs) are hybrid proteins consisting of an antibody binding fragment fused to protein signaling domains that cause T-cells which express the CAR to become cytotoxic. Once activated, these cytotoxic T-cells can selectively eliminate the cells which they recognize via the antibody binding fragment of the CAR. Thus, by engineering a T-cell to

express a CAR that is specific for a certain cell surface protein, it is possible to selectively target those cells for destruction. This is a promising new therapeutic approach known as adoptive cell therapy.

CD22 is a cell surface protein that is expressed on a large number of B-cell lineage hematological cancers, such as leukemia and lymphoma. Several promising therapies are being developed which target CD22, including therapeutic antibodies and immunotoxins. This technology concerns the use of a high affinity antibody binding fragment to CD22 (known as m971), as the targeting moiety of a CAR. The resulting CAR can be used in adoptive cell therapy treatment for cancer.

Potential Commercial Applications:

- Treatment of diseases associated with increased or preferential expression of CD22
 - Specific diseases include hematological cancers such as chronic lymphocytic leukemia (CLL), hairy cell leukemia (HCL) and pediatric acute lymphoblastic leukemia (ALL)
- Competitive Advantages:*
- High affinity of the m971 antibody binding fragment increases the likelihood of successful targeting
 - Targeted therapy decreases non-specific killing of healthy, essential cells, resulting in fewer non-specific side-effects and healthier patients
 - Hematological cancers are susceptible to cytotoxic T-cells for treating because they are present in the bloodstream
 - Expression of CD22 only on mature cells allows the avoidance of stem cell elimination during treatment

Development Stage: Pre-clinical.

Inventors: Rimas J. Orentas et al. (NCI).

Intellectual Property: HHS Reference No. E-291-2012/0—US Provisional Application No. 61/717,960 filed 24 Oct 2012.

Related Technology: HHS Reference No. E-080-2008/0—U.S. Patent Application No. 12/934,214 filed 23 Sep 2010.

Licensing Contact: David A. Lambertson, Ph.D.; 301-435-4632; lambertsond@mail.nih.gov.

Modified Peptide Nucleic Acids (PNAs) for Detection of DNA or RNA and Identification of a Disease or Pathogen

Description of Technology: The NIH announces a novel method for fast, simple, and accurate detection of nucleic acids outside the modern laboratory. Nucleic acid testing is highly specific and often provides definitive

identification of a disease or pathogen. Methods to detect nucleic acid sequences and identify a disease or pathogen are dominated by PCR, but applying PCR-based techniques in remote settings is challenging.

Researchers at the NIH have developed a universal, colorimetric, nucleic acid-responsive diagnostic system that uses two short peptide nucleic acid (PNA) probes and does not rely on PCR. The design of a cyclopentane-modified surface probe and a biotin-containing reporter probe allows excellent DNA and RNA detection. NIH researchers have specifically demonstrated this technology's suitability for early detection of HIV RNA or anthrax DNA.

Potential Commercial Applications:

- Ultra-high sensitive detection of nucleic acids
- Convenient, universal, colorimetric diagnostic tool
- Can be used to detect any kind of infectious disease by simply changing the PNA sequences of the specific probe
- Suitable for early detection of HIV, anthrax, tuberculosis, human papilloma virus (HPV), avian flu, E. coli, and more

Competitive Advantages:

- Eliminates requirement for PCR
- Fast, simple method that can be used outside the laboratory
- Modified PNAs provide resistance to degradation by enzymes and a high degree of stability to any diagnostic device

Development Stage:

- Prototype
- In vitro data available

Inventors: Daniel Appella (NIDDK), Christopher Micklitsch (NIDDK), Chao Zhao (NIDDK), Bereket Oquare (ImClone Systems, Inc.).

Publication: Micklitsch CM, et al. Cyclopentane-Peptide nucleic acids for qualitative, quantitative, and repetitive detection of nucleic acids. *Anal Chem.* 2013 Jan 2;85(1):251–7. [PMID 23214925].

Intellectual Property: HHS Reference No. E-260-2012/0—US Application No. 61/684,354 filed 17 Aug 2012.

Licensing Contact: Charlene Sydnor, Ph.D.; 301-435-4689; sydnorc@mail.nih.gov.

Collaborative Research Opportunity: The NIDDK is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Modified Peptide Nucleic Acids (PNAs) for Detection of DNA or RNA. For collaboration opportunities, please contact Cindy K. Fuchs, J.D. at Cindy.Fuchs@nih.hhs.gov or 301-451-3636.

Novel Vaccine for Prevention and Treatment of Chlamydia Infection

Description of Technology: The invention provides novel vectors, attenuated pathogens, compositions, methods and kits for preventing and/or treating chlamydia infections.

Chlamydia trachomatis is an obligate intracellular human pathogen with a unique biphasic developmental growth cycle. It's the etiological agent of trachoma, the world's leading cause of preventable blindness and the most common cause of bacterial sexually transmitted disease. *C. trachomatis* isolates maintain a highly conserved plasmid and naturally occurring plasmidless clinical isolates are rare, implicating its importance in chlamydial pathogenesis.

Understanding the plasmid's role in chlamydial pathogenesis at a molecular level is an important objective for the future control of chlamydial infections. The NIAID inventor had studied chlamydia strains in both non-human primate and murine infectious models providing evidence that plasmids play an important role in chlamydial pathogenesis. In addition, the study results of macaque model of trachoma supports the use of plasmid-deficient organisms as novel live-attenuated chlamydial vaccines.

Potential Commercial Applications: Novel live-attenuated chlamydial vaccines.

Competitive Advantages:

- Virulence attenuated vectors that can be used as vaccines against chlamydia.
- Combination of vector with attenuated pathogenic agent improves the stability and replicative capacity of the pathogen.
- Features nucleic acids, attenuated pathogens, compositions, methods and kits to treat and prevent chlamydia infections.

Development Stage:

- Prototype
- In vitro data available
- In vivo data available (animal)
- In vivo data available (human)

Inventor: Harlan D Caldwell (NIAID). *Publications:*

1. Song L, et al. The Chlamydia trachomatis plasmid-encoded Pgp4 is a transcriptional regulator of virulence associated genes. *Infect Immun.* 2013 Jan 14 (Epub ahead of print). [PMID 23319558]

2. Kari L, et al. A live-attenuated chlamydial vaccine protects against trachoma in nonhuman primates. *J Exp Med.* 2011 Oct 24;208(11):2217–23. [PMID 21987657]

Intellectual Property: HHS Reference No. E-133-2012/0—US Provisional

Application No. 61/753,320 filed 16 Jan 2013

Licensing Contact: John Stansberry, Ph.D.; 301-435-5236; stansbej@mail.nih.gov

Collaborative Research Opportunity: The NIAID Laboratory of Intracellular Parasites is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize chlamydia vaccine. For collaboration opportunities, please contact Harlan D. Caldwell, Ph.D. at hcaldwell@niaid.nih.gov.

A High-Throughput Assay for Detection and Monitoring of Endocrine-Disrupting Chemicals in Water Sources

Description of Technology: This technology describes a high-throughput, fluorescence-based method to detect endocrine-disrupting chemicals (EDCs) in water sources.

There is growing awareness that a wide variety of synthetic and natural compounds that may lead to adverse health effects are present in water sources, such as streams, wells, and ground water; however, these compounds are often difficult to measure and thus are not commonly monitored. Even low concentrations of these compounds are of concern, as they may have biological effects at concentrations of parts per billion (PPB) or less. The presence of EDCs in the environment, in particular, is under examination for potential adverse effects on human health and on wildlife, such as cancer, immune suppression, impaired fertility, and increased incidence of diabetes and obesity.

Inventors at NCI have discovered a novel assay methodology for detecting endocrine EDCs in contaminated water. The assay utilizes fluorescently-labeled nuclear receptors in a high-throughput, cell-based format, and has the capability to detect very low concentrations of EDCs in water or other liquid samples. The inventors have already demonstrated proof of concept for this technology by using this assay to test for the presence of glucocorticoid and androgen receptor disruptors in water samples from 14 U.S. states, and also plan future studies for other types of EDCs. A product or service based on this technology could fulfill an unmet need for a high-throughput, rapid method for screening water samples for contaminants with potential endocrine-disrupting effects.

Potential Commercial Applications: Product or service for screening and detection of endocrine disrupting chemicals (EDCs) in samples from water sources and waste water.

Competitive Advantages:

- Rapid results—one day or less from sample retrieval to result
- Detects very low concentrations of EDCs
- Readily adaptable for use with a variety of endocrine receptor targets
- High-throughput format allows testing of many samples at once, with multiple types of endocrine receptor targets
- Tests for activity rather than a specific chemical, therefore can detect many variants modified in the environment

Development Stage:

- Prototype
- In vitro data available

Inventors: Gordon L. Hager and Diana A. Stavreva (NCI)

Publication: Stavreva D, et al.

Prevalent Glucocorticoid and Androgen Activity in US Water Sources. *Sci Rep.* 2012;2:937. [PMID 23226835]

Intellectual Property: HHS Reference No. E-269-2011/0—US Provisional Application No. 61/656,473 filed 06 Jun 2012

Licensing Contact: Tara Kirby, Ph.D.; 301-435-4426; tarak@mail.nih.gov

Collaborative Research Opportunity: The NCI Laboratory of Receptor Biology & Gene Expression is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Detection and Monitoring of Endocrine-Disrupting Chemicals in Water Sources. For collaboration opportunities, please contact John Hewes, Ph.D. at hewesj@mail.nih.gov.

Novel Diagnostic Marker for Prediction of Clearance of Hepatitis C Virus Infection

Description of Technology: One of the unfortunate aspects of hepatitis C virus (HCV) infection is that the majority of infected individuals will develop a chronic HCV infection. The current treatment for HCV infection involves direct acting antiviral drugs, such as HCV protease inhibitors, with or without pegylated IFN-alpha/ribavirin. Not all patients respond to treatments and the treatments themselves can cause severe adverse effects. The subject invention (*IFNL4-deltaG*) is a novel genetic polymorphism in the newly discovered *Interferon Lambda 4 (IFNL4)* gene, which is located near the *IFNL3* (former *IL28B*) gene. The *IFNL4-deltaG* polymorphism can predict the likelihood of whether or not a patient will respond to treatment of HCV and, possibly, of other diseases treated with IFN-alpha (or other interferons). In particular, *IFNL4-deltaG* was found to

be a better predictor of clinical outcome for IFN-alpha based treatment in people of African descent than the currently available diagnostic test ('*IL28B*' genotype, defined by rs12979860 located within first intron of *IFNL4*). The predictive value of the *IFNL4-deltaG* polymorphism for response to IFN-alpha based treatment in HCV-infected Caucasians and Asians is comparable to current diagnostics. In addition, *IFNL4-deltaG* can predict the likelihood of a whether a person who is acutely infected with HCV infection will spontaneously clear the infection or develop chronic infection. As with treatment outcome, among individuals of African ancestry, genotype for *IFNL4-deltaG* is a better predictive marker for spontaneous clearance of HCV than '*IL28B*' genotype, while providing similar predictive value in individuals of European or Asian descent.

Potential Commercial Applications:

- Diagnostic for prediction of patient response to HCV treatment
- Diagnostic for prediction of patient response to treatment with IFN-alpha (or other interferons)
- Diagnostic tool for prediction of spontaneous clearance of HCV infection

Competitive Advantages:

- Better than current '*IL28B*' based diagnostics for predicting response to IFN-alpha based HCV treatments for people of African descent.
- Comparable predictive capabilities to current '*IL28B*' based diagnostics for response to IFN-alpha based HCV treatments in Caucasians and Asians.

Development Stage:

- Early-stage
- Pre-clinical
- In vitro data available

Inventors: Liudmila Prokunina (NCI), Thomas R. O'Brien (NCI), Brian P. Muchmore (NCI), Raymond P. Donnelly (FDA)

Publication: Prokunina-Olsson L, et al. A variant upstream of *IFNL3* (*IL28B*) creating novel interferon gene *IFNL4* is associated with impaired clearance of hepatitis C virus. *Nat Genet.* 2013 Feb;45(2):164-71. [PMID 23291588]

Intellectual Property: HHS Reference No. E-217-2011/0—

- U.S. Provisional Patent Application No. 61/543,620 filed 05 Oct 2011
- International PCT Application No. PCT/US2012/59048 filed 05 Oct 2012

Related Technology: HHS Reference No. E-217-2011/1—U.S. Provisional Patent Application No. 61/616,664 filed 28 Mar 2012

Licensing Contact: Kevin W. Chang, Ph.D.; 301-435-5018; changke@mail.nih.gov

Collaborative Research Opportunity: The NCI Division of Cancer Epidemiology & Genetics, Laboratory of Translational Genomics, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize development of a gene-based test to be used in the clinic. For collaboration opportunities, please contact John Hewes, Ph.D. at hewesj@mail.nih.gov.

Novel Host Target for Treatment of Hepatitis C Virus Infection

Description of Technology: The subject technology is a newly discovered Interferon-lambda 4 (*IFNL4*) protein found through analysis of genomic data derived from primary human hepatocytes, molecular cloning and functional annotation. The *IFNL4* protein is related to but distinct from other known IFNs and its expression is inducible in conditions that mimic viral infection. Preliminary studies indicate that this protein may play a role in impaired natural and treatment induced clearance of HCV. These findings suggest that the protein can potentially be a new target for treating HCV infection.

Potential Commercial Applications:

- Novel target for treatment of HCV infection.
- Diagnostics can be developed for detection of *IFNL4* mRNA or protein.
- Existing biological reagents for detection of *IFNL4*—expression assays, antibodies and protein.

Competitive Advantages: *IFNL4* is created by a genetic variant *IFNL4-deltaG*, which is present only in a subset of individuals, suggesting that *IFNL4* is not an essential protein and its functional inactivation may be well-tolerated.

Development Stage:

- Early-stage
- Pre-clinical
- In vitro data available

Inventors: Liudmila Prokunina (NCI), Thomas R. O'Brien (NCI), Brian P. Muchmore (NCI), Raymond P. Donnelly (FDA)

Publication: Prokunina-Olsson L, et al. A variant upstream of *IFNL3* (*IL28B*) creating novel interferon gene *IFNL4* is associated with impaired clearance of hepatitis C virus. *Nat Genet.* 2013 Feb;45(2):164-71. [PMID 23291588]

Intellectual Property: HHS Reference No. E-217-2011/1—U.S. Provisional Patent Application No. 61/616,664 filed 28 Mar 2012

Related Technology: HHS Reference No. E-217-2011/0—

- U.S. Provisional Patent Application No. 61/543,620 filed 05 Oct 2011

- International PCT Application No. PCT/US2012/59048 filed 05 Oct 2012
Licensing Contact: Kevin W. Chang, Ph.D.; 301-435-5018; changke@mail.nih.gov

Collaborative Research Opportunity:

The NCI Division of Cancer Epidemiology & Genetics, Laboratory of Translational Genomics, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize development of tools for detection of IFNL4 mRNA and protein and modulation of its function. For collaboration opportunities, please contact John Hewes, Ph.D. at hewesj@mail.nih.gov.

Brachyury-Directed Vaccine for the Prevention or Treatment of Cancers

Description of Technology: Tumor invasion and metastasis are the primary drivers of cancer-related mortality. Therapies that have an ability to specifically target invasive and/or metastatic cells are anticipated to have a significant impact in the clinical management of advanced cancers.

Researchers at the NIH have developed a vaccine technology that stimulates the immune system to selectively destroy metastasizing cells. Brachyury, a master transcription factor that governs the epithelial-mesenchymal transition, was shown to be significantly overexpressed in primary and metastasizing tumors relative to normal human tissues. Stimulation of T cells with the Brachyury peptide promoted a robust immune response and the targeted lysis of invasive tumor cells. Brachyury overexpression has been demonstrated in a range of human tumors (breast, lung, colon and prostate, among others) suggesting that a therapeutic vaccine derived from this technology would be broadly applicable for the treatment of cancer.

Potential Commercial Applications:

- Preventative cancer vaccine for patients with precancerous lesions of the breast, colon or prostate.
- Therapeutic cancer vaccine for the treatment of disseminated and late-stage tumors.
- Vaccine component of a multi-modal cancer therapy.

Competitive Advantages:

- Treatment targets invasive and metastatic tumor cells which are the primary cause of cancer-related mortality.
- Vaccine can eliminate cancer stem cells which are resistant to conventional therapies.
- Compatible with the clinically-proven TRICOM cancer vaccine platform.

- Available (Optimized) for use with non-pox, non-yeast vectors including: Adenovirus, lentivirus, etc., and for use with protein- or peptide-based vaccines.

Development Stage:

- Pre-clinical
- In vitro data available
- In vivo data available (animal)
- In vivo data available (human)

Inventors: Claudia Palena and Jeffrey Schlom (NCI)

Publications:

1. Fernando RI, et al. The T-box transcription factor Brachyury promotes epithelial-mesenchymal transition in human tumor cells. *J Clin Invest.* 2010 Feb;120(2):533-44. [PMID 20071775]
2. Palena C, et al. The human T-box mesodermal transcription factor Brachyury is a candidate target for T-cell-mediated cancer immunotherapy. *Clin Cancer Res.* 2007 Apr 15;13(8):2471-8. [PMID 17438107]

Intellectual Property: HHS Reference No. E-055-2011/0—US Application No. 61/701,525 filed 14 Sep 2012

Licensing Contact: Sabarni Chatterjee, Ph.D.; 301-435-5587; chatterjeesa@mail.nih.gov

Collaborative Research Opportunity:

The National Cancer Institute Laboratory of Tumor Immunology and Biology is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Brachyury-directed cancer vaccine technology. For collaboration opportunities, please contact John D. Hewes, Ph.D. at hewesj@mail.nih.gov.

Novel Plasmid Vectors for the Soluble Expression of Recombinant Proteins in Escherichia coli

Description of Technology: A series of novel plasmid vectors for the soluble expression and subsequent purification of recombinant proteins that have historically proven to be extremely difficult to purify from *Escherichia coli* (*E. coli*) are provided. Because of its ease of growth and generally low cost to cultivate, *E. coli* is often employed as the host for vectors expressing recombinant proteins. In an ideal situation, the recombinant protein is expressed from a strong promoter, highly soluble, and recovered in high yield and activity. Unfortunately, it is quite common that the overproduced recombinant protein is either detrimental to the cell or simply compartmentalized into insoluble inclusion bodies. Recently, NIH investigators have developed plasmid vectors that enable the recovery and

purification of recombinant proteins that have previously proven to be difficult to express in soluble form. These vectors have a pSC101 origin of replication and, therefore, are maintained in *E. coli* at approximately five (5) copies per cell (plasmid details and maps will be provided upon request). These vectors express the recombinant proteins at low basal levels and this feature facilitates higher solubility and correct folding of the expressed protein. The utility of these vectors is verified by expressing and purifying full-length human DNA polymerases from *E. coli* and showing that the purified DNA polymerases are catalytically active *in vitro*.

Potential Commercial Applications:

The expression vectors described here can be used to:

- (a) obtain recombinant proteins that were previously hard to purify,
- (b) produce recombinant proteins from a number of sources and with different catalytic activities, and
- (c) express multimeric protein complexes.

Competitive Advantages: The

- expression vectors described here:
- (a) dramatically increase the proportion of soluble protein that can be obtained in *E. coli*,
 - (b) fully compatible with the replicons of conventional high-expression systems (e.g., pET vectors, EMD Biosciences, and
 - (c) facilitate the correct folding of the recombinant protein and increases its solubility.

Development Stage:

- Prototype
- Early-stage
- In vitro data available

Inventors: Roger Woodgate, John P. McDonald, and Karata Kiyonobu (NICHHD)

Publication: Frank EG, et al. A strategy for the expression of recombinant proteins traditionally hard to purify. *Anal Biochem.* 2012 Oct 15;429(2):132-9. [PMID: 22828411]

Intellectual Property: HHS Reference No. E-028-2010/0—Research Tools. Patent protection is not being pursued for this technology.

Licensing Contact: Suryanarayana (Sury) Vepa, Ph.D., J.D.; 301-435-5020; vepas@mail.nih.gov

Dated: February 21, 2013.

Richard U. Rodriguez,
Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2013-04481 Filed 2-26-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel Research Careers in Environmental Health.

Date: March 19, 2013.

Time: 1:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: NIEHS/National Institutes of Health, Keystone Building, 530 Davis Drive, Research Triangle Park, NC 27709, (Telephone Conference Call).

Contact Person: Linda K Bass, Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute Environmental Health Sciences, P.O. Box 12233, MD EC-30, Research Triangle Park, NC 27709, (919) 541-1307, bass@niehs.nih.gov.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel Conference Review Meeting.

Date: March 21, 2013.

Time: 1:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Nat. Institute of Environmental Health Sciences, Keystone Building, 3118, 530 Davis Drive, Research Triangle Park, NC 27709, (Telephone Conference Call).

Contact Person: Janice B Allen, Ph.D., Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Science, P.O. Box 12233, MD EC-30/Room 3170 B, Research Triangle Park, NC 27709, 919/541-7556.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to

Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: February 20, 2013.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-04450 Filed 2-26-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel, Innovative Pilot Studies of Novel Mechanism of Action Compounds for Treating Psychiatric Disorders.

Date: March 18, 2013.

Time: 2:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Vinod Charles, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6151, MSC 9606, Bethesda, MD 20892-9606, 301-443-1606, charlesvi@mail.nih.gov.

Name of Committee: National Institute of Mental Health Special Emphasis Panel, National Cooperative Drug Discovery & Development Groups.

Date: March 18, 2013.

Time: 3:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Vinod Charles, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center,

6001 Executive Blvd., Room 6151, MSC 9606, Bethesda, MD 20892-9606, 301-443-1606, charlesvi@mail.nih.gov.

Name of Committee: National Institute of Mental Health Special Emphasis Panel, Dimensional Approaches to Research Classification in Psychiatric Disorders (RDoc).

Date: March 20, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, DC, 2401 M Street, NW., Washington, DC 20037.

Contact Person: Rebecca C Steiner, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6149, MSC 9608, Bethesda, MD 20892-9608, 301-443-4525, steinerr@mail.nih.gov.

Name of Committee: National Institute of Mental Health Special Emphasis Panel, Biobehavioral Research Awards for Innovative New Scientists (BRAINS).

Date: March 28, 2013.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Palomar, 2121 P Street NW., Washington, DC 20037.

Contact Person: Megan Kinnane, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6148, MSC 9609, Rockville, MD 20852-9609, 301-402-6807, libbeym@mail.nih.gov.

Name of Committee: National Institute of Mental Health Special Emphasis Panel, NIMH Research Education Applications (R25).

Date: March 28, 2013.

Time: 1:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Rebecca C Steiner, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6149, MSC 9608, Bethesda, MD 20892-9608, 301-443-4525, steinerr@mail.nih.gov.

Name of Committee: National Institute of Mental Health Special Emphasis Panel, Therapeutic Gaming Software SBIR.

Date: April 12, 2013.

Time: 11:30 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: David I. Sommers, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Blvd., Room 6154, MSC 9606, Bethesda, MD 20892-9606, 301-443-7861, dsommers@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: February 21, 2013.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-04447 Filed 2-26-13; 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. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Global Partnership for Social Science AIDS Research (R24).

Date: March 21-22, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda Downtown, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Carla T. Walls, PHD, Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health And Human Development, NIH, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892-7510, 301-435-6898, wallsc@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: February 20, 2013.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-04455 Filed 2-26-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Meetings

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App), notice is hereby given of a meeting of the Board of Scientific Counselors, Lister Hill Center for Biomedical Communications.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for review, discussion, and evaluation of individual intramural programs and projects conducted by the NATIONAL LIBRARY OF MEDICINE, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, Lister Hill Center for Biomedical Communications.

Date: April 11-12, 2013.

Open: April 11, 2013, 9:00 a.m. to 12:00 p.m.

Agenda: Review of research and development programs and preparation of reports of the Lister Hill Center for Biomedical Communications.

Place: National Library of Medicine, Building 38, 2nd Floor, Board Room, 8600 Rockville Pike, Bethesda, MD 20892.

Closed: April 11, 2013, 12:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate personal qualifications, performance, and competence of individual investigators.

Place: National Library of Medicine, Building 38, 2nd Floor, Board Room, 8600 Rockville Pike, Bethesda, MD 20892.

Closed: April 12, 2013, 9:00 a.m. to 10:00 a.m.

Agenda: To review and evaluate personal qualifications, performance, and competence of individual investigators.

Place: National Library of Medicine, Building 38, 2nd Floor, Board Room, 8600 Rockville Pike, Bethesda, MD 20892.

Contact Person: Karen Steely, Program Assistant, Lister Hill Center for Biomedical Communications, National Library of Medicine, Building 38A, Room 7S709, Bethesda, MD 20892, 301-435-3137, ksteely@mail.nih.gov.

Open: April 12, 2013, 10:00 a.m. to 11:15 a.m.

Agenda: Review of research and development programs and preparation of reports of the Lister Hill Center for Biomedical Communications.

Place: National Library of Medicine, Building 38, 2nd Floor, Board Room, 8600 Rockville Pike, Bethesda, MD 20892.

Contact Person: Karen Steely, Program Assistant, Lister Hill Center for Biomedical Communications, National Library of Medicine, Building 38A, Room 7S709, Bethesda, MD 20892, 301-435-3137, ksteely@mail.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program No. 93.879, Medical Library Assistance, National Institutes of Health, HHS).

Dated: February 20, 2013.

Michelle Trout,

Program Analyst, Office of the Federal Advisory Committee Policy.

[FR Doc. 2013-04444 Filed 2-26-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial

property such as patentable materials, 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 Neurological Disorders and Stroke Initial Review Group Neurological Sciences and Disorders K.

Date: March 7, 2013.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Palomar, 2121 P Street NW., Washington, DC 20037.

Contact Person: Shanta Rajaram, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS, NSC, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892-9529, (301) 435-6033, rajarams@nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Udall Center Review.

Date: April 9-10, 2013.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Alexandria, 1900 Diagonal Road, Alexandria, VA 22314.

Contact Person: Birgit Neuhuber, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS, NSC, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892-9529, neuhuber@ninds.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: February 20, 2013.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-04446 Filed 2-26-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging: Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C.,

as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Member Conflict.

Date: April 1, 2013.

Time: 11:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Ave., Suite 2C-212, Bethesda, MD 20814, (Telephone Conference Call).

Contact Person: Ramesh Vemuri, Ph.D., Scientific Review Branch, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C-212, Bethesda, MD 20892, 301-402-7700, rv23r@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: February 21, 2013.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-04459 Filed 2-26-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Chronic Kidney Disease in Children.

Date: April 4, 2013.

Time: 11:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Elena Sanovich, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 750, 6707 Democracy Boulevard, Bethesda, MD 20892-2542, 301-594-8886, sanoviche@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: February 21, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-04451 Filed 2-26-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel NIAID Peer Review Meeting.

Date: March 19-20, 2013.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817, (Telephone Conference Call).

Contact Person: Yong Gao, Ph.D., Scientific Review Officer, Scientific Review Program, DHHS/NIH/NIAID/DEA, 6700B Rockledge Drive, Room 3127, Bethesda, MD 20892, 301-443-8115, gaol2@niaid.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: February 20, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-04457 Filed 2-26-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel NIAAA Member Conflict SEP.

Date: March 18, 2013.

Time: 11:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: NIAAA, National Institute of Health, 5635 Fishers Lane Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Ranga Srinivas, Ph.D., Chief, Extramural Project Review Branch EPRB, NIAAA, National Institutes of Health, 5635 Fishers Lane, Room 2085, Rockville, MD 20852 (301) 451-2067 srinivar@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.273, Alcohol Research Programs; National Institutes of Health, HHS)

Dated: February 21, 2013.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-04458 Filed 2-26-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Cancer Therapy.

Date: March 7, 2013.

Time: 12:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Syed M Quadri, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6210, MSC 7804, Bethesda, MD 20892, 301-435-1211, quadris@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: AIDS and AIDS Related Research.

Date: March 11, 2013.

Time: 12:00 p.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: St. Gregory Hotel, 2033 M Street NW., Washington, DC 20036, Robert Freund, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5216, MSC 7852, Bethesda, MD 20892, 301-435-1050, freundr@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business; Nephrology.

Date: March 18-19, 2013.

Time: 8:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting), Ryan G Morris, Ph.D.,

Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4205, MSC 7814, Bethesda, MD 20892, 301-435-1501, morrisr@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: AIDS and AIDS Related Research.

Date: March 18, 2013.

Time: 12:00 p.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Mayflower Park Hotel, 405 Olive Way, Seattle, WA 98101.

Contact Person: Robert Freund, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3200, MSC 7848, Bethesda, MD 20892, 301-435-1050, freundr@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflicts: Language, Speech, and Motor Function.

Date: March 19, 2013.

Time: 8:30 a.m. to 8:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Maribeth Champoux, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3170, MSC 7848, Bethesda, MD 20892, 301-594-3163, champoum@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Genes, Genomes, and Genetics.

Date: March 19, 2013.

Time: 2:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Michael M. Sveda, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2204, MSC 7890, Bethesda, MD 20892, 301-435-3565, svedam@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Skeletal Biology, Dental, Arthritis and Tissue Engineering.

Date: March 20-21, 2013.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Aruna K Behera, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4211, MSC 7814, Bethesda, MD 20892, 301-435-6809, beheraak@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; R15s: Vascular and Hematology.

Date: March 20, 2013.

Time: 1:30 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Larry Pinkus, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4132, MSC 7802, Bethesda, MD 20892, (301) 435-1214, pinkusl@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: February 20, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-04461 Filed 2-26-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel Program Projects in Anesthesiology.

Date: March 15, 2013.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Room 3An.18K, Bethesda, MD 20814, (Telephone Conference Call).

Contact Person: Brian R. Pike, PHD, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.18K, Bethesda, MD 20892, 301-594-3907, pikbr@mail.nih.gov.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel R24 Legacy Resources Review.

Date: March 19, 2013.

Time: 1:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Room 3An.18K, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Brian R. Pike, PHD, Scientific Review Officer, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.18K, Bethesda, MD 20892, 301-594-3907, pikbr@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: February 21, 2013.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-04449 Filed 2-26-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App), 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 materials, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; NIH Pathway to Independence Award (Parent K99/R00).

Date: March 8, 2013.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Eliane Lazar-Wesley, Ph.D., Scientific Review Officer, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 4245, MSC 9550, 6001 Executive Blvd., Bethesda, MD 20892-9550, 301-451-4530, el6r@nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing

limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: February 20, 2013.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-04452 Filed 2-26-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App), notice is hereby given of a meeting of the Board of Scientific Counselors, National Center for Biotechnology Information.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for review, discussion, and evaluation of individual intramural programs and projects conducted by the National Library of Medicine, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Center for Biotechnology Information.

Date: April 23, 2013.

Open: 8:30 a.m. to 12:00 p.m.

Agenda: Program Discussion.

Place: National Library of Medicine, Building 38, 2nd Floor, Board Room, 8600 Rockville Pike, Bethesda, MD 20892.

Closed: 12:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Library of Medicine, Building 38, 2nd Floor, Board Room, 8600 Rockville Pike, Bethesda, MD 20892.

Open: 2:00 p.m. to 3:00 p.m.

Agenda: Program Discussion.

Place: National Library of Medicine, Building 38, 2nd Floor, Board Room, 8600 Rockville Pike, Bethesda, MD 20892.

Contact Person: David J. Lipman, MD, Director, National Center of Biotechnology Information, National Library of Medicine, Department of Health and Human Services, Building 38A, Room 8N805, Bethesda, MD 20892, 301-435-5985, dlipman@mail.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program No. 93.879, Medical Library Assistance, National Institutes of Health, HHS).

Dated: February 20, 2013.

Michelle Trout,

Program Analyst, Office of the Federal Advisory Committee Policy.

[FR Doc. 2013-04445 Filed 2-26-13; 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 and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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; Function, Integration, and Rehabilitation Sciences Subcommittee.

Date: March 21, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW, Washington, DC 20015.

Contact Person: Anne Krey, PHD, Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health And Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892, 301-435-6908, ak41o@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: February 20, 2013.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-04453 Filed 2-26-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business; Hematology.

Date: March 18-19, 2013.

Time: 11:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place:

National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Bukhtiar H Shah, DVM, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4120, MSC 7802, Bethesda, MD 20892, 301-806-7314, shahb@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Project: Heterochromatin and the HP1 Platform.

Date: March 20-21, 2013.

Time: 8:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Michael H Chaitin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5202, MSC 7850, Bethesda, MD 20892, (301) 435-0910, chaitinm@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: High Throughput Screening Assays for Probe Discovery.

Date: March 20-21, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Kee Hyang Pyon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5148, MSC 7806, Bethesda, MD 20892, pyonkh2@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Microbial Pathogens.

Date: March 20, 2013.

Time: 1:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Liangbiao Zheng, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3202, MSC 7808, Bethesda, MD 20892, 301-996-5819, zhengli@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; DNA Damage and Repair.

Date: March 20, 2013.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Michael L Bloom, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6187, MSC 7804, Bethesda, MD 20892, 301-451-0132, bloomm2@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: February 20, 2013.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-04462 Filed 2-26-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel; "Interventions RFA".

Date: March 19, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn Washington DC/ Bethesda, 7301 Waverly Street, Bethesda, MD 20814.

Contact Person: Lisa A. Dunbar, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.12, Bethesda, MD 20892, 301-594-2849, dunbarl@mail.nih.gov.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel; Systems Biology Grant Applications.

Date: March 19, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn Washington DC/ Bethesda, 7301 Waverly Inn, Bethesda, MD 20814.

Contact Person: Saraswathy Seetharam, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.12C, Bethesda, MD 20892, 301-594-2763, seetharams@nigms.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: February 21, 2013.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-04448 Filed 2-26-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel; NIAMS BIRT grant review.

Date: March 19-20, 2013.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Suite 800, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Kan Ma, Ph.D., Scientific Review Officer, National Institute of Arthritis, Musculoskeletal and Skin Diseases, National Institutes of Health, 6701 Democracy Plaza, Suite 800, Bethesda, MD 20892-4872, 301-451-4838, mak2@mail.nih.gov.

Name of Committee: National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel; Special Emphasis Panel for Clinical Study and Trial Grant Applications.

Date: March 19, 2013.

Time: 10:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Suite 800, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Helen Lin, Ph.D., Scientific Review Officer, National Institute of Arthritis, Musculoskeletal and Skin Diseases, National Institutes of Health, 6701 Democracy Blvd., Suite 800, MSC 4872, Bethesda, MD 20892, 301-594-4952, linh1@mail.nih.gov.

Name of Committee: National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel; NIAMS Small Grant Program for New Investigators (R03).

Date: March 20, 2013.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Suite 824, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Eric H. Brown, MS, Ph.D., Scientific Review Officer, National Institute of Arthritis, Musculoskeletal and Skin Diseases, National Institutes of Health, 6701 Democracy Blvd., Room 824, MSC 4872, Bethesda, MD 20892-4872, (301) 594-4955, browneri@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: February 21, 2013.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-04456 Filed 2-26-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Ethical Issues in Research on HIV/AIDS and its Co-morbidities.

Date: March 18, 2013.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Jose H Guerrier, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, 301-435-1137, guerriej@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Gene Expression and Stability.

Date: March 19, 2013.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Dominique Lorang-Leins, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Room 5108, MSC 7766, Bethesda, MD 20892, 301.326.9721, Lorangd@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Diabetes, Obesity and Reproductive Sciences.

Date: March 21, 2013.

Time: 8:00 a.m. to 5:00 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: Krish Krishnan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6164, MSC 7892, Bethesda, MD 20892, (301) 435-1041, krishnak@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Respiratory Sciences.

Date: March 21-22, 2013.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Ghenima Dirami, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4122, MSC 7814, Bethesda, MD 20892, 240-498-7546, diramig@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Infectious Diseases and Microbiology.

Date: March 21-22, 2013.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Alexander D Politis, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3210, MSC 7808, Bethesda, MD 20892, (301) 435-1150, politisa@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Multidisciplinary Studies of HIV/AIDS and Aging.

Date: March 21, 2013

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Robert Freund, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5216, MSC 7852, Bethesda, MD 20892, 301-435-1050, freundr@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Fungal and Vector Parasites.

Date: March 21-22, 2013.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Fouad A El-Zaatari, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3206, MSC 7808, Bethesda, MD 20892, (301) 435-1149, elzaataf@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Dermatology.

Date: March 21, 2013.

Time: 1:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Richard Ingraham, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4116, MSC 7814, Bethesda, MD 20892, 301-496-8551, ingrahamrh@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Liver and Gastrointestinal Physiology, Pathology and Pharmacology.

Date: March 21, 2013.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Martha Garcia, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2186, Bethesda, MD 20892, 301-435-1243, garciamc@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Bioengineering Sciences and Technologies.

Date: March 21, 2013.

Time: 2:30 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Marie-Jose Belanger, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5181, MSC, Bethesda, MD 20892, belangerm@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR-12-140: Role of the Microflora in the Etiology of Gastro-Intestinal Cancer.

Date: March 21, 2013.

Time: 12:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Peter J Perrin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2180, MSC 7818, Bethesda, MD 20892, (301) 435-0682, perrinp@csr.nih.gov.

Name of Committee: AIDS and Related Research Integrated Review Group; AIDS-associated Opportunistic Infections and Cancer Study Section.

Date: March 22, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The St. Regis Washington DC, 923 16th Street NW., Washington, DC 20006.

Contact Person: Eduardo A Montalvo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5108, MSC 7852, Bethesda, MD 20892, (301) 435-1168, montalve@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: February 21, 2013.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-04460 Filed 2-26-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Food Quality Indicators

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services (HHS), is contemplating the grant of a worldwide exclusive patent license to practice the inventions embodied in:

HHS Ref. No. E-093-1997/0 "Food Quality Indicator;"

Patent application No.	Territory	Filing date	Status
61/052,674	US	July 16, 1997	Expired.
PCT/US1998/14780	Int'l	July 16, 1998	Nationalized.
7,014,816	US	July 16, 1998	Issued (expires July 16, 2017).
782088	AU	July 16, 1998	Issued (expires July 16, 2018).
10-0764516-0	KR	July 16, 1998	Issued (expires July 16, 2018).
98934602.8	EP	July 16, 1998	Pending (expected expiry July 16, 2018).
129002	IL	July 16, 1998	Issued (expires July 16, 2018).
4538106	JP	July 16, 1998	Issued (expires July 16, 2018).
2268477	CA	July 16, 1998	Issued (expires July 16, 2018).
241666	MX	July 16, 1998	Issued (expires July 16, 2018).

to Vivione Biosciences, LLC, a company incorporated under the laws of the State of Delaware having its headquarters in Jonesboro, Arkansas. The United States of America is the assignee of the rights in the above inventions. The contemplated exclusive license may be granted in a field of use limited to devices for detecting volatile compounds indicative of food spoilage.

DATES: Only written comments and/or applications for a license received by the NIH Office of Technology Transfer on or before March 29, 2013 will be considered.

ADDRESSES: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Michael A. Shmilovich, Esq., CLP, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5019; Facsimile: (301) 402-0220; Email: shmilovm@mail.nih.gov. A signed confidentiality nondisclosure agreement will be required to receive copies of any patent applications that have not been published by the United States Patent and Trademark Office or the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION: The patent applications (including any patents issuing therefrom or claiming priority thereto) intended for licensure describe and claim indicator strips for monitoring food quality and freshness in real time. The major factor for food spoilage is the release of volatile gases due to the action of enzymes contained within the food or produced by microorganisms growing in the food. The rate of release of such gases depends on food's storage history. In this technology, a reactive dye locked in a water-repellent material reacts with the gases released during food decomposition, and changes color. Thus a rapid and informed decision can be made about quality of food and its shelf life under the storage conditions used. Since the detection is based on biological processes that are the root

cause for food spoilage, these indicators are much more reliable. This technology provides an alternative to the current methods for assessing food quality that cannot accurately estimate shelf life of food products due to unreliable storage history. These indicators have been successfully tested on seafood and meats and can be easily adapted to dairy products.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within thirty (30) days from the date of this published notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: February 20, 2013.

Richard Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2013-04442 Filed 2-26-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS-2012-0022]

Information Collection Request: Technical Resource for Incident Prevention (TRIPwire) User Registration

AGENCY: National Protection and Programs Directorate, DHS.

ACTION: 60-day notice and request for comments; New Information Collection Request: 1670-NEW.

SUMMARY: The Department of Homeland Security (DHS), National Protection and Programs Directorate, (NPPD), Protective Security Coordination Division (PSCD), Office for Bombing Prevention (OBP) will submit the following Information Collection Request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. Chapter 35).

DATES: Comments are encouraged and will be accepted until April 29, 2013. This process is conducted in accordance with 5 CFR 1320.1.

ADDRESSES: Written comments and questions about this Information Collection Request should be forwarded to Department of Homeland Security (Attn: NPPD/PSCD/OBP) 245 Murray Lane SW., Mail Stop 0612, Arlington, VA 20598-0612. Emailed requests should go to William.Cooper@hq.dhs.gov. Written comments should reach the contact person listed no later than April 29, 2013. Comments must be identified by "DHS-2012-0022" and may be submitted by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>.

- **Email:** Include the docket number in the subject line of the message.

Instructions: All submissions received must include the words "Department of Homeland Security" and the docket number for this action. Comments received will be posted without alteration at <http://www.regulations.gov>, including any personal information provided.

OMB is particularly interested in comments that:

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; or

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 submissions of responses.

SUPPLEMENTARY INFORMATION: The Technical Resource for Incident Prevention (TRIPwire) is OBP's online, collaborative, information-sharing network for bomb squad, law enforcement, and other emergency services personnel to learn about current terrorist improvised explosive device (IED) tactics, techniques, and procedures, including design and emplacement considerations. TRIPwire was established as an IED information-sharing resource under Homeland Security Presidential Directive 19 (HSPD-19), which calls for a unified national policy for the prevention and detection of, protection against, and response to terrorist use of explosives in the United States. Users from Federal, state, local, and tribal government entities, as well as business and for-profit industries can register through the TRIPwire Secure Portal. The TRIPwire portal contains sensitive information related to terrorist use of explosives and therefore user information is needed to verify eligibility and access to the system. TRIPwire applicants must provide their full name, assignment, citizenship, job title, employer name, professional address and contact information, as well as an Employment Verification Contact and their contact information. The system does not store sensitive personally identifiable information (PII) such as social security numbers. The collection of PII by TRIPwire to establish user accounts occurs in accordance with the DHS Privacy Impact Assessment PIA-015, "DHS Web Portals," DHS/ALL-004—General Information Technology Access Account Records System (GITAARS) September 29, 2009, 74 FR 49882, and DHS/ALL-002—Department of Homeland Security Mailing and Other Lists System November 25, 2008, 73 FR 71659. The TRIPwire User Registration is a voluntary registration designed to measure users' suitability to access the secure environment.

The information collected during the TRIPwire user registration process is reviewed electronically by the project team to vet the user's "need to know," which determines their eligibility for and access to TRIPwire. Memberships are re-verified annually based on the information users provide upon registration or communication with the TRIPwire help desk analysts. The information collected is for internal TRIPwire and OBP use only.

Analysis

Agency: Department of Homeland Security, National Protection and Programs Directorate, Office of Infrastructure Protection, Protective Security Coordination Division, Office for Bombing Prevention.

Title: Technical Resource for Incident Prevention (TRIPwire) User Registration.

OMB Number: 1670-NEW.

Frequency: Once.

Affected Public: Federal, state, local, and tribal government entities, and business or other for-profit.

Number of Respondents: 3,500 respondents (estimate).

Estimated Time per Respondent: 10 minutes.

Total Burden Hours: 583 burden hours.

Total Burden Cost (capital/startup): \$0.

Total Recordkeeping Burden: \$0.

Total Burden Cost (operating/maintaining): \$11,803.19.

Dated: February 13, 2013.

Michael Butcher,

Acting Chief Information Officer, National Protection and Programs Directorate, Department of Homeland Security.

[FR Doc. 2013-04476 Filed 2-26-13; 8:45 am]

BILLING CODE P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

Extension of Agency Information Collection Activity Under OMB Review: Security Threat Assessment for Individuals Applying for a Hazardous Materials Endorsement for a Commercial Drivers License

AGENCY: Transportation Security Administration, DHS.

ACTION: 30-day notice.

SUMMARY: This notice announces that the Transportation Security Administration (TSA) has forwarded the Information Collection Request (ICR), Office of Management and Budget

(OMB) control number 1652-0027, abstracted below to OMB for review and approval of an extension of the currently approved collection under the Paperwork Reduction Act (PRA). The ICR describes the nature of the information collection and its expected burden. TSA published a **Federal Register** notice, with a 60-day comment period soliciting comments, of the following collection of information on October 22, 2012, 77 FR 64533. The collection involves applicant submission of biometric and biographic information for TSA's security threat assessment required before obtaining the hazardous materials endorsement (HME) on a commercial drivers license (CDL) issued by the States and the District of Columbia.

DATES: Send your comments by March 29, 2013. A comment to OMB is most effective if OMB receives it within 30 days of publication.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, OMB. Comments should be addressed to Desk Officer, Department of Homeland Security/TSA, and sent via electronic mail to oir_submission@omb.eop.gov or faxed to (202) 395-6974.

FOR FURTHER INFORMATION CONTACT: Susan Perkins, TSA PRA Officer, Office of Information Technology (OIT), TSA-11, Transportation Security Administration, 601 South 12th Street, Arlington, VA 20598-6011; telephone (571) 227-3398; email TSAPRA@dhs.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The ICR documentation is available at www.reginfo.gov. Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement 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;

(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 using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Information Collection Requirement

Title: Security Threat Assessment for Individuals Applying for a Hazardous Materials Endorsement for a Commercial Drivers License

Type of Request: Revision of a currently approved collection.

OMB Control Number: 1652-0027.

Forms(s): N/A.

Affected Public: Drivers seeking a hazardous material endorsement (HME) on their commercial driver's license (CDL).

Abstract: This collection supports the implementation of sec. 1012 of the USA PATRIOT Act (Pub. L. 107-56, 115 Stat. 272, 396, Oct. 26, 2001; 49 U.S.C. 5103a), which mandates that no State or the District of Columbia may issue a HME on a CDL unless TSA has first determined the driver is not a threat to transportation security. TSA's regulations at 49 CFR part 1572 describe the procedures, standards, and eligibility criteria for security threat assessments on individuals seeking to obtain, renew, or transfer a HME on a CDL. In order to conduct the security threat assessment, States (or a TSA designated agent in States that elect to have TSA perform the collection of information) must collect information in addition to that already collected for the purpose of HME applications, which will occur once approximately every five years. The driver is required to submit an application that includes personal biographic information (for instance, height, weight, eye and hair color, date of birth); information concerning legal status, mental health defects history, and criminal history; and fingerprints. In addition, 49 CFR part 1572 requires States to maintain a copy of the driver application for a period of one year.

TSA proposes to amend the application to collect minor additional information, such as legal status document information and whether the driver is a new applicant or renewing or transferring the HME. This will enable TSA to better understand and forecast driver retention, transfer rate, and drop-rate, thus improving customer service, reducing program costs, and enhancing comparability with other Federal background checks, including the Transportation Workers Identification Credential (TWIC).

Number of Respondents: 295,000.

Estimated Annual Burden Hours: An estimated 960,000 hours annually.

Issued in Arlington, Virginia, on February 21, 2013.

Susan Perkins,

TSA Paperwork Reduction Act Officer, Office of Information Technology.

[FR Doc. 2013-04427 Filed 2-26-13; 8:45 am]

BILLING CODE 9110-05-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615-0040]

Agency Information Collection Activities: Application for Employment Authorization, Form I-765; Form I-765 Work Sheet, Form I-765WS; Revision of a Currently Approved Collection

ACTION: 30-day notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. 3501 *et seq.*), the Department of Homeland Security (DHS) is requesting public comment on a proposed revision to an approved information collection. On August 15, 2012, the Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS), submitted an information collection request, utilizing emergency review procedures, to the Office of Management and Budget (OMB) for review and clearance. OMB approved the information collection request. DHS, U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to OMB for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection notice was recently published in the **Federal Register** on December 17, 2012, at 77 FR 74687, allowing for a 60-day public comment period. USCIS did receive comments in connection with the 60-day notice.

DATES: The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until March 29, 2013. This process is conducted in accordance with 5 CFR 1320.10.

ADDRESSES: Written comments and suggestions regarding items contained in this notice, and especially with regard to the estimated public burden and associated response time should be directed to the OMB USCIS Desk Officer via email at oir_submission@omb.eop.gov. The

comments submitted to the OMB USCIS Desk Officer may also be submitted to DHS via the Federal eRulemaking Portal Web site at <http://www.regulations.gov> under e-Docket ID number USCIS-2005-0035 or via email at uscisfrcomment@uscis.dhs.gov. All submissions received must include the agency name and the OMB Control Number [1615-0040] and e-Docket ID.

Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at <http://www.regulations.gov>, and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or that is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of <http://www.regulations.gov>.

Note: The address listed in this notice should only be used to submit comments concerning this information collection. Please do not submit requests for individual case status inquiries to this address. If you are seeking information about the status of your individual case, please check "My Case Status" online at: <https://egov.uscis.gov/cris/Dashboard.do>, or call the USCIS National Customer Service Center at 1-800-375-5283.

SUPPLEMENTARY INFORMATION:

Issues for Comment Focus

DHS, USCIS invites the general public and other Federal agencies to comment upon this proposed revision of a currently approved collection of information. In accordance with the Paperwork Reduction Act of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, and the estimated burden (i.e. the time, effort, and resources used by the respondents to respond).

For Forms I-765 and I-765WS, USCIS is especially interested in the public's experience, input, and estimate of the burden in terms of time and money incurred by applicants for the following aspects of this information collection:

- The time burden incurred by preparers (persons who assist the respondent with the preparation of the form) who are not paid by the respondent.

- For preparers who are paid, the time and expense to the respondent to find and secure such preparers for assistance.

- The amount that paid preparers charge for their services.
- The time required to obtain supporting documents for Forms I-765 and I-765WS.

- The monetary costs incurred to secure supporting documents from sources such as a landlord, church, utility, public agency (housing, social services, law enforcement, local/state governments), school, medical care provider, advocacy group, law firm, or military service.

- The average time required and cost incurred to secure secondary evidence such as an affidavit or a statement.

- The percentage of total applicants who require English translations of their supporting documents.

- The percentage of supporting documents for each individual applicant that require translation into English.

- The time required to find, hire or otherwise obtain translations of supporting documents for immigration benefit requests.

- The average out of pocket monetary cost if any to obtain translations of supporting documents when required.

USCIS requested input on these questions in its 60-day notice and received no comments. If no comments are received from knowledgeable individuals, USCIS will perform its own analysis using information from other sources to estimate these costs for its next submission to OMB for this information collection.

In addition, to be helpful in the improvement of this form and the program associated with this information collection, written comments and suggestions are requested to provide USCIS with clear and specific suggestions on the data elements captured through these forms and the evidence required to be submitted with a focus on one or more of the following four points:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) How to enhance the quality, utility, and clarity of the information to be collected; and

(4) How to reduce or 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 information collection.

(2) *Title of the Form/Collection:* Application for Employment Authorization; Form I-765 Work Sheet.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form I-765 and Form I-765WS, U.S. Citizenship and Immigration Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or Households. The information collected on this form is used by USCIS to determine eligibility for the issuance of the employment authorization document.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 1,420,000 responses related to Form I-765 at 3.42 hours per response; 1,043,992 responses related to Biometrics at 1.17 hours; 706,057 responses related to Form I-765WS at .50 hours; and 1,420,000 responses related to Passport-Style Photographs at .50 hours per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 7,140,900 annual burden hours.

If you need a copy of the information collection instrument with instructions, or additional information, please visit the Federal eRulemaking Portal site at: <http://www.regulations.gov>. We may also be contacted at: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, 20 Massachusetts Avenue NW., Washington, DC 20529-2140, Telephone number 202-272-8377.

Dated: February 22, 2013.

Laura Dawkins,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2013-04584 Filed 2-26-13; 8:45 am]

BILLING CODE 9111-97-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615-0092]

Agency Information Collection Activities: E-Verify Program; Revision of a Currently Approved Collection

ACTION: 30-day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection notice was previously published in the **Federal Register** on September 11, 2012, at 77 FR 55858, allowing for a 60-day public comment period. USCIS received two comments for this information collection. A discussion of the comments and USCIS' responses are addressed in item 8 of the supporting statement that can be viewed at: <http://www.regulations.gov>.

DATES: The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until March 29, 2013. This process is conducted in accordance with 5 CFR 1320.10.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to DHS, and to the OMB USCIS Desk Officer. Comments may be submitted to: DHS, USCIS, Office of Policy and Strategy, Chief, Regulatory Coordination Division, 20 Massachusetts Avenue NW., Washington, DC 20529-2140. Comments may also be submitted to DHS via email at uscisfrcomment@dhs.gov, to the OMB USCIS Desk Officer via facsimile at 202-395-5806 or via email at oira_submission@omb.eop.gov and via the Federal eRulemaking Portal Web site at <http://www.Regulations.gov> under e-Docket ID number USCIS-2007-0023. When submitting comments by email, please make sure to add [Insert OMB Control Number 1615-0092] in the subject box.

All submissions received must include the agency name, OMB Control Number and Docket ID. Regardless of the method used for submitting comments or material, all submissions

will be posted, without change, to the Federal eRulemaking Portal at <http://www.regulations.gov>, and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. For additional information please read the Privacy Act notice that is available via the link in the footer of <http://www.regulations.gov>.

Note: The address listed in this notice should only be used to submit comments concerning this information collection. Please do not submit requests for individual case status inquiries to this address. If you are seeking information about the status of your individual case, please check "My Case Status" online at: <https://egov.uscis.gov/cris/Dashboard.do>, or call the USCIS National Customer Service Center at 1-800-375-5283.

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies 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 Request:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* E-Verify Program.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* No Agency Form Number; File OMB-18. U.S. Citizenship and Immigration Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for profit. E-Verify allows employers to

electronically verify the employment eligibility status of newly hired employees.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:*

- 65,000 respondents averaging 2.26 hours (2 hours 16 minutes) per response (enrollment time includes review and signing of the MOU, registration, new user training, and review of the user guides); plus

- 425,000, the number of already-enrolled respondents receiving training on new features and system updates averaging 1 hour per response; plus

- 425,000, the number of respondents submitting E-Verify cases averaging .129 hours (approximately 8 minutes) per case.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 3,587,275 annual burden hours.

If you need a copy of the information collection instrument with supplementary documents, or need additional information, please visit <http://www.regulations.gov>. We may also be contacted at: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, 20 Massachusetts Avenue NW., Washington, DC 20529-2140; Telephone 202-272-8377.

Dated: February 22, 2013.

Laura Dawkins,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2013-04590 Filed 2-26-13; 8:45 am]

BILLING CODE 9111-97-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615-0124]

Agency Information Collection Activities: Consideration of Deferred Action for Childhood Arrivals, Form I-821D; Revision of a Currently Approved Collection

ACTION: 30-day notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. 3501 *et seq.*), the Department of Homeland Security (DHS) is requesting public comment on a proposed revision to an approved information collection. On August 15, 2012, the Department of Homeland

Security (DHS), U.S. Citizenship and Immigration Services (USCIS), submitted an information collection request, utilizing emergency review procedures, to the Office of Management and Budget (OMB) for review and clearance. OMB approved the information collection request.

USCIS will be submitting the following information collection request to OMB for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection notice was previously published in the **Federal Register** on December 14, 2012, at 77 FR 74488, allowing for a 60-day public comment period. USCIS received comments in connection with the 60-day notice. A discussion of the comments and USCIS' responses are addressed in item 8 of the supporting statement that can be viewed at: <http://www.regulations.gov>.

DATES: The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until March 29, 2013. This process is conducted in accordance with 5 CFR 1320.10.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to DHS, and to the OMB USCIS Desk Officer. Comments may be submitted to: DHS, USCIS, Office of Policy and Strategy, Chief, Regulatory Coordination Division, 20 Massachusetts Avenue NW., Washington, DC 20529-2140. Comments may also be submitted to DHS via email at uscisfrcomment@dhs.gov, to the OMB USCIS Desk Officer via facsimile at 202-395-5806 or via email at oir_submission@omb.eop.gov and via the Federal eRulemaking Portal Web site at <http://www.Regulations.gov> under e-Docket ID number USCIS-2012-0012. When submitting comments by email, please make sure to add [Insert OMB Control Number 1615-0124] in the subject box.

All submissions received must include the agency name, OMB Control Number and Docket ID. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at <http://www.regulations.gov>, and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make

to DHS. For additional information please read the Privacy Act notice that is available via the link in the footer of <http://www.regulations.gov>.

Note: The address listed in this notice should only be used to submit comments concerning this information collection. Please do not submit requests for individual case status inquiries to this address. If you are seeking information about the status of your individual case, please check "My Case Status" online at: <https://egov.uscis.gov/cris/Dashboard.do>, or call the USCIS National Customer Service Center at 1-800-375-5283.

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies 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 Request:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Consideration of Deferred Action for Childhood Arrivals.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* Form I-821D. U.S. Citizenship and Immigration Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or Households. The information collected on this form is used by USCIS to determine eligibility of certain individuals who were brought to the United States as children and meet the following guidelines to be considered for deferred action for childhood arrivals:

1. Were under the age of 31 as of June 15, 2012;

2. Came to the United States before reaching their 16th birthday;

3. Have continuously resided in the United States since June 15, 2007, up to the present time;

4. Were present in the United States on June 15, 2012, and at the time of making their request for consideration of deferred action with USCIS;

5. Entered without inspection before June 15, 2012, or their lawful immigration status expired as of June 15, 2012;

6. Are currently in school, have graduated or obtained a certificate of completion from high school, have obtained a general education development certificate, or are an honorably discharged veteran of the Coast Guard or Armed Forces of the United States; and

7. Have not been convicted of a felony, significant misdemeanor, three or more other misdemeanors, and do not otherwise pose a threat to national security or public safety.

These individuals will be considered for relief from removal from the United States or from being placed into removal proceedings as part of the deferred action for childhood arrivals process. Those who submit requests with USCIS and demonstrate that they meet the threshold guidelines may have removal action in their case deferred for a period of two years, subject to renewal (if not terminated), based on an individualized, case by case assessment of the individual's equities. Only those individuals who can demonstrate, through verifiable documentation, that they meet the threshold guidelines will be considered for deferred action for childhood arrivals, except in exceptional circumstances.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 700,000 responses at 2 hours and 45 minutes (2.75 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 1,925,000 annual burden hours.

On August 15, 2012, in a 30-day notice in the **Federal Register** at 77 FR 49451, USCIS requested interested members of the general public to provide input and estimates on the burden in terms of time and money incurred by applicants for the following aspects of this information collection:

- The time burden incurred by preparers (persons who assist the respondent with the preparation of the form) who are not paid.
- For preparers who are paid, the time and expense to the respondent to find and secure such preparers for assistance.

- The amount that paid preparers charge for their services.

- The time required to obtain supporting documents for Form I-821D.

- The monetary costs incurred to obtain supporting documents from sources such as a landlord, church, utility, public agency (housing, social services, law enforcement), school, medical care provider, advocacy group, law firm, or military service.

- The average time required and money expended to secure secondary evidence such as an affidavit.

- The percentage of total applicants who require English translations of their supporting documents.

- The percentage of supporting documents for each individual applicant that require translation into English.

- The time required to find, hire, or otherwise obtain translations of supporting documents for immigration benefit requests.

- The average out of pocket monetary cost if any to obtain translations of supporting documents when required.

No commenter provided input on these questions. Thus DHS and USCIS is again requesting estimates and/or data that would support our analysis of this burden during the 30-day comment period provided under this notice.

If you need a copy of the information collection instrument with supplementary documents, or need additional information, please visit <http://www.regulations.gov>. We may also be contacted at: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, 20 Massachusetts Avenue NW., Washington, DC 20529-2140; Telephone 202-272-8377.

Dated: February 22, 2013.

Laura Dawkins,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2013-04576 Filed 2-26-13; 8:45 am]

BILLING CODE 9111-97-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Camin Cargo Control, Inc., as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Camin Cargo Control, Inc., as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Camin Cargo Control, Inc., has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes for the next three years as of August 1, 2012.

DATES: *Effective Dates:* The accreditation and approval of Camin Cargo Control, Inc., as commercial gauger and laboratory became effective on August 1, 2012. The next triennial inspection date will be scheduled for August 2015.

FOR FURTHER INFORMATION CONTACT: Approved Gauger and Accredited Laboratories Manager, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW., Suite 1500N, Washington, DC 20229, tel. 202-344-1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, Camin Cargo Control, Inc., 218 Centaurus St., Corpus Christi, TX 78405, has been approved to gauge and accredited to test petroleum and petroleum products, organic chemicals and vegetable oils for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquires regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344-1060. The inquiry may also be sent to cbp.labhq@dhs.gov. Please reference the Web site listed below for a complete listing of CBP approved gaugers and accredited laboratories. http://cbp.gov/linkhandler/cgov/trade/basic_trade/labs_scientific_svcs/commercial_gaugers/gaulist.ctt/gaulist.pdf.

Dated: February 19, 2013.

Ira S. Reese,

Executive Director, Laboratories and Scientific Services.

[FR Doc. 2013-04618 Filed 2-26-13; 8:45 am]

BILLING CODE 9111-14-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-5687-N-06]

Notice of Proposed Information Collection; Comment Request: Section 811 Project Rental Assistance for Persons With Disabilities

AGENCY: Office of the Assistant Secretary for Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* April 29, 2013.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Reports Liaison Officer, Department of Housing and Urban Development, 451 7th Street SW., L'Enfant Plaza Building, Room 9120, Washington, DC 20410 or the number for the Federal Relay Service (1-800-877-8339).

FOR FURTHER INFORMATION CONTACT: Catherine M. Brennan, Director, Office of Housing Assistance and Grant Administration, Office of Housing, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410, telephone (202) 708-3000 (this is not a toll free number) for copies of the proposed forms and other available information.

SUPPLEMENTARY INFORMATION: The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection 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; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including the use of appropriate automated collection techniques or other forms of

information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Section 811 Supportive Housing for Persons with Disabilities—Project Rental Assistance (811 PRA) Program.

OMB Control Number, if applicable: 2502—New.

Description of the need for the information and proposed use: The collection of this information is necessary to assist HUD in determining applicant eligibility and capacity to award and administer the HUD Section 811 Project Rental Assistance funds within statutory and program criteria. A thorough evaluation of an applicant's submission is necessary to protect the Federal Government's financial interest.

Agency form numbers, if applicable: SF-424, SF-424 Supplement, SF-LLL, HUD-2880, HUD-424CB, HUD-2993, HUD-2990, HUD-96011, HUD-2994-A, HUD-96010.

Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: The estimated number of burden hours needed to prepare the information collection is 11,273.05, the number of respondents is 720 generating approximately 765 annual responses; the frequency of response is on occasion; and the estimated time needed to prepare the response varies from 30 minutes to 21.5 hours.

Status of the proposed information collection: Extension of a currently approved collection.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C., Chapter 35, as amended.

Dated: February 21, 2012.

Laura M. Marin,

Acting General Assistant Secretary for Housing-Acting General Deputy Federal Housing Commissioner.

[FR Doc. 2013-04586 Filed 2-26-13; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

Wildland Fire Executive Council Meeting Schedule

AGENCY: Office of the Secretary, Interior.

ACTION: Notice of meeting.

SUMMARY: In accordance with the requirements of the Federal Advisory Committee Act, 5 U.S.C. App., 2, the U.S. Department of the Interior, Office of the Secretary, Wildland Fire

Executive Council (WFEC) will meet as indicated below.

DATES: The next meeting will be held on March 19–20, 2013.

ADDRESSES: The meetings will be held from 8:30 a.m. to 2:30 p.m. on March 19 and from 10:00 a.m. to 11:00 a.m. on March 20 at the Peppermill Resort, 2707 South Virginia Street, Reno, NV 89502.

FOR FURTHER INFORMATION CONTACT: Shari Eckhoff, Designated Federal Officer, 300 E. Mallard Drive, Suite 170, Boise, Idaho 83706; telephone (208) 334-1552; fax (208) 334-1549; or email Shari_Eckhoff@ios.doi.gov.

SUPPLEMENTARY INFORMATION: The WFEC is established as a discretionary advisory committee under the authorities of the Secretary of the Interior and Secretary of Agriculture, in furtherance of 43 U.S.C. 1457 and provisions of the Fish and Wildlife Act of 1956 (16 U.S.C. 742a–742j), the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1701 *et seq.*), the National Wildlife Refuge System improvement Act of 1997 (16 U.S.C. 668dd–668ee), and the National Forest Management Act of 1976 (16 U.S.C. 1600 *et seq.*) and in accordance with the provisions of the Federal Advisory Committee Act, as amended, 5 U.S.C. App. 2. The Secretary of the Interior and Secretary of Agriculture certify that the formation of the WFEC is necessary and is in the public interest.

The purpose of the WFEC is to provide advice on coordinated national-level wildland fire policy and to provide leadership, direction, and program oversight in support of the Wildland Fire Leadership Council. Questions related to the WFEC should be directed to Shari Eckhoff (Designated Federal Officer) at Shari_Eckhoff@ios.doi.gov or (208) 334-1552 or 300 E. Mallard Drive, Suite 170, Boise, Idaho 83706-6648.

Meeting Agenda: The meeting agenda will include: (1) Welcome and introduction of Council members; (2) Wildland Fire Governance; (3) Barriers and Critical Success Factors related to the Cohesive Strategy; (4) Regional Action Plans; (5) Communications Update; (6) Administrative Items; (7) Public comments which will be scheduled for 10:00 to 11:00 on March 20; (8) and closing remarks.

Participation is open to the public.

Public Input: All WFEC meetings are open to the public. Members of the public who wish to participate must notify Shari Eckhoff at Shari_Eckhoff@ios.doi.gov no later than the Friday preceding the meeting. Those who are not committee members and wish to present oral statements or obtain information should contact Shari

Eckhoff via email no later than the Friday preceding the meeting. Depending on the number of persons wishing to comment and time available, the time for individual oral comments may be limited.

Questions about the agenda or written comments may be emailed or submitted by U.S. Mail to: Department of the Interior, Office of the Secretary, Office of Wildland Fire, Attention: Shari Eckhoff, 300 E. Mallard Drive, Suite 170, Boise, Idaho 83706-6648. WFEC requests that written comments be received by the Friday preceding the scheduled meeting. Attendance is open to the public, but limited space is available. Persons with a disability requiring special services, such as an interpreter for the hearing impaired, should contact Ms. Eckhoff at (202) 527-0133 at least seven calendar days prior to the meeting.

Dated: February 19, 2013.

Shari Eckhoff,

Designated Federal Officer.

[FR Doc. 2013-04500 Filed 2-26-13; 8:45 am]

BILLING CODE 4310-J4-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLWO200000.13X.L1010.LXSICLMT0000.PH]

Notice of Availability of the Colorado Plateau Rapid Ecoregional Assessment

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: This notice announces the availability of the Bureau of Land Management's (BLM) first Rapid Ecoregional Assessment (REA) covering land in four western states. The Colorado Plateau REA includes parts of Arizona, Colorado, New Mexico and Utah. It has an area of 32,387 square miles and includes all or portions of 16 BLM field offices.

ADDRESSES: The REA, and its associated data, are available through the BLM Web site at: http://www.blm.gov/wo/st/en/prog/more/Landscape_Approach.html.

FOR FURTHER INFORMATION CONTACT:

Karen Prentice, Natural Resource Specialist, 202-912-7223, kprentic@blm.gov. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 to contact the above individuals during business hours. The FIRS is available 24

hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: This notice announces the availability of the first REA issued by the BLM covering land in four western states. Although the BLM is publishing this Notice for the first REA, subsequent REAs will be made available on the Web site listed in the **ADDRESSES** section without publication in the **Federal Register**. REAs assemble information that can be used to guide public lands management. They use existing scientific information to identify resource conditions and trends within an ecoregion, a large geographic area that shares similar characteristics. This innovative large-scale approach is designed to help identify patterns of environmental change that may not be evident when managing smaller land areas. Additional REAs covering the Central Basin and Range, Mojave Basin and Range, Northwestern Great Plains/Northwestern Glaciated Plains, Middle Rockies, Sonoran Desert, and the Seward Peninsula-Nulato Hills-Kotzebue Lowlands ecoregions are in preparation and will be made publicly available on the BLM Web site as they are completed. In 2013, the BLM plans to complete REAs for the Northern Basin and Range, Snake River Plain, Wyoming Basin, and Yukon River Lowlands/Kuskokwim Mountains/Lime Hills, all of which began in 2011. The BLM is conducting pre-assessment work for potential REAs in the Beaufort Coastal Plain, Brooks Hills, Chihuahuan Desert, Southern Great Plains (3 ecoregions), and Madrean Archipelago. Each REA highlights and maps areas of both high and low ecological values. Lands with relatively high ecological values can be managed to ensure that their wildlife habitat is properly conserved. Lands with relatively low ecological value could be best-suited for siting future development, such as transmission lines. Each REA also gauges the potential risks to these lands from four key environmental "change agents:" Climate change, wildfires, invasive species, and development. REAs use information about the natural resources of all the lands within an ecoregion. In this way, the REAs can provide a foundation for formulating coordinated strategies that can respond more effectively to climate change, wildfire, and other environmental challenges that transcend land management boundaries. The BLM prepared its REAs in cooperation with

other Federal and state land management agencies.

Procedural Requirements: The REAs provide science-based information and tools for land managers and stakeholders to consider in resource planning and decision-making processes, such as Resource Management Plans and Environmental Impact Statements. Consequently, the REAs do not contain findings and recommendations, nor do they make management decisions or allocate resource uses. The issuance of REAs by the BLM does not constitute a rulemaking.

Edwin Roberson,

Assistant Director, Bureau of Land Management.

[FR Doc. 2013-04343 Filed 2-26-13; 8:45 am]

BILLING CODE 4310-84-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNVS00000 L12200000.PM0000
LXSS006F0000 261A; 12-08807; MO#
4500034358; TAS: 14X1109]

Notice of Public Meetings: Sierra Front-Northwestern Great Basin Resource Advisory Council, Nevada

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meetings.

SUMMARY: In accordance with the Federal Land Policy and Management Act (FLPMA) and the Federal Advisory Committee Act of 1972 (FACA), the U.S. Department of the Interior, Bureau of Land Management (BLM) Sierra Front-Northwestern Great Basin Resource Advisory Council (RAC), will hold two meetings in Nevada in fiscal year 2013. The meetings are open to the public.

DATES AND TIMES: April 4–5 at the BLM Carson City District Office, 5665 Morgan Mill Road in Carson City, Nevada and a field trip on April 5; August 8–9 at the BLM Winnemucca District Office, 5100 East Winnemucca Blvd. and a field trip on August 9. Approximate meeting times are 8 a.m. to 4 p.m. However, meetings could end earlier if discussions and presentations conclude before 4 p.m. All meetings will include a public comment period at approximately 2 p.m.

FOR FURTHER INFORMATION CONTACT: Lisa Ross, Public Affairs Specialist, Carson City District Office, 5665 Morgan Mill Road, Carson City, NV 89701, telephone: (775) 885-6107, email: lross@blm.gov. Persons who use a telecommunications device for the deaf

(TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The 15-member Council advises the Secretary of the Interior, through the BLM, on a variety of planning and management issues associated with public land management in Nevada. Topics for discussion at each meeting will include, but are not limited to:

- April 4–5 (Carson City)—rangeland health assessments, Carson City Resource Management Plan, greater sage-grouse/Bi State conservation, recreation, and fire restoration (field trip on April 5).
- August 8–9 (Winnemucca)—landscape vegetative management and ongoing monitoring, recreation/wilderness management and Emergency Stabilization and Restoration (field trip on August 9).

Managers' reports of field office activities will be given at each meeting. The Council may raise other topics at the meetings.

Final agendas will be posted on-line at the BLM Sierra Front-Northwestern Great Basin RAC Web site at http://www.blm.gov/nv/st/en/res/resource_advisory.html and will be published in local and regional media sources at least 14 days before each meeting.

Individuals who need special assistance such as sign language interpretation or other reasonable accommodations, or who wish to receive a copy of each agenda, may contact Lisa Ross no later than 10 days prior to each meeting.

Erica Haspiel-Szlosek,

Chief, Office of Communications.

[FR Doc. 2013-04499 Filed 2-26-13; 8:45 am]

BILLING CODE 4310-HC-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNV912000 L10100000.PH0000
LXSS0006F0000; 12-08807;
MO#4500048585; TAS: 14X1109]

Notice of Public Meetings: Mojave-Southern Great Basin Resource Advisory Council, Nevada

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meetings.

SUMMARY: In accordance with the Federal Land Policy and Management Act (FLPMA) and the Federal Advisory Committee Act of 1972 (FACA), the U.S. Department of the Interior, Bureau of Land Management (BLM) Mojave-Southern Great Basin Resource Advisory Council (RAC), will hold three meetings in Nevada in fiscal year 2013. The meetings are open to the public.

DATES AND TIMES: March 21–22 in Las Vegas, Nevada, location to be determined; July 11 in Las Vegas, Nevada, location to be determined; and Sept. 12 via video teleconference. Meeting times will be published in local and regional media sources at least 14 days before each meeting. All meetings will include a public comment period.

FOR FURTHER INFORMATION CONTACT:

Chris Hanefeld, Public Affairs Specialist, Ely District Office, 702 North Industrial Way, HC 33 Box 33500, Ely, NV 89301, telephone: (775) 289-1842, email: chanefel@blm.gov. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The 15-member Council advises the Secretary of the Interior, through the BLM, on a variety of planning and management issues associated with public land management in Nevada. Topics for discussion at each meeting will include, but are not limited to:

- March 21–22 (Las Vegas)—Southern Nevada Public Land Management Act (SNPLMA), Battle Mountain District and Southern Nevada District resource management plans, and permitted recreation (date of field trip to be determined).

- July 11 (Las Vegas)—Energy and transmission, Battle Mountain District and Southern Nevada District resource management plans, and permitted recreation.

- September 12 (video teleconference)—Energy and transmission, and desert tortoise. Managers' reports of field office activities will be given at each meeting. The Council may raise other topics at the meetings.

Final agendas will be posted on-line at the BLM Mojave-Southern Great Basin RAC Web site at http://www.blm.gov/nv/st/en/res/resource_advisory.html and will be published in local and regional media

sources at least 14 days before each meeting.

Individuals who need special assistance such as sign language interpretation or other reasonable accommodations, or who wish to receive a copy of each agenda, may contact Chris Hanefeld no later than 10 days prior to each meeting.

Erica Haspiel-Szlosek,

Chief, Office of Communications.

[FR Doc. 2013-04504 Filed 2-26-13; 8:45 am]

BILLING CODE 4310-HC-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-WASO-BSAD-CONC-12056; 133 PPMVSCS1Y.Y00000, PPWOBSADC0]

Information Collection Request Sent to the Office of Management and Budget (OMB) for Approval; Submission of Offers in Response to Concession Opportunities

AGENCY: National Park Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: We (National Park Service, NPS) have sent an Information Collection Request (ICR) to OMB for review and approval. We summarize the ICR below and describe the nature of the collection and the estimated burden and cost. This information collection is scheduled to expire on March 31, 2013. We 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. However, under OMB regulations, we may continue to conduct or sponsor this information collection while it is pending at OMB.

DATES: You must submit comments on or before March 29, 2013.

ADDRESSES: Send your comments and suggestions on this information collection to the Desk Officer for the Department of the Interior at OMB-OIRA at (202) 395-5806 (fax) or *OIRA_Submission@omb.eop.gov* (email). Please provide a copy of your comments to the Information Collection Clearance Officer, National Park Service, 1201 I Street NW., MS 1237, Washington, DC 20005 (mail); or *madonna_baucum@nps.gov* (email). Please reference OMB Control Number

1024-0125 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Deborah Harvey, Acting Chief, Commercial Services Program, 1201 I Street, NW., Washington, DC 20005. You may send an email to *Deborah_Harvey@nps.gov* or contact her by telephone at (202) 513-7150 or via fax at (202) 371-2090. You may review the ICR online at *http://www.reginfo.gov*. Follow the instructions to review Department of the Interior collections under review by OMB.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 1024-0125.

Title: Submission of Offers in Response to Concession Opportunities, 36 CFR 51.

Service Form Number: None.

Type of Request: Extension of a currently approved collection.

Description of Respondents: Businesses, individuals, and nonprofit organizations.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion.

Activity	Number of respondents	Number of responses	Completion time per response (hours)	Total annual burden hours
Large Concessions	30	30	240	7,200
Small Concessions	60	60	80	4,800
Totals	90	90	12,000

Estimated Annual Nonhour Burden Cost: \$420,000. We estimate that the average nonhour cost per respondent is \$3,000 for small operations and \$8,000 for large operations.

Abstract: The regulations at 36 CFR Part 51 primarily implement Title IV of the National Parks Omnibus Management Act of 1998 (Pub. L. 105-391), which provides legislative authority, policies, and requirements for the solicitation, award, and administration of NPS concession contracts. The regulations require the submission of offers by parties interested in applying for an NPS concession contract.

The public solicitation process begins with the issuance of a prospectus to invite the general public to submit proposals for the contract. The prospectus describes the terms and conditions of the concession contract to be awarded, the procedures to be followed in the selection of the best proposal, and the information that must

be provided. Information that we collect includes, but is not limited to:

- Description of how respondent will conduct operations to minimize disturbance to wildlife.
- Specific actions, steps, or programs that respondent will implement to protect park resources.
- Steps that respondent will take to provide visitors with a consistent, high quality, safe, and enjoyable visitor experience at a reasonable rate.
- Organizational structure and history.
- Experience with similar operations.
- Details on violations or infractions and how they were handled.
- Financial information and demonstration that respondent has credible, proven track record of meeting obligations.
- Ability to obtain funds for start-up costs.
- How respondent will communicate an environmental ethic to employees and visitors.

We use this information to objectively evaluate offers received for a particular business opportunity, assure that the park resources will be adequately protected, and determine which respondent will provide the best service to visitors.

Comments: On July 24, 2012, we published in the **Federal Register** (77 FR 43354) a notice of our intent to request that OMB renew approval for this information collection. In that notice, we solicited comments for 60 days, ending on September 24, 2012. We did not receive any comments.

We again invite comments concerning this information collection on:

- Whether or not the collection of information is necessary, including whether or not the information will have practical utility;
- The accuracy of our estimate of the burden for this collection of information;

- Ways to enhance the quality, utility, and clarity of the information to be collected; and
- Ways to minimize the burden of the collection of information on respondents.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask OMB in your comment to withhold your personal identifying information from public review, we cannot guarantee that it will be done.

Dated: February 13, 2013.

Madonna L. Baucum,

*Information Collection Clearance Officer,
National Park Service.*

[FR Doc. 2013-04537 Filed 2-26-13; 8:45 am]

BILLING CODE 4312-EH-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-NER-HPPC-11732; PPWONRADE2
PMP00E105]

Chronic Wasting Disease Management Plan/Environmental Impact Statement, Shenandoah National Park

AGENCY: National Park Service, Interior.

ACTION: Notice of Intent.

SUMMARY: Pursuant to Section 102(2)(C) the National Environmental Policy Act of 1969 and the Council on Environmental Quality regulations, the National Park Service (NPS) is preparing a Chronic Wasting Disease Management Plan and Environmental Impact Statement (CWD Management Plan/EIS) for Shenandoah National Park, Virginia. Action is needed at this time prevent the establishment of CWD in the white-tailed deer population of Shenandoah National Park and, should the disease become established, to slow the spread of the disease. To ensure that all significant issues are identified and considered, all interested parties are invited to comment on the proposed scope of the project, the purpose, need, and objectives of the plan, and draft alternatives.

DATES: The National Park Service will accept comments from the public for a period of 60 days after the date of publication in the **Federal Register**. Public meetings will be held during the review period to facilitate the

submission of public comment. Once scheduled, the meeting dates will be announced on the NPS's Planning Environment and Public Comment (PEPC) Web site (<http://parkplanning.nps.gov/shen>); by newsletter posted on the Shenandoah National Park Web page (www.nps.gov/shen); and by a press release to the local media.

ADDRESSES: The preferred method of comment is to submit comments electronically through the NPS PEPC Web site (<http://parkplanning.nps.gov/shen>). You may also mail comments to Superintendent, Shenandoah National Park, 3655 U.S. Highway 211 East, Luray, VA, 22835.

FOR FURTHER INFORMATION CONTACT: Erin Flanagan, National Park Service, Denver Service Center, at (303) 969-2327.

SUPPLEMENTARY INFORMATION: A long-range CWD Management Plan is needed at this time because: CWD is established and spreading within the region and represents a threat to white-tailed deer, which are an important park resource; the risk of CWD introduction and amplification is high because of high deer population density in certain areas of the park and deer movement in and out of the park; there is no known treatment to eliminate CWD once it is established in the population; a variety of management options must be considered to limit the prevalence and minimize spread; and CWD is a nonnative disease process, therefore, NPS policy states that CWD should be managed or eliminated, if prudent and feasible.

To date, Shenandoah National Park has prepared a CWD Detection and Assessment Plan and Environmental Assessment which, when completed and approved, will guide future actions for detecting and responding to initial CWD cases within the park. The next step is to comprehensively evaluate alternative approaches for long-term management of CWD, which is the purpose of the proposed CWD Management Plan/EIS.

The objectives of the long-range CWD management plan are to: Prevent CWD establishment and, should CWD become established, slow the spread of CWD within the park; monitor disease progression and impacts on park resources; provide a framework to assess or evaluate the success of the management actions and for the NPS to cooperate with other state and federal agencies on the management of CWD; develop public support for CWD management through education; minimize disruption to visitor use and experience from management actions;

and minimize the potential for health and safety issues for park staff and visitors during CWD management activities.

The NPS has begun development of two action alternatives that will be made available for public comment as part of the scoping process. The first action alternative proposes a phased approach to CWD management and would be implemented when CWD is identified within a specified distance from the park. In slight contrast, the second alternative would initiate management actions immediately, rather than in response to proximity of CWD detection to the boundaries of the park. The NPS will also evaluate a no action alternative, under which current management approaches would continue, including implementation of the approved CWD detection and assessment plan.

To ensure that all significant issues are identified and considered, all interested parties are invited to comment on the proposed scope of the project; the purpose, need and objectives of the plan; and draft alternatives. These materials will be available for review and comment on the NPS PEPC Web site (<http://parkplanning.nps.gov/shen>) and the park's Web page (www.nps.gov/shen).

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: November 20, 2012.

Dennis R. Reidenbach,

Regional Director, Northeast Region, National Park Service.

[FR Doc. 2013-04549 Filed 2-26-13; 8:45 am]

BILLING CODE 4310-WV-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-PWR-PWRO-11436;
PXP0137227A001]

Draft Environmental Impact Statement for the Cottonwood Cove and Katherine Landing Development Concept Plans, Clark County, NV, and Mohave County, AZ

AGENCY: National Park Service, Interior.

ACTION: Notice of availability.

SUMMARY: Pursuant to the National Environmental Policy Act of 1969, 42 U.S.C. 4332(2)(C), the National Park Service announces the availability of a Draft Environmental Impact Statement (EIS) for the Cottonwood Cove and Katherine Landing Development Concept Plans, Lake Mead National Recreation Area. The Draft EIS identifies and analyzes three alternatives, as follows. Alternative 1 *Continue Current Management Trends* (no action alternative) reflects current management direction and serves as a baseline for comparison with the other alternatives. Existing facilities would be retained with minimal changes. Alternative 2 *Implement Previous Planning Proposals* would implement previous planning proposals that separate day use and marina facilities, maintain the type of overnight facilities, and provide flood mitigation. Alternative 3 *Enhance Visitor Experience and Park Operations* (agency-preferred alternative) would enhance day-use opportunities, upgrade and expand the type of overnight facilities, and provide flood mitigation. The Draft EIS also evaluates the potential environmental impacts of the alternatives, including potential impacts to native plant communities and soils, wildlife, threatened, endangered, and special status species; floodplains; archeological resources; historic structures; cultural landscape; ethnographic resources; visitor use, experience, and safety; park operations; and socioeconomic environment.

DATES: The National Park Service will accept comments on the Draft EIS from the public for 60 days after the date the Environmental Protection Agency publishes its notice in the **Federal Register**. The National Park Service will also hold public meetings during the public comment period; the date, time, and location of the meetings will be announced on Project Web site <http://parkplanning.nps.gov/lake>, as well as via local and regional press media.

ADDRESSES: Respondents may submit comments by one of two methods. You may mail written comments to Lake Mead National Recreation Area, Attn: DCP-DEIS, 601 Nevada Highway, Boulder City, NV 89005. You may also submit comments electronically via the Internet at <http://parkplanning.nps.gov/lake>. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying

information from public review, we cannot guarantee that we will be able to do so.

FOR FURTHER INFORMATION CONTACT: Mr. Jim Holland, Park Planner, Lake Mead National Recreation Area, 601 Nevada Highway, Boulder City, NV 89005 (702) 293-8986.

SUPPLEMENTARY INFORMATION: The purpose of the development concept plans is to reevaluate the implementation strategies for these two areas that were identified in the 1986 *Lake Mead National Recreation Area General Management Plan/Development Concept Plans/Final Environmental Impact Statement* and to incorporate the concepts and carrying capacities that were approved in the 2003 *Lake Mead National Recreation Area Lake Management Plan/Final Environmental Impact Statement*. Each development concept plan provides an integrated plan for development with site specific guidance for the extent, type, and location of facilities and services that is consistent with the management direction and intent established in the general management plan and lake management plan.

The general management plan addressed the need to provide recreational opportunities while preserving and protecting natural and cultural resources. It established land-based management zones and included development concept plans for Cottonwood Cove and Katherine Landing that identified limits on the development, established the number and type of facilities, and addressed flood hazards. The general management plan's vision for both areas was to accommodate increasing use, enhance the visitor experience, and mitigate flood hazards. The lake management plan established water-based management zones and provided further guidance for the long-term protection of park resources while allowing a range of recreational opportunities to support visitor needs. A number of the management actions identified in both approved plans require more site-specific development planning. There are also a number of management issues that have not been adequately addressed or resolved in the previous planning efforts and that require a more detailed examination of development and operational needs.

The primary issues affecting the management of the Cottonwood Cove and Katherine Landing developed areas are as follows:

- Providing flood mitigation

- Enhancing shoreline-based day-use opportunities and facilities to meet a growing demand
 - Improving the safety and ease of access, providing better organized and more convenient parking, and providing an appropriate number of parking spaces
 - Improving NPS campgrounds to function effectively to meet visitor needs while protecting the cultural landscape
 - Providing adequate visitor information and education programs and determining if commercial services and NPS educational and interpretive services be provided in a joint facility enhancing operational facilities to function effectively and efficiently, meeting the needs of both park staff and visitors
 - Identifying which concession facilities or services are still necessary and appropriate at these sites for public use and enjoyment of the park
- Decision Process:** Following due consideration of all comments received, a Final EIS will be prepared. As a delegated EIS, the official responsible for a final decision is the Regional Director, Pacific West Region. Subsequently the official responsible for implementing the approved development concept plans and for monitoring results is the Superintendent, Lake Mead National Recreation Area.

Dated: September 28, 2012.

Martha J. Lee,

Acting Regional Director, Pacific West Region.

[FR Doc. 2013-04538 Filed 2-26-13; 8:45 am]

BILLING CODE 4312-FF-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-WASO-NRNHL-12225;
PPWOCRADIO, PCU00RP14.R50000]

Landmarks Committee of the National Park System Advisory Board Meeting

AGENCY: National Park Service, Interior.

ACTION: Notice of meeting.

SUMMARY: Notice is hereby given in accordance with the Federal Advisory Committee Act, 5 U.S.C. Appendix (1988), that a teleconference meeting of the Landmarks Committee of the National Park System Advisory Board will be held beginning at 1:00 p.m. on April 9, 2013, at the following location. Members of the public may attend the meeting in person in Washington, DC, or may participate via teleconference.

DATES: The meeting will be held on April 9, 2013, from 1:00 p.m. to 3:30 p.m., Eastern Daylight Time.

Location: The teleconference meeting will be held at the National Park Service, 1201 Eye Street NW., 2nd Floor, Washington, DC 20005.

Agenda: The National Park System Advisory Board and its Landmarks Committee may consider the following nominations:

Illinois

ADLAI E. STEVENSON II HOUSE,
Mettawa

Michigan

THE DETROIT INDUSTRY MURALS,
DETROIT INSTITUTE OF ARTS, Detroit

Pennsylvania

GEORGE NAKASHIMA WOODWORKER
COMPLEX, Bucks County

The committee may also consider the following historic trail:

BUTTERFIELD OVERLAND NATIONAL
HISTORIC TRAIL

FOR FURTHER INFORMATION CONTACT:

Patricia Henry, National Historic Landmarks Program, National Park Service; 1201 Eye Street NW., 8th Floor; Washington, DC 20005; Telephone (202) 354-2216; Email: Patty_Henry@nps.gov.

SUPPLEMENTARY INFORMATION:

The purpose of the meeting of the Landmarks Committee of the National Park System Advisory Board is to evaluate nominations of historic properties in order to advise the National Park System Advisory Board of the qualifications of each property being proposed for National Historic Landmark (NHL) designation, and to make recommendations regarding the possible designation of those properties as National Historic Landmarks to the National Park System Advisory Board at a subsequent meeting at a place and time to be determined. The members of the committee, with exception of the Chair, will be participating remotely at this meeting. The members of the Landmarks Committee are:

Mr. Ronald James, Chair
Dr. James M. Allan
Dr. Cary Carson
Dr. Darlene Clark Hine
Mr. Luis Hoyos, AIA
Dr. Barbara J. Mills
Dr. William J. Murtagh
Dr. Franklin Odo
Dr. William D. Seale
Dr. Michael E. Stevens

The meeting will be open to the public at the location provided above or via teleconference. Due to the limited scope of this meeting, the NPS has determined that a teleconference will be the most efficient way to convene the Committee members. The Committee meeting will be open to the public in the same way that other Committee

meetings have been open to the public in the past. Space and facilities to accommodate the public are limited and attendees will be accommodated on a first-come basis. Opportunities for oral comment will be limited to no more than 3 minutes per speaker and no more than 15 minutes total per property. The Committee Chairman will determine how time for oral comments will be allotted. To participate via teleconference interested parties must provide their name and email address to the Program by Friday, April 5; submit the requested contact information to Ms. Patty Henry at (202) 354-2216, or via email at Patty_Henry@nps.gov.

Pursuant to 36 CFR Part 65, any member of the public may file, for consideration by the Landmarks Committee of the National Park System Advisory Board, written comments concerning the National Historic Landmarks nominations. Comments should be submitted to J. Paul Loether, Chief, National Register of Historic Places and National Historic Landmarks Program, National Park Service; 1201 Eye Street NW., 8th Floor; Washington, DC 20005; Email: Paul_Loether@nps.gov.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: February 6, 2013.

J. Paul Loether,

*Chief, National Register of Historic Places
and National Historic Landmarks Program;
National Park Service, Washington, DC*

[FR Doc. 2013-04489 Filed 2-26-13; 8:45 am]

BILLING CODE 4312-51-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-WASO-NRNHL-12172; 2200-3200-665]

**National Register of Historic Places;
Notification of Pending Nominations
and Related Actions**

Nominations for the following properties being considered for listing or related actions in the National Register were received by the National Park Service before January 19, 2013. Pursuant to section 60.13 of 36 CFR part 60, written comments are being

accepted concerning the significance of the nominated properties under the National Register criteria for evaluation. Comments may be forwarded by United States Postal Service, to the National Register of Historic Places, National Park Service, 1849 C St. NW., MS 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service, 1201 Eye St. NW., 8th floor, Washington, DC 20005; or by fax, 202-371-6447. Written or faxed comments should be submitted by March 14, 2013. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: January 23, 2013.

J. Paul Loether,

*Chief, National Register of Historic Places/
National Historic Landmarks Program.*

ILLINOIS

Cook County

Passionist Fathers Monastery, 5700 N.
Harlem Dr., Chicago, 13000048

Storkline Furniture Corporation Factory,
4400-4418 W. 26th St., Chicago, 13000049

MASSACHUSETTS

Essex County

North Street Fire Station, 142 North St.,
Salem, 13000050

Swampscott Cemetery, 400 Essex St.,
Swampscott, 13000051

NEW YORK

Erie County

Burt, F.N., Company Factory, (Hydraulics/
Larkin Neighborhood, Buffalo, Erie County,
NY MPS), 500 Seneca St., Buffalo,
13000053

Rensselaer County

United Waste Manufacturing Company
Building, 1 Jackson St., Troy, 13000054

Ulster County

Hasbrouck, Judge Jonathan, House, 20 Elwyn
Ln., Woodstock, 13000056

Washington County

Old Stone House Library, The, 36 St. George
St., Fort Ann, 13000055

OREGON

Deschutes County

Deedon, Ed and Genevieve, Homestead,
15600 Deedon Rd., La Pine, 13000057

Multnomah County

Halprin Open Space Sequence, SW Open Spaces & Pedestrian Malls from Lincoln to Clay Sts., Portland, 13000058

PENNSYLVANIA**Chester County**

Coatesville Veterans Administration Hospital Historic District, (United States Second Generation Veterans Hospitals MPS) 1400 Blackhorse Hill Rd., Coatesville, 13000059

SOUTH CAROLINA**Florence County**

Florence Downtown Historic District (Boundary Increase), 124–201 W. Evans St., Florence, 13000060

WISCONSIN**Ozaukee County**

Little Meadowmere, 8414 W. County Line Rd., Mequon, 13000061

In the interest of preservation a request to shorten the comment period to three days has been made for the following resource:

MASSACHUSETTS**Worcester County**

Dana Common Historic and Archaeological District, Gate 40 off Hardwick Rd., Petersham, 13000052

[FR Doc. 2013–04490 Filed 2–26–13; 8:45 am]

BILLING CODE 4312–51–P

DEPARTMENT OF THE INTERIOR**National Park Service**

[NPS–AKR–WRST–11805; PPAKWRSTS3, PPMRSNR1Z.NU0000]

Wrangell-St. Elias National Park and Preserve, Alaska; Proposed Mining Plan of Operations

AGENCY: National Park Service, Interior.

ACTION: Notice of availability.

SUMMARY: Pursuant to the provisions of Section 2 of the Act of September 28, 1976, 16 U.S.C. 1902, and in accordance with the provisions of 36 C.F.R. 9.17, notice is hereby given that Thomas and Kathryn Lamal have filed a proposed plan of operations to conduct a mining operation on lands embracing the Shamrock (AA026813) and Tony M (AA026810) unpatented placer claims within Wrangell-St. Elias National Park and Preserve.

Public Availability: This plan of operations is available for inspection during normal business hours at the following locations:

Wrangell-St. Elias National Park and Preserve Headquarters, Mile 106.8 Richardson Highway, Post Office Box 439, Copper Center, Alaska 99573.
National Park Service, Alaska Regional Office—Natural Resources Division,

240 West 5th Avenue, Anchorage, Alaska 99501.

FOR FURTHER INFORMATION CONTACT: Rick Obernesser, Superintendent, and Danny Rosenkrans, Senior Management Analyst, Wrangell-St. Elias National Park and Preserve, P.O. Box 439, Copper Center, Alaska 99573; telephone (907) 822–5234.

Dated: February 4, 2013.

Sue E. Masica,

Regional Director, Alaska.

[FR Doc. 2013–04530 Filed 2–26–13; 8:45 am]

BILLING CODE 4312–EF–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 731–TA–1202–03 (Final)]

Xanthan Gum from Austria and China; Scheduling of the Final Phase of an Antidumping Investigation

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of the final phase of antidumping investigation Nos. 731–TA–1202–03 (Final) under section 735(b) of the Tariff Act of 1930 (19 U.S.C. 1673d(b)) (the Act) to determine whether an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of less-than-fair-value imports from Austria and/or China of xanthan gum, provided for in subheading 3913.90.20 of the Harmonized Tariff Schedule of the United States.¹

¹ For purposes of this investigation, the Department of Commerce has defined the subject merchandise as Adry xanthan gum, whether or not coated or blended with other products. Further, xanthan gum is included in this investigation regardless of physical form, including, but not limited to, solutions, slurries, dry powders of any particle size, or unground fiber.

Xanthan gum that has been blended with other product(s) is included in this scope when the resulting mix contains 15 percent or more of xanthan gum by dry weight. Other products with which xanthan gum may be blended include, but are not limited to, sugars, minerals, and salts.

Xanthan gum is a polysaccharide produced by aerobic fermentation of *Xanthomonas campestris*. The chemical structure of the repeating pentasaccharide monomer unit consists of a backbone of two P–1,4–D–Glucose monosaccharide units, the second with a trisaccharide side chain consisting of P–D–Mannose–(1,4)–P–D–Glucuronic acid–(1,2)–a–D–Mannose monosaccharide units. The terminal mannose may be pyruvylated and the internal mannose unit may be acetylated.

Merchandise covered by the scope of this investigation is classified in the Harmonized Tariff Schedule of the United States at subheading 3913.90.20. This tariff classification is provided for

For further information concerning the conduct of this phase of the investigations, hearing procedures, and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

DATED: *Effective Date:* January 10, 2013.

FOR FURTHER INFORMATION CONTACT:

Cynthia Trainor (202–205–3354), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter 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 (<http://www.usitc.gov>). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at <http://edis.usitc.gov>.

SUPPLEMENTARY INFORMATION:

Background.—The final phase of these investigations is being scheduled as a result of affirmative preliminary determinations by the Department of Commerce that imports of xanthan gum from Austria and China are being sold in the United States at less than fair value within the meaning of section 733 of the Act (19 U.S.C. 1673b). The investigations were requested in a petition filed on June 5, 2012, by C.P. Kelco U.S., Atlanta, GA.

Participation in the investigations and public service list.—Persons, including industrial users of the subject merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the final phase of these investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11 of the Commission's rules, no later than 21 days prior to the hearing date specified in this notice. A party that filed a notice of appearance during the preliminary phase of these investigations need not file an additional notice of appearance during this final phase. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations.

Limited disclosure of business proprietary information (BPI) under an

convenience and customs purposes; however, the written description of the scope is dispositive."

administrative protective order (APO) and BPI service list.—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in the final phase of these investigations available to authorized applicants under the APO issued in the investigations, provided that the application is made no later than 21 days prior to the hearing date specified in this notice. Authorized applicants must represent interested parties, as defined by 19 U.S.C. 1677(9), who are parties to the investigations. A party granted access to BPI in the preliminary phase of the investigations need not reapply for such access. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Staff report.—The prehearing staff report in the final phase of these investigations will be placed in the nonpublic record on May 7, 2013, and a public version will be issued thereafter, pursuant to section 207.22 of the Commission's rules.

Hearing.—The Commission will hold a hearing in connection with the final phase of these investigations beginning at 9:30 a.m. on May 23, 2013, at the U.S. International Trade Commission Building. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before May 15, 2013. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should attend a prehearing conference to be held at 9:30 a.m. on May 17, 2013, at the U.S. International Trade Commission Building. Oral testimony and written materials to be submitted at the public hearing are governed by sections 201.6(b)(2), 201.13(f), and 207.24 of the Commission's rules. Parties must submit any request to present a portion of their hearing testimony *in camera* no later than 7 business days prior to the date of the hearing.

Written submissions.—Each party who is an interested party shall submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of section 207.23 of the Commission's rules; the deadline for filing is May 14, 2013. Parties may also file written testimony in connection with their presentation at the hearing, as provided in section 207.24 of the Commission's rules, and posthearing briefs, which must conform with the provisions of section 207.25 of the Commission's rules. The deadline for

filing posthearing briefs is May 30, 2013. In addition, any person who has not entered an appearance as a party to the investigations may submit a written statement of information pertinent to the subject of the investigations, including statements of support or opposition to the petition, on or before May 30, 2013. On June 13, 2013, the Commission will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information on or before June 17, 2013, but such final comments must not contain new factual information and must otherwise comply with section 207.30 of the Commission's rules. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. Please be aware that the Commission's rules with respect to electronic filing have been amended. The amendments took effect on November 7, 2011. See 76 Fed. Reg. 61937 (Oct. 6, 2011) and the newly revised Commission's Handbook on E-Filing, available on the Commission's Web site at <http://edis.usitc.gov>.

Additional written submissions to the Commission, including requests pursuant to section 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.21 of the Commission's rules.

Issued: February 22, 2013.

By order of the Commission.

Lisa R. Barton,

Acting Secretary to the Commission.

[FR Doc. 2013-04505 Filed 2-26-13; 8:45 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 731-TA-929-931 (Second Review)]

Silicomanganese From India, Kazakhstan, and Venezuela; Scheduling of Full Five-Year Reviews Concerning the Antidumping Duty Orders on Silicomanganese From India, Kazakhstan, and Venezuela

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of full reviews pursuant to section 751(c)(5) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(5)) (the Act) to determine whether revocation of the antidumping duty orders on silicomanganese from India, Kazakhstan, and Venezuela would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time. For further information concerning the conduct of these reviews and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

DATED: *Effective Date:* February 21, 2013.

FOR FURTHER INFORMATION CONTACT: Angela M. W. Newell (202-708-5409), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter 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 (<http://www.usitc.gov>). The public record for these reviews may be viewed on the Commission's electronic docket (EDIS) at <http://edis.usitc.gov>.

SUPPLEMENTARY INFORMATION:

Background.—On January 4, 2013, the Commission determined that responses to its notice of institution of the subject five-year reviews were such that full reviews pursuant to section 751(c)(5) of the Act should proceed (78 FR 4437, January 22, 2013). A record of the Commission's votes, the Commission's statement on adequacy, and any individual Commissioner's statements are available from the Office

of the Secretary and at the Commission's Web site.

Participation in the reviews and public service list.—Persons, including industrial users of the subject merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in this reviews as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11 of the Commission's rules, by 45 days after publication of this notice. A party that filed a notice of appearance following publication of the Commission's notice of institution of the reviews need not file an additional notice of appearance. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the reviews.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in these reviews available to authorized applicants under the APO issued in the reviews, provided that the application is made by 45 days after publication of this notice. Authorized applicants must represent interested parties, as defined by 19 U.S.C. 1677(9), who are parties to the reviews. A party granted access to BPI following publication of the Commission's notice of institution of the reviews need not reapply for such access. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Staff report.—The prehearing staff report in the reviews will be placed in the nonpublic record on June 20, 2013, and a public version will be issued thereafter, pursuant to section 207.64 of the Commission's rules.

Hearing.—The Commission will hold a hearing in connection with the reviews beginning at 9:30 a.m. on July 18, 2013, at the U.S. International Trade Commission Building. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before July 1, 2013. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should attend a prehearing conference to be held at 9:30 a.m. on July 15, 2013, at the U.S. International Trade Commission Building. Oral testimony and written materials to be submitted at

the public hearing are governed by sections 201.6(b)(2), 201.13(f), 207.24, and 207.66 of the Commission's rules. Parties must submit any request to present a portion of their hearing testimony *in camera* no later than 7 business days prior to the date of the hearing.

Written submissions.—Each party to the reviews may submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of section 207.65 of the Commission's rules; the deadline for filing is July 1, 2013. Parties may also file written testimony in connection with their presentation at the hearing, as provided in section 207.24 of the Commission's rules, and posthearing briefs, which must conform with the provisions of section 207.67 of the Commission's rules. The deadline for filing posthearing briefs is July 29, 2013; witness testimony must be filed no later than three days before the hearing. In addition, any person who has not entered an appearance as a party to the reviews may submit a written statement of information pertinent to the subject of the reviews on or before July 29, 2013. On August 13, 2013, the Commission will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information on or before August 15, 2013, but such final comments must not contain new factual information and must otherwise comply with section 207.68 of the Commission's rules. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. Please be aware that the Commission's rules with respect to electronic filing have been amended. The amendments took effect on November 7, 2011. See 76 FR 61937 (Oct. 6, 2011) and the newly revised Commission's Handbook on E-Filing, available on the Commission's Web site at <http://edis.usitc.gov>.

Additional written submissions to the Commission, including requests pursuant to section 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the reviews must be served on all other parties to the reviews (as identified by

either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: These reviews are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

Issued: February 21, 2013.

By order of the Commission.

Lisa R. Barton,

Acting Secretary to the Commission.

[FR Doc. 2013-04503 Filed 2-26-13; 8:45 am]

BILLING CODE 7020-02-P

DEPARTMENT OF JUSTICE

[OMB Number 1121-0255]

Agency Information Collection Activities; Proposed Collection; Comments Requested: Reinstatement, With Change, of a Previously Approved Collection for Which Approval Has Expired; 2012 Census of Law Enforcement Training Academies

ACTION: 60-day notice of information collection under review.

The Department of Justice (DOJ), Office of Justice Programs, Bureau of Justice Statistics, 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. Comments are encouraged and will be accepted for 60 days until April 29, 2013. This process is conducted in accordance with 5 CFR 1320.10.

If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Brian A. Reaves, Statistician, Bureau of Justice Statistics, 810 Seventh Street NW., Washington, DC 20531 (phone: 202-616-3287).

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 Bureau of Justice

- Statistics, 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;
- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; 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:* Reinstatement, with change, of a previously approved collection for which approval has expired.
2. *The Title of the Form/Collection:* 2012 Census of Law Enforcement Training Academies (CLETA).
3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* The form number is CJ-52. The applicable component within the Department of Justice is the Bureau of Justice Statistics, Office of Justice Programs.
4. *Affected public who will be asked or required to respond, as well as a brief abstract:* This information collection is a census of regional, state, and local law enforcement training academies that operated a basic training programs during the period 2010–2012. The information will provide national statistics on staff, recruits/trainees, curricula, facilities, and policies of law enforcement training academies.
5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* A projected 700 respondents will take an average of 2 hours each to complete form CJ-52. In addition, 70 respondents of these respondents will be used for reliability testing averaging 1 hour each.
6. *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 1,470 total burden hours associated with this collection.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution

Square, 145 N Street NE., Suite 3W–1407B, Washington, DC 20530.

Dated: February 21, 2013

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2013–04465 Filed 2–26–13; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Trade Adjustment Assistance Program Reserve Funding Request

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Employment and Training Administration (ETA) sponsored information collection request (ICR) titled, “Trade Adjustment Assistance Program Reserve Funding Request,” to the Office of Management and Budget (OMB) for review and approval for continued use in accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 et seq.).

DATES: Submit comments on or before March 29, 2013

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained from the RegInfo.gov Web site, <http://www.reginfo.gov/public/do/PRAMain>, on the day following publication of this notice or by contacting Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or sending an email to DOL_PRA_PUBLIC@dol.gov.

Submit comments about this request to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–ETA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503, Fax: 202–395–6881 (this is not a toll-free number), email: OIRA_submission@omb.eop.gov.

FOR FURTHER INFORMATION CONTACT: Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or by email at DOL_PRA_PUBLIC@dol.gov.

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: The DOL requires financial data for the Trade Adjustment Assistance (TAA) and North America Free Trade Agreement-TAA

programs administered by States. The required data are necessary in order to meet statutory requirements prescribed in the Trade Act of 1974, as amended by the Trade Adjustment Assistance Act of 2002, the American Recovery and Reinvestment Act of 2009 (Division B, Title I, Subtitle I), the Omnibus Trade and Competitiveness Act of 1988, and the North American Free Trade Act. Using Form ETA–9117, States may request reserve funds before the final distribution to cover training costs, job search allowances, relocation allowances, employment and case management services, and State administration of these benefits.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. See 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1205–0275. The current approval is scheduled to expire on February 28, 2013; however, it should be noted that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional information, see the related notice published in the **Federal Register** on November 27, 2012 (77 FR 70832).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within 30 days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1205–0275. The OMB is particularly interested in comments that:

- 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: DOL-ETA.

Title of Collection: Trade Adjustment Assistance Program Reserve Funding Request.

OMB Control Number: 1205-0275.

Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Respondents: 25.

Total Estimated Number of Responses: 25.

Total Estimated Annual Burden

Hours: 50.

Total Estimated Annual Other Costs Burden: \$0.

Dated: February 15, 2013.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2013-04539 Filed 2-26-13; 8:45 am]

BILLING CODE 4510-FN-P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Standard Job Corps Contractor Information Gathering

ACTION: Notice.

SUMMARY: On February 28, 2013, the Department of Labor (DOL) will submit the Employment and Training Administration (ETA) sponsored information collection request (ICR) revision titled, "Standard Job Corps Contractor Information Gathering," to the Office of Management and Budget (OMB) for review and approval for use in accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 et seq.).

DATES: Submit comments on or before March 29, 2013.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained from the RegInfo.gov Web site, <http://www.reginfo.gov/public/do/PRAMain>, on March 1, 2013, or by contacting Michel Smyth by

telephone at 202-693-4129 (this is not a toll-free number) or sending an email to DOL_PRA_PUBLIC@dol.gov.

Submit comments about this request to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL-ETA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503, Fax: 202-395-6881 (this is not a toll-free number), email: OIRA_submission@omb.eop.gov.

FOR FURTHER INFORMATION: Contact Michel Smyth by telephone at 202-693-4129 (this is not a toll-free number) or by email at DOL_PRA_PUBLIC@dol.gov.

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: This ICR seeks to extend PRA authorization for standard operating and/or reporting forms for the operation of a Job Corps Center. The ICR includes Forms ETA 3-28; ETA-6-131 A, B, and C; ETA 6-61; ETA-640; ETA-2110; and ETA-2181.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. See 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1205-0219. The current approval is scheduled to expire on February 28, 2013; however, it should be noted that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional information, see the related notice published in the **Federal Register** on November 26, 2012 (77 FR 70475).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within 30 days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1205-0219. The OMB is particularly interested in comments that:

- 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: DOL-ETA.

Title of Collection: Standard Job Corps Contractor Information Gathering.

OMB Control Number: 1205-0219.

Affected Public: Private Sector—businesses or other for-profits and not-for-profit institutions.

Total Estimated Number of Respondents: 97.

Total Estimated Number of Responses: 184,628.

Total Estimated Annual Burden Hours: 38,610.

Total Estimated Annual Other Costs Burden: \$0.

Dated: February 21, 2013.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2013-04507 Filed 2-26-13; 8:45 am]

BILLING CODE 4510-FT-P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

Public Availability of the National Aeronautics and Space Administration FY 2012 Service Contract Inventory (SCI)

AGENCY: Office of Procurement, National Aeronautics and Space Administration.

ACTION: Notice of Public Availability of the FY 2012 Service Contract Inventory, PSC codes selected for FY12 SCI Analysis, and FY 2011 Service Contract Inventory Analysis.

SUMMARY: In accordance with Section 743 of Division C of the Consolidated Appropriations Act of 2010 (Pub. L. 111-117), the National Aeronautics and Space Administration (NASA) is publishing this notice to advise the public of the availability of its analysis of FY 2011 Service Contract Inventory and its FY 2012 Service Contract Inventory. This inventory provides information on service contract actions

over \$25,000 that were accomplished in FY 2012. The inventory has been developed in accordance with guidance issued on December 19, 2011, by the Office of Management and Budget's Office of Federal Procurement Policy (OFPP). NASA has posted documents associated with the Service Contract Inventory, including the documents addressed above, on the NASA Office of Procurement homepage at the following link: <http://www.hq.nasa.gov/office/procurement/scinventory/index.html>.

Point of contact for this initiative is Craig Bowers (202) 358-2235, craig.w.bowers@nasa.gov.

William McNally,

Assistant Administrator for Procurement.

[FR Doc. 2013-04570 Filed 2-26-13; 8:45 am]

BILLING CODE 7510-01-P

NATIONAL SCIENCE FOUNDATION

Advisory Committee for International Science and Engineering; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92-463, as amended), the National Science Foundation announces the following meeting:

Name: Advisory Committee for International Science and Engineering (25104).

Date/Time:

March 14, 2013 9:30 a.m.–5:00 p.m.

March 15, 2013 8:30 a.m.–12:30 p.m.

Place: National Science Foundation, Stafford II, Room 1155, Arlington, VA 22230. If you are attending the meeting and need access to the NSF, please contact the individual listed below so your name may be added to the building access list.

Type of Meeting: Open.

Contact Person: Robert Webber, Office of International Science and Engineering, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230 Telephone: 703/292-8569

Purpose of Meeting: To provide advice and recommendation concerning support for the research, education, and related activities involving the U.S. science and engineering community working in a global context, as well as strategic efforts to promote a more effective NSF role in international science and engineering.

Agenda:

International Activities across NSF and Beyond.

Disciplinary International Activities. Meetings with NSF Senior Management.

Dated: February 22, 2013.

Susanne Bolton,

Committee Management Officer.

[FR Doc. 2013-04541 Filed 2-26-13; 8:45 am]

BILLING CODE 7555-01-P

NATIONAL TRANSPORTATION SAFETY BOARD

Sunshine Act Meetings.

TIME AND DATE: 9:30 a.m., Tuesday, March 12, 2013.

PLACE: NTSB Conference Center, 429 L'Enfant Plaza SW., Washington, DC 20594.

STATUS: The one item is open to the public.

MATTER TO BE CONSIDERED: 8469 General Aviation Safety Education and Training; Five Safety Alerts, "Reduced Visual References Require Vigilance," "Prevent Aerodynamic Stalls at Low Altitude," "Is Your Aircraft Talking to You? Listen!," "Mechanics: Manage Risks to Ensure Safety," and "Pilots: Manage Risks to Ensure Safety."

NEWS MEDIA CONTACT: Telephone: (202) 314-6100.

The press and public may enter the NTSB Conference Center one hour prior to the meeting for set up and seating.

Individuals requesting specific accommodations should contact Rochelle Hall at (202) 314-6305 or by email at Rochelle.Hall@ntsb.gov by Friday, March 8, 2013.

The public may view the meeting via a live or archived Webcast by accessing a link under "News & Events" on the NTSB home page at www.nts.gov.

Schedule updates including weather-related cancellations are also available at www.nts.gov.

FOR MORE INFORMATION CONTACT: Candi Bing, (202) 314-6403 or by email at bingc@ntsb.gov.

FOR MEDIA INFORMATION CONTACT: Peter Knudson, (202) 314-6100 or by email at peter.knudson@ntsb.gov.

Dated: Monday, February 25, 2013.

Candi R. Bing,

Federal Register Liaison Officer.

[FR Doc. 2013-04674 Filed 2-25-13; 4:15 pm]

BILLING CODE 7533-01-P

NUCLEAR REGULATORY COMMISSION

[NRC-2013-0040; Docket Nos. 50-334 and 50-412; License Nos. DPR-66 and NPF-73; EA-12-254]

In the Matter of FirstEnergy Nuclear Operating Co. (Beaver Valley Units 1 and 2); Confirmatory Order Modifying License

I

FirstEnergy Nuclear Operating Company (FENOC, the licensee) is the

holder of Renewed Facility Operating License Nos. DPR-66 and NPF-73 issued by the U.S. Nuclear Regulatory Commission (NRC) pursuant to part 50 of Title 10 of the *Code of Federal Regulations* (10 CFR), "Domestic Licensing of Production and Utilization Facilities," on November 5, 2009. The licenses authorize the operation of the Beaver Valley Power Station, Units 1 and 2 (Beaver Valley, facility), in accordance with conditions specified therein. The facility is located on the licensee's site in Shippingport, Pennsylvania.

II

On December 22, 2005, FENOC notified the NRC of its intent to transition the facility to the National Fire Protection Association (NFPA) Standard 805 fire protection program in accordance with 10 CFR 50.48(c). Under this initiative, the NRC has exercised enforcement discretion for most fire protection noncompliances that are identified during the licensee's transition to NFPA 805, and for certain existing identified noncompliances that reasonably may be resolved at the completion of transition. NFPA 805 was adopted in 10 CFR 50.48(c) as an alternative fire protection rule, which is one path to resolving longstanding fire protection issues. To receive enforcement discretion for these noncompliances, the licensee must meet the specific criteria, as stated in Section 9.1, "Enforcement Discretion for Certain Fire Protection Issues (10 CFR 50.48)," of the "NRC Enforcement Policy," dated June 7, 2012, and submit an acceptable license amendment application by the date, as specified in the licensee's commitment letter. In a letter dated June 29, 2011, FENOC committed to submit their license amendment application by September 30, 2012.

III

In a public meeting held on August 1, 2012, between the NRC and FENOC, the licensee described its progress for transitioning Beaver Valley to NFPA 805. FENOC also notified the NRC that the development of a high-quality application will require more time than originally anticipated and that they will be unable to meet their previously committed submittal date of September 30, 2012. FENOC expressed a desire to continue enforcement discretion, and a willingness to commit to the new submittal date.

In a letter dated August 29, 2012, FENOC reiterated the current transition strategy for Beaver Valley, and notified the NRC that FENOC will submit its license amendment request (LAR) no

later than December 31, 2013. The newly proposed submittal date is beyond the previously committed submittal date and, thus, exceeds FENOC's enforcement discretion (i.e., until September 30, 2012) that was granted to FENOC for certain fire protection noncompliances. However, if provided with adequate justification, the NRC may revise the submittal date through the use of an Order that would continue the enforcement discretion provided in Section 9.1 of the Enforcement Policy.

By letter dated October 18, 2012, the NRC requested that FENOC provide additional justification for the proposed submittal date. This requested information was further discussed with FENOC in a public teleconference that was held on October 18, 2012. FENOC provided the requested supplemental information in a letter dated November 2, 2012, as discussed more fully below.

The staff reviewed and evaluated the Beaver Valley NPPA 805 transition progress and milestones, as described in the licensee's submittals dated August 29, 2012, and November 2, 2012. In its review and evaluation, the staff considered the key transition activities discussed by FENOC, as they relate to Classical Fire Protection, Nuclear Safety Capability Assessment, Probabilistic Risk Assessment, and Non-Power Operations, as well as the licensee's parallel efforts to address identified fire protection non-compliances to reduce fire risk, ahead of the staff's review of an NPPA 805 LAR. Based on the licensee's current status, scheduled key activities, and planned modifications, the NRC staff has determined that the licensee has provided adequate justification for revising the LAR submittal date. Therefore, the NRC has determined that the date for submitting an acceptable NPPA 805 LAR should be extended. This Order is being issued to revise the original Beaver Valley LAR submittal date of September 30, 2012, to December 31, 2013. The new submittal date supports FENOC's continued progress in activities related to the transition to NPPA 805, as described in the letter dated August 29, 2012.

FENOC may, at any time, cease its transition to NPPA 805 and comply with Beaver Valley's existing licensing basis and the regulations set forth in 10 CFR 50.48, as applicable. As indicated in the Enforcement Policy, if FENOC decides not to complete the transition to 10 CFR 50.48(c), it must submit a letter stating its intent to retain its existing licensing basis and withdrawing its letter of intent to comply with 10 CFR 50.48(c). If FENOC fails to meet the new LAR submittal date and fails to comply

with its existing licensing basis, the NRC will take appropriate enforcement action, consistent with its Enforcement Policy.

On February 13, 2013, FENOC consented to issuing this Order, as described in Section V below. FENOC further agreed that this Order will be effective upon issuance and that it has waived its rights to a hearing.

IV

Based on the licensee's current status, scheduled key activities, and planned modifications, the NRC has determined that the licensee has provided adequate justification for its commitment given in Section V, and, thus, for the extension of enforcement discretion. Because the licensee will continue to perform modifications to reduce current fire risk in parallel with the development of its NPPA 805 LAR, the staff finds this acceptable to ensure public health and safety. Based on the above and FENOC's consent, this Order is effective upon issuance.

V

Accordingly, pursuant to Sections 103, 161b, 161i, 161o, 182, and 186 of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's regulations in 10 CFR 2.202, "Orders," *it is hereby ordered that license nos. DPR-66 AND NPF-73 are modified as follows:*

A. FENOC will submit an acceptable license amendment request for Beaver Valley Power Station, Units 1 and 2, to adopt NPPA Standard 805 by no later than December 31, 2013.

B. FENOC will continue to receive enforcement discretion until December 31, 2013. If the NRC finds that the LAR is not acceptable, the NRC will take steps consistent with the Enforcement Policy.

The Director of the Office of Enforcement, in consultation with the Director of the Office of Nuclear Reactor Regulation, may, in writing, relax or rescind any of the above conditions upon demonstration by the licensee of good cause.

VI

In accordance with 10 CFR 2.202, the licensee must, and any other person adversely affected by this Order may, submit an answer to this Order within 30 days from the date of this Order. In addition, any other person adversely affected by this Order may request a hearing on this Order within 30 days from the date of this Order. Where good cause is shown, consideration will be given to extending the time to answer or request a hearing. A request for

extension of time must be directed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and include a statement of good cause for the extension.

If a hearing is requested by a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearings. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained.

All documents filed in the NRC adjudicatory proceedings, including a request for a hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with NRC E-Filing rule (72 FR 49139; August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at hearing.docket@nrc.gov, or by telephone at 301-415-1677, to request (1) a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital certificate). Based on this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals/apply-certificates.html>. System requirements for accessing the E-Submittal server are detailed in the NRC's "Guidance for Electronic Submission," which is available on the agency's public Web site at <http://www.nrc.gov/site-help/e-submittals.html>. Participants may

attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, web-based submission form. In order to serve documents through the Electronic Information Exchange System, users will be required to install a web browser plug-in from the NRC's Web site. Further information on the web-based submission form, including the installation of the web browser plug-in, is available on the NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals.html>.

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for a hearing or petition for leave to intervene. Submissions should be in portable document format (PDF) in accordance with the NRC guidance available on the NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals.html>. A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the agency's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk thorough the "Contact Us" link located on the NRC's Web site at <http://www.nrc.gov/site-help/e-submittals.html>, by email at MSHD.Resource@nrc.gov, or by a toll

free call at 1-866-672-7640. The NRC Meta System Help Desk is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an extension request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party using E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket, which is available to the public at <http://ehd1.nrc.gov/ehd>, unless excluded pursuant to an order of the Commission, or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submissions.

If a person other than the licensee requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.309(d) and (f).

In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, the provisions specified in Section V above shall be final 30 days from the date of this Order without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Section V shall be final when the extension expires if a hearing request has not been received.

For the Nuclear Regulatory Commission

Dated at Rockville, Maryland this 20th of February 2013.

Roy P. Zimmerman,

Director, Office of Enforcement.

[FR Doc. 2013-04529 Filed 2-26-13; 8:45 am]

BILLING CODE 7590-01-P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94-409, that the Securities and Exchange Commission will hold a Closed Meeting on Friday, March 1, 2013 at 12:30 p.m.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the Closed Meeting. Certain staff members who have an interest in the matters also may be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (7), 9(B) and (10) and 17 CFR 200.402(a)(3), (5), (7), 9(ii) and (10), permit consideration of the scheduled matters at the Closed Meeting.

Commissioner Gallagher, as duty officer, voted to consider the items listed for the Closed Meeting in a closed session.

The subject matter of the Closed Meeting will be:

Institution and settlement of injunctive actions;
Institution and settlement of administrative proceedings;
Other matters relating to enforcement proceedings; and
An adjudicatory matter.

At times, changes in Commission priorities require alterations in the scheduling of meeting items.

For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact the Office of the Secretary at (202) 551-5400.

Dated: February 22, 2013.

Elizabeth M. Murphy,
Secretary.

[FR Doc. 2013-04651 Filed 2-25-13; 11:15 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-68965; File No. SR-BOX-2013-08]

Self-Regulatory Organizations; BOX Options Exchange LLC; Notice of Filing of Proposed Rule Change To Reduce the Directed Order Exposure Period on BOX From Three Seconds to One Second

February 21, 2013.

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 February 15, 2013, BOX Options Exchange LLC (the “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 self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to reduce the exposure period for Directed Orders from three seconds to one second. The text of the proposed rule change is available from the principal office of the Exchange, at the Commission’s Public Reference Room and also on the Exchange’s Internet Web site at <http://boxexchange.com>.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rules [sic] 8040(d)(6) (Obligations of Market Makers) to reduce the exposure period for Directed Orders from three seconds to one second.³ Based on trading systems technology today, an exposure period of multiple seconds is simply unnecessary.⁴ Additionally, such lengthy time periods expose market participants to additional, and because of current systems technology, unnecessary, market risk.

Currently, upon receipt of a Directed Order, an Executing Participant (“EP”) must either submit the Directed Order to the Price Improvement Period (“PIP”)⁵ or send the Directed Order to the BOX Book. When the EP sends the Directed Order to the BOX Book and the EP’s quotation on the opposite side of the market from the Directed Order is equal to the National Best Bid or Offer (“NBBO”) and the Directed Order is also executable against the NBBO, the BOX Trading Host immediately takes down the EP’s quote and guarantees the EP’s execution of the Directed Order for at least the price and size of the EP’s quote (“Guaranteed Directed Order” or “GDO”). Once the GDO has been generated by the Trading Host, the EP is systemically prohibited from posting a quotation for three seconds. The

³ A Directed Order is any Customer Order to buy or sell which has been directed to a particular Market Maker by an Order Flow Provider (“OFP”). See Rule 100(a)(19). Note that the Exchange is not proposing any change to the 3 second period in Rule 8040(d)(4) that an Executing Participant has to take action after receipt of a Directed Order. The exposure period that the Exchange proposes amending in this proposal occurs after a Directed Order is sent to the BOX Book.

⁴ See Securities Exchange Act Release Nos. 59638 (March 27, 2009), 74 FR 15020 (April 2, 2009) (SR-BX-2009-015) (Order Granting Approval of Reduction of Certain Order Handling and Exposure Periods on BOX From Three Seconds to One Second), and 66306 (February 2, 2012), 77 FR 6608 (February 8, 2012) (SR-BX-2011-084) (Order Granting Approval to Reduce the PIP From One Second to One Hundred Milliseconds). Note that in connection with both proposals, BOX distributed a survey to Participants. The results indicated that the time it takes a message to travel between BOX and the Participants typically is not more than 50 milliseconds each way, and that it typically takes not more than 10 milliseconds for Participant systems to process the information and generate a response. The speed at which technology systems can process information has only increased since then. As such, the Exchange believes that the information gathered from Participants supports the assertion that reducing the exposure period from 3 seconds to 1 second will continue to provide Participants with sufficient time to ensure effective interaction with orders.

⁵ See Rule 8040(d).

Exchange proposes to reduce the time period of the GDO from three seconds to one second. This proposed change will reduce the EP’s market risk related to the GDO and accommodate faster processing as current technology systems allow.

The EP’s pending quote will not be released until either (i) the Directed Order is modified by the submitting OFP;⁶ (ii) the EP submits the Directed Order to the PIP; or (iii) the Directed Order is submitted to the BOX Book, and one of the following occurs: (a) the Directed Order trades in full; (b) the Directed Order exposition ends; or (c) the Directed Order is modified or cancelled by the submitting OFP during such exposition.

When the EP does not submit the Directed Order to the PIP, but rather, releases it to the BOX Book, the Directed Order immediately executes against the BOX Book if the BOX Best Bid or Offer is equal to or better than the NBBO and GDO. Any remaining quantity not executed is exposed to BOX Participants at the better of the NBBO or GDO price for three (3) seconds, during which time any Options Participant, except for the EP as outlined above, may submit an order to the BOX Book in response. Any orders submitted to the BOX Book during the three second exposure period execute immediately against any remaining quantity of the Directed Order, in time priority. The Exchange proposes to reduce this exposure and response period to one second as the three second processing time is unnecessary.⁷

If a Directed Order is not executable against the current NBBO, then the Trading Host exposes the order at the better GDO price for three (3) seconds. During the exposure period when the Directed Order is executable against the current NBBO, the EP must not decrement the size, worsen the price of his GDO or submit a contra order. Because the Trading Host automatically creates the GDO and shelves the EP’s quote, it does not process such changes

⁶ See 8040(d)(5). If the Directed Order is modified once the Trading Host has automatically established the GDO, then the modified Directed Order is no longer considered a Directed Order and is immediately released to the BOX Book and treated as a regular order. Upon modification or cancellation of the Directed Order, the Trading Host immediately reestablish the EP’s quote, including any of the EP’s pending quote modifications, with a new time priority; or in the case of a pending quote cancellation, the EP’s quote is cancelled. Also, it is considered conduct inconsistent with just and equitable principles of trade for any Options Participant or person to communicate with an EP about the terms or conditions of a Directed Order prior to its outcome in the BOX Trading Host (e.g. execution, cancellation).

⁷ *Supra*, note 4.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

to the GDO or pending quote, except a decrementation of the GDO size down to the size of the remaining Directed Order after execution with the BOX Book.⁸ The Exchange proposes to reduce this exposure period to one second. As discussed, BOX believes the longer exposure period is unnecessary for current technology systems, and reducing the period will reduce market risk for all market participants.

When approving the existing one second exposure periods on the BOX Book and in the PIP, the Commission concluded that, in the electronic environment of BOX, reducing these time periods to one second was fully consistent with the electronic nature of the BOX market.⁹ BOX is not proposing any change to the requirement in Rule 7140 and related Interpretive Material that requires an OFP to expose its customer's order on the BOX Book for at least one second before executing its own principal order against such customer order. BOX recognizes that one second, as three seconds is now, is not long enough to allow human interaction with orders. Rather, BOX believes that Participants operate sufficiently automated electronic systems so that they can react and respond to orders in a meaningful way within fractions of a second. BOX fully anticipates that this will continue within the one second exposure period proposed for Directed Orders.

BOX believes that further reducing its Directed Order exposure period from three seconds to one second will benefit all market participants. BOX believes it is in all participants' best interests to minimize the time of any exposure period while continuing to allow Participants adequate time to electronically respond, as both the order being exposed and Participants responding are subject to market risk during the exposure period of an order. Indeed, most participants wait until the end of the last second of the current three second period before responding to exposed orders so as to minimize market risk. BOX believes that even reducing the Directed Order exposure period to one second will continue to provide market participants with sufficient time to respond and compete for Directed Orders sent to the BOX

Book. Additionally, a one second exposure period will provide investors and other market participants with more timely executions, thereby reducing their market risk. BOX believes that reducing the Directed Order exposure period from three seconds to one second will provide all market participants sufficient time for effective interaction with Directed Orders. BOX Participants are able to respond to orders in fractions of a second and BOX does not believe it is necessary or beneficial to orders being exposed to continue to subject them to market risk for three seconds.

After the notice of effectiveness of the proposed rule change, and at least one week prior to the operative date, the Exchange will issue a regulatory circular to inform BOX Participants of the operative date for the reduction of the Directed Order exposure period from three seconds to one second. BOX believes this will give Participants an opportunity to change any system settings to coincide with the implementation date so as to comply with the requirement in Rule 8040(d)(6)(i) that an EP not submit to BOX a contra order to the Directed Order for his proprietary account during the 1 second following his submission of the Directed Order to BOX.

2. Statutory Basis

The Exchange believes that the proposal is consistent with the requirements of Section 6(b) of the Act,¹⁰ in general, and Section 6(b)(5) of the Act,¹¹ in particular, in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism for a free and open market and a national market system and, in general, to protect investors and the public interest. In particular, the proposed rule change will facilitate and provide investors with prompt and timely execution of their options orders, while continuing to provide market participants with an opportunity to compete for exposed Directed Orders on BOX.

Additionally, the proposed change will reduce market risk for BOX Participants submitting and responding to Directed Orders. As such, BOX believes the proposed rule change would help perfect the mechanism for a free and open national market system, and generally help protect investors'

and the public interest. The Exchange believes the proposed rule change is not unfairly discriminatory because the exposure time period for responding to Directed Orders would be the same for all Participants. All Participants on BOX have today, and will continue to have, an equal opportunity to respond to Directed Orders exposed on BOX.¹² As such, the Exchange believes that a reduction in the Directed Order exposure period on BOX would not be unfairly discriminatory and would benefit investors.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes the proposed change will reduce market risk for BOX Participants submitting and responding to Directed Orders, and that the proposed rule change is not unfairly discriminatory because the exposure time period for responding to Directed Orders would be the same for all Participants. All Participants on BOX have today, and will continue to have, an equal opportunity to respond to Directed Orders exposed on BOX. As such, the Exchange believes that a reduction in the Directed Order exposure period on BOX would not be unfairly discriminatory and would benefit investors. For these reasons, the Exchange 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 has neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change 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, it has become effective pursuant to Section 19(b)(3)(A) of the

⁸During the exposure period, the EP also may increase the size or better the price of his GDO. The EP may also modify his pending quote to be reestablished, but the Trading Host will not apply such modifications until the quote is reestablished.

⁹See Securities Exchange Act Release No. 59638 (March 27, 2009), 74 FR 15020 (April 2, 2009) (SR-BX-2009-015) Order Granting Approval of Reduction of Certain Order Handling and Exposure Periods on BOX From Three Seconds to One Second.

¹⁰ 15 U.S.C. 78f(b).

¹¹ 15 U.S.C. 78f(b)(5).

¹²Directed Orders exposed as set forth in Exchange Rule 8040(d)(6) are displayed through the BOX High Speed Vendor Feed ("HSVF"). The HSVF is a proprietary feed of BOX market information made available to all market participants. See Rule 7130(a)(2).

Act¹³ and Rule 19b-4(f)(6) thereunder.¹⁴

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend 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 email to rule-comments@sec.gov. Please include File Number SR-BOX-2013-08 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-BOX-2013-08. This file number should be included on the subject line if email 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 Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 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-BOX-2013-08 and should be submitted on or before March 20, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁵

Kevin M. O'Neill,
Deputy Secretary.

[FR Doc. 2013-04545 Filed 2-26-13; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-68964; File No. SR-C2-2013-008]

Self-Regulatory Organizations; C2 Options Exchange, Incorporated; Notice of Filing of a Proposed Rule Change, as Modified by Amendment No. 1 Thereto, Relating to Market-Maker Continuous Quoting Obligations

February 21, 2013.

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 February 8, 2013, C2 Options Exchange, Incorporated (the "Exchange" or "C2") 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. On February 20, 2013, the Exchange

submitted Amendment No. 1 to the proposed rule change. 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 its Rules relating to Market-Maker continuous quoting obligations. The text of the proposed rule change is available on the Exchange's Web site (<http://www.c2exchange.com/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 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 purpose of the proposed rule change is to add language to Exchange Rules 8.5 and 8.17 to exclude intra-day add-on series ("Intra-day Adds") on the day during which such series are added for trading from Market-Makers'³ quoting obligations. Additionally, the proposed rule change clarifies in Rule 8.19 that Designated Primary Market-Makers ("DPMs), respectively (Market-Makers and DPMs are collectively referred to in this filing as "Market-Makers" unless the context provides otherwise) may still receive participation entitlements pursuant to those Rules in all Intra-day Adds on the day during which such series are added for trading in which they are quoting provided that Market-Maker meets all other entitlement requirements as set forth in the applicable rule.

Intra-Adds are series that are added to the Exchange system after the opening of the Exchange. These series

¹³ 15 U.S.C. 78s(b)(3)(A).

¹⁴ 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.

The Commission notes that the Exchange asserted in its filing that

The proposed change brings the Directed Order exposure period closer in line with the exposure periods already in existence on BOX. The time period for Participants to respond in the BOX Solicitation Auction and Facilitation Auction is one second. [footnote omitted] Additionally, the PIP duration is 100 milliseconds. [footnote omitted] The BOX trading system that processes Directed Orders is the same BOX system that processes Solicitation and Facilitation Auctions and the PIP. The proposed rule change makes no substantive change to the operation of BOX, or the execution of Directed Orders on BOX, other than reducing the Directed Order exposure period to be more in line with the time periods already in existence in other mechanisms on BOX.

See SR-BOX-2013-08 (Form 19b-4).

¹⁵ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Exchange Rule 8.1 which defined Market-Makers as participants that "have certain rights and bear certain responsibilities beyond those of other Participants."

may be added throughout the trading day which differs from other newly added series which are only added prior to the beginning of trading. In the event a series is added after the open of trading on the Exchange, the Exchange, in real time, disseminates a message to the Exchange application program interfaces, which any Exchange Trading Permit Holder (“TPH”) can receive, that a new series has been listed. In addition, there is a corresponding product state change message disseminated when the new series moves from pre-opening rotation to an open state. Any Market-Maker with an appointment in the class in which the series was added is permitted to quote in the new series.

Currently, Exchange Rules 8.5 and 8.17 impose certain obligations on Market-Makers and DPMs, respectively, including obligations to provide continuous quotes as follows⁴:

- Rule 8.5 requires that Market-Makers provide a continuous two-sided market in 60% of the non-adjusted option series of the Market-Maker’s appointed class that have a time to expiration of less than nine months;
- Rule 8.17(a)(1) requires DPMs to provide continuous quotes in at least the lesser of 99% or 100% minus one call-put pair⁵ of the non-adjusted option series of each class allocated to it.

Exchange Rule 8.19 provides that DPMs generally will receive the participation entitlements in their assigned classes when quoting at the best price if they satisfy their obligations and other conditions set forth in the rules. Specifically, Rule 8.19 provides that the DPM participation entitlement will be 50% when there is one Market-Maker also quoting at the best price on the Exchange and 40% when there are two Market-Makers also quoting at the best price on the Exchange.⁶

In order to comply with their continuous quoting obligations, Exchange Market-Makers have automated systems in place that use

⁴ For purposes of Rules 8.5(a)(1), and 8.17(a)(1), “continuous” means 90% of the time. If a technical failure of limitation of the System prevents a Market-Maker from maintaining timely and accurate quotes in a series, the duration of such failure will not be included in the 90% determination.

⁵ See Rule 8.17(a)(1) which defines a “call-up pair” as “one call and one put that cover the same underlying instrument and have the same expiration date and exercise price.”

⁶ The participation entitlements of DPMs are based on the number of contracts remaining after all public customer orders in the book at the best price on the Exchange have been satisfied. Additionally, a DPM may not be allocated a total quantity greater than the quantity for which the DPM is quoting at the best price. See Rules 8.19(b)(1)(B) and (C).

complex calculations based on a variety of market factors to compute quotes in their appointed classes and transmit these quotes to the Exchange’s System (the “System”).⁷ Their system computations also factor in their market risk models. Several Market-Makers have communicated to the Exchange that their trading systems do not automatically produce continuous quotes in Intra-day Adds on the trading day during which those series are added. They further indicated that the only way they could quote in these series on the trading day during which they were added would be to completely shut down and restart their systems. As a result, it is the Exchange’s understanding that several Market-Makers do not currently quote Intra-day Adds during the trading day on which such series are added (although the Market-Makers generally do quote these series upon the opening of the next trading day, assuming those series are still listed on the Exchange). The required work on Market-Makers’ systems to quote Intra-day Adds, as further communicated to the Exchange, would be significant and costly.

Intra-day Adds make it extremely difficult for Market-Makers to comply with their obligation to quote in a substantial percentage of series in their appointed classes during a trading day on which Intra-day Adds are added in those classes. For example, if there are 1,000 series listed in a DPM’s appointed class and the DPM is quoting in 990 of these series, the DPM is in compliance with the current minimum requirement to quote in 99% of series in its appointed class (assuming the DPM quotes in this number of series 90% of the trading day). However, if an Intra-day Add is added in the DPM’s appointed class during the trading day, and the DPM’s system does not automatically quote in this series, then the DPM would not comply, as it would be quoting in 990 of 1,001 series. This noncompliance would be compounded if more than one Intra-day Add is listed in a class during the same trading day. Further, if these Market-Makers turned their systems off to quote in Intra-day Adds on the trading day during which those series are added, then the Market-Makers could satisfy the standard to quote in a minimum percentage of series in their appointed classes but would then risk violating their obligation to quote for minimum percentage of the trading day as, theoretically, these Market-Makers might need to repeatedly

turn their systems off to accommodate the Intra-day Adds.

The Exchange believes that it would be impracticable, particularly given that a number of Market-Makers use their systems to quote on multiple markets and not solely on the Exchange, for Market-Makers to turn off their entire systems to accommodate quoting in Intra-day Adds on the day during which those series are added on the Exchange. In addition, the Exchange believes this would interfere with the continuity of its market and reduce liquidity, which would ultimately harm investors and contradicts the purpose of the Market-Maker continuous quoting obligation.

This proposed rule change excludes Intra-day Adds from these continuous quoting obligations to address this conflict. Specifically, the Exchange is proposing to add text to Rules 8.5 and 8.17 to exclude Intra-day Adds on the day during which such series are added for trading from Market-Makers’ quoting obligations. Based on communications from Market-Makers, the Exchange is concerned that Market-Makers may withdraw from the DPM program and that other market participants may be discouraged from requesting Market-Maker appointments or applying to the DPM program if they are required to quote Intra-day Adds on the trading day during which those series are added. The Exchange believes that withdrawals from, and reduced applications for, Market-Maker appointments would negatively impact liquidity and volume on the Exchange in those classes. The Exchange believes that providing Market-Makers with relief from their quoting obligations with respect to Intra-day Adds on the trading day during which they are added for trading will prevent these withdrawals and encourage market participants to apply for or continue their Market-Maker class appointments.

The Exchange does not believe this relief will result in any material decrease in liquidity. As mentioned above, it is the Exchange’s understanding that several Market-Makers currently do not quote Intra-day Adds on the trading day during which they are added, so the Exchange believes this proposed relief would result in a minimal reduction, if any, in liquidity in these series. These Market-Makers’ systems would add these series the next trading day, so if there is any slight reduction in liquidity in these few series, it would only last for a short period of time (until the following trading day). Additionally, this potential small reduction in liquidity would be far outweighed by the reduction in liquidity that the Exchange believes

⁷ See Rule 1.1 which defines “System” as the “automated trading system used by the Exchange for the trading of options contracts.”

would result from the withdrawals from and reductions in applications for Market-Maker appointments if the Exchange did not provide this relief.

The current quoting obligation in Intra-day Adds is a minor part of a Market-Maker's overall obligations. Specifically, Intra-day Adds represent only approximately 0.10% of the number of series listed on the Exchange, so Market-Makers will still be obligated to provide continuous two-sided markets in a substantial number of series in their appointed classes.⁸ Intra-day Adds are rarely added on the Exchange, so Market-Makers will still be obligated to provide continuous two-sided markets in a substantial number of series in their appointed classes. Further, Market-Makers would still be obligated to quote the Intra-day Adds the following day, and, thus, their quoting relief is very short-lived and could, potentially, only last a few hours or until the opening of trading the following day. The Exchange believes that the burden of continuous quoting in this extremely small number of series is counter to the Exchange's efforts to continuously increase liquidity in its listed option classes.

The Exchange believes the proposed rule change will continue to ensure that Market-Makers create a fair and orderly market in the option classes to which they are assigned, as it does not absolve Market-Makers from providing continuous quotes in a significant percentage of series of each class for a substantial portion of the trading day. Market-Makers must engage in activities that constitute a course of dealings reasonably calculated to contribute to the maintenance of a fair and orderly market, including (1) competing with other Market-Makers to improve markets in all series of options classes comprising their appointments, (2) making markets that, absent changed market conditions, will be honored in accordance with firm quote rules, and (3) updating market quotations in response to changed market condition in their appointed options classes and to assure that any market quote it causes to be disseminated is accurate.⁹

The relief proposed in this filing is mitigated by a Market-Maker's other obligations. For example, the proposed rule change would not excuse a Market-Maker from its obligation to submit a single quote or maintain continuous quotes in one or more series of a class

to which the Maker-Maker is appointed when called upon by an Exchange official if, in the judgment of such official, it is necessary to do so in the interest of maintaining a fair and orderly market.¹⁰

The proposed rule change also clarifies in the Exchange Rules that while Market-Makers are not required to provide continuous quotes in Intra-day Adds on the day during which such series are added for trading, a Market-Maker may still receive a participation entitlement in such series if it elects to quote in that series and otherwise satisfies the other entitlement requirements set forth in accordance with the Rules. Specifically, the Exchange is proposing to add language to Rule 8.19 clearly stating that DPMs may still receive participation entitlements pursuant to those Rules in all Intra-day Adds on the day during which such series are added for trading in which they are quoting provided that Market-Maker meets all other entitlement requirements as set forth in Rule 8.19(b).

Market-Makers already receive participation entitlements in series they are not required to quote. For example, a DPM is currently required to provide continuous quotes in at least 99% of the non-adjusted option series or 100% of the non-adjusted series minus one call-pair of each option class allocated to it for 90% of the trading day.¹¹ If the DPM elects to quote in 100% of the non-adjusted series in an option class allocated to it, it will receive a participation entitlement in all of those series when quoting at the best price, including the 1% of the series in which it is not required to quote in. Thus, under the proposed rule change, the market would continue to function as it does now. The Exchange believes this benefit is appropriate, as it incentivizes Market-Makers to quote in as many series as possible in their appointed classes, even those series in which the Rules do not require them to continuously quote.

The Exchange does not believe that the proposed rule change would adversely affect the quality of the Exchange's markets or lead to a material decrease in liquidity. Rather, the Exchange believes that its current market structure, with its high rate of participation by Market-Makers, permits the proposed rule change without fear of losing liquidity. The Exchange also believes that market-making activity and liquidity could materially decrease without the proposed rule change to

exclude Intra-day Adds from Market-Maker continuous quoting obligations on the trading day during which they are added for trading. The Exchange believes that this proposed relief will encourage Market-Makers to continue appointments and other TPHs to request Market-Maker appointments, and, as a result, expand liquidity in options classes listed on the Exchange to the benefit of the Exchange and its TPHs and public customers. The Exchange believes that its Market-Makers would be disadvantaged without this proposed relief, and other TPHs and public customers would also be disadvantaged if Market-Makers withdrew from appointments in options classes, resulting in reduced liquidity and volume in these classes. Additionally, the Exchange believes that the proposed rule change to clarify that Market-Makers may receive participation entitlements in Intraday Adds on the day during which such series are added for trading if it satisfies the other entitlement requirements as set forth in Exchange Rules, even if the Rules do not require the Market-Makers to continuously quote in those series, will incent Market-Makers to quote in series in which they are not required to quote, which may increase liquidity in their appointed classes.

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 thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.¹² Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹³ requirements that the rules of an exchange be 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 regulating, clearing, settling, processing information with respect to, and facilitation transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹⁴ requirement that the rules of an exchange not be designed

⁸ From January 1, 2013 through February 19, 2013, there have been 37 Intra-day Adds listed on the Exchange, and, in that time period, there have been a total of 35,502 series added on the Exchange. Thus, the Intra-day Adds represent 0.10%.

⁹ See Rule 8.5(a).

¹⁰ See Rule 8.5(d).

¹¹ See Rule 8.17(a).

¹² 15 U.S.C. 78f(b).

¹³ 15 U.S.C. 78f(b)(5).

¹⁴ *Id.*

to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes the proposed rule change to exclude Intra-day Adds during the day which such series are added for trading from Market-Makers' quoting obligations promotes just and equitable principles of trade because it promotes liquidity and continuity in the marketplace and would prevent interruptions in quoting or reduced liquidity that may otherwise result. The Exchange also believes that the proposed rule change supports the quality of the Exchange's markets because it does not significantly change the current quoting obligations of Market-Makers. Market-Makers must still provide continuous quotes for a significant part of the trading day in a substantial number of series of each appointed class. Even if a Market-Maker does not quote Intra-day Adds on the trading day during which they are added, this would be offset by the Market-Maker's continued other obligations. The proposed relief is further offset by a Market-Maker's obligation to quote in these series beginning the next trading day. Accordingly, the proposed rule change supports the quality of the Exchange's trading markets by helping to ensure that Market-Makers will continue to be obligated to quote in Intra-day Adds if, and when, the need arises and on an ongoing basis following the trading day during which the series are added. The Exchange believes this proposed change is reasonable and is offset by Market-Makers' continued responsibilities to provide significant liquidity to the market to the benefit of market participants.

The Exchange believes this proposed rule change, on balance, is a minor change and should not impact the quality of the Exchange's trading markets. Among other things, Intra-day Adds represent an insignificant percentage of series listed on the Exchange each day. The Exchange further believes that the potential small reduction in liquidity in Intra-day Adds that may result from the proposed relief would be far outweighed by the significant reduction in liquidity in appointed classes that the Exchange believes could occur from withdrawals from and reductions in applications for Market-Maker appointments without the proposed relief. The proposed rule change also removes impediments to and allows for a free and open market, while protecting investors, by promoting additional transparency regarding Market-Makers' obligations and benefits in the Exchange Rules. In addition, the Exchange believes that the

proposed rule change is designed to not permit unfair discrimination among Market-Makers, as the proposed rule change provides the proposed relief for all Market-Makers.

The proposed rule change to clarify that Market-Makers may receive participation entitlements in Intra-day Adds in their appointed classes in which they are quoting, even though they are not required to quote, if the other requirements set forth in the Rules are satisfied, further supports the quality of the Exchange's trading markets because it encourages Market-Makers to quote in as many series as possible, which ultimately benefits all investors. This benefit is offset by the Market-Makers' continued quoting obligations and the fact that their quotes in these "non-required" series must still satisfy all of the Market-Makers' other obligations under the Rules. The Exchange also believes that this proposed change is consistent with its current practice, pursuant to which Market-Makers receive participation entitlements in additional series in which they elect to quote above the minimum percentage of series in which they are required to continuously quote under the Rules.

For the foregoing reasons, the Exchange believes that the proposed rule change is appropriate and consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

C2 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. The Exchange does not believe the proposed rule change to exclude Intra-day Adds during the day which such series are added for trading from Market-Makers' quoting obligations will cause any unnecessary burden on intramarket competition because it provides the same relief to a group of similarly situated market participants—Market-Makers. The Exchange does not believe the proposed change will cause any unnecessary burden on intermarket competition because Intra-day Adds are a very small portion of series on the Exchange. Exchange further believes that the potential small reduction in liquidity in Intra-day Adds that may result from the proposed relief would be far outweighed by the significant reduction in liquidity in appointed classes that the Exchange believes could occur from withdrawals from and reductions in applications for Market-Maker appointments without the proposed relief. In addition, the Exchange believes that the proposed

rule change will in fact relieve any burden on, or otherwise promote, competition. The Exchange believes that excluding Intra-day Adds on the day during which they are added for trading from Market-Maker obligations will promote trading activity on the Exchange to the benefit of the Exchange, its TPHs, and market participants.

The Exchange does not believe the proposed rule change to clarify that Market-Makers may receive participation entitlements in Intra-day Adds in their appointed classes in which they are quoting, even though they are not required to quote, if the other requirements set forth in the Rules are satisfied, will cause any unnecessary burden on intramarket competition because it too provides the same relief to a group of similarly situated market participants—Market-Makers. The Exchange does not believe the proposed change will cause any unnecessary burden on intermarket competition because Market-Makers are currently entitled to receive participation entitlements on series they are not obligated to quote in under the Rules. In addition, the Exchange believes that the proposed rule change will in fact relieve any burden on, or otherwise promote, competition. The Exchange believes allowing Market-Makers to receive a participation entitlements in Intra-day Adds will promote trading activity on the Exchange because it will incentivize Market-Makers to quote in such series though not obligated to do so to the benefit of the Exchange, its TPHs, and market participants.

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 proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will:

A. By order approve or disapprove such proposed rule change, or

B. Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, 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 email to rule-comments@sec.gov. Please include File Number SR–C2–2013–008 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–C2–2013–008. This file number should be included on the subject line if email 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 Web site viewing and printing in the Commission’s Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 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–C2–2013–008, and should be submitted on or before March 20, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁵

Kevin M. O’Neill,
Deputy Secretary.

[FR Doc. 2013–04544 Filed 2–26–13; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #13496 and #13497]

Mississippi Disaster # MS–00065

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Mississippi (FEMA–4101–DR), dated 02/19/2013.

Incident: Severe Storms, Tornadoes, and Flooding.

Incident Period: 02/10/2013 and continuing.

Effective Date: 02/19/2013

Physical Loan Application Deadline: 04/22/2013

Economic Injury (EIDL) Loan Application Deadline Date: 11/19/2013

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President’s major disaster declaration on 02/19/2013, Private Non-Profit organizations that provide essential services of governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Forrest, Lamar, Marion, Wayne.

The Interest Rates are:

	Percent
<i>For Physical Damage:</i>	
Non-Profit Organizations With Credit Available Elsewhere ...	2.875
Non-Profit Organizations Without Credit Available Elsewhere	2.875
<i>For Economic Injury:</i>	

¹⁵ 17 CFR 200.30–3(a)(12).

	Percent
Non-Profit Organizations Without Credit Available Elsewhere	2.875

The number assigned to this disaster for physical damage is 13496C and for economic injury is 13497C.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

James E. Rivera,
Associate Administrator for Disaster Assistance.

[FR Doc. 2013–04463 Filed 2–26–13; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #13492 and #13493]

Mississippi Disaster Number MS–00064

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of Mississippi (FEMA–4101–DR), dated 02/13/2013.

Incident: Severe Storms, Tornadoes, and Flooding

Incident Period: 02/10/2013 and continuing.

Effective Date: 02/15/2013

Physical Loan Application Deadline Date: 04/15/2013

EIDL Loan Application Deadline Date: 11/13/2013

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416

SUPPLEMENTARY INFORMATION: The notice of the Presidential disaster declaration for the State of Mississippi, dated 02/13/2013 is hereby amended to include the following areas as adversely affected by the disaster:

Primary Counties: (Physical Damage and Economic Injury Loans): Marion, Wayne.

Contiguous Counties: (Economic Injury Loans Only):

Mississippi: Clarke, Greene, Jasper, Lawrence, Walthall.

Alabama: Choctaw, Washington. Louisiana: Washington.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2013-04454 Filed 2-26-13; 8:45 am]

BILLING CODE 8025-01-P

DEPARTMENT OF STATE

[Public Notice 8206]

30-Day Notice of Proposed Information Collection: DS-2028, Overseas Schools Grant Status Report, OMB 1405-0033

ACTION: Notice of request for public comment and submission to OMB of proposed collection of information.

SUMMARY: The Department of State has submitted the information collection described below to the Office of Management and Budget (OMB) for approval. In accordance with the Paperwork Reduction Act of 1995 we are requesting comments on this collection from all interested individuals and organizations. The purpose of this Notice is to allow 30 days for public comment.

DATES: Submit comments directly to the Office of Management and Budget (OMB) up to March 29, 2013.

ADDRESSES: Keith Miller, Department of State, Office of Overseas Schools, A/OPR/Os, Room H328, SA-1, Washington, DC 20522-0103, who is reachable on 202-261-8200. Direct comments to the Department of State Desk Officer in the Office of Information and Regulatory Affairs at the Office of Management and Budget (OMB). You may submit comments by the following methods:

- *Email:*

oira_submission@omb.eop.gov. You must include the DS form number, information collection title, and the OMB control number in the subject line of your message.

- *Fax:* 202-395-5806. Attention: Desk Officer for Department of State.

FOR FURTHER INFORMATION CONTACT:

Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Wanda Lyles, Department of State, Office of Overseas Schools, A/OPR/OS, Room H328, SA-1, Washington, DC 20522-0103, who is reachable on 202-261-8200 or *lyleswm2@state.gov.*

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* DS-2028, Overseas Schools Grant Status Report

- *OMB Control Number:* OMB 1405-0033

- *Type of Request:* Extension of a Currently Approved Collection

- *Originating Office:* Office of Overseas Schools, A/OPR/OS

- *Form Number:* DS-2028

- *Respondents:* Overseas schools grantees

- *Estimated Number of Respondents:* 196

- *Estimated Number of Responses:* 196

- *Average Time per Response:* 15 minutes

- *Total Estimated Burden Time:* 49 hours

- *Frequency:* Annually

- *Obligation to Respond:* Required to Retain a Benefit

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.

- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.

- Enhance the quality, utility, and clarity of the information to be collected.

- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of proposed collection: The Office of Overseas Schools of the Department of State (A/OPR/OS) is responsible for determining that adequate educational opportunities exist at Foreign Service Posts for dependents of U.S. Government personnel stationed abroad, and for assisting American-sponsored overseas schools to demonstrate U.S. educational philosophy and practice. The information gathered provides the technical and professional staff of A/OPR/OS the means by which obligations, expenditures and reimbursements of the grant funds are monitored to ensure the grantee is in compliance with the terms of the grant.

Methodology: Information is collected via electronic and paper submission.

Dated: February 8, 2013.

William S. Amoroso,

Executive Director, Bureau of Administration, Department of State.

[FR Doc. 2013-04587 Filed 2-26-13; 8:45 am]

BILLING CODE 4710-24-P

DEPARTMENT OF STATE

[Public Notice 8205]

30-Day Notice of Proposed Information Collection: Office of Language Services Contractor Application Form

ACTION: Notice of request for public comment and submission to OMB of proposed collection of information.

SUMMARY: The Department of State has submitted the information collection described below to the Office of Management and Budget (OMB) for approval. In accordance with the Paperwork Reduction Act of 1995 we are requesting comments on this collection from all interested individuals and organizations. The purpose of this Notice is to allow 30 days for public comment.

DATE(S): Submit comments directly to the Office of Management and Budget (OMB) up to March 29, 2013.

ADDRESSES: Direct comments to the Department of State Desk Officer in the Office of Information and Regulatory Affairs at the Office of Management and Budget (OMB). You may submit comments by the following methods:

- *Email:*

oira_submission@omb.eop.gov. You must include the DS form number, information collection title, and the OMB control number in the subject line of your message.

- *Fax:* 202-395-5806. Attention: Desk Officer for Department of State.

FOR FURTHER INFORMATION CONTACT:

Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Martha Allen at 2401 E Street NW., Fourteenth Floor, Washington, DC 20522, who may be reached on 202-261-8800 or at *AllenML2@state.gov.*

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Office of Language Services Contractor Application Form.

- *OMB Control Number:* 1405-0191.

- *Type of Request:* Extension of Currently Approved Collection.

- *Originating Office:* Bureau of Administration (A/OPR/LS).

- *Form Number:* DS-7651.

• *Respondents*: Individuals Applying for Translator and/or Interpreter Contract Positions.

• *Estimated Number of Respondents*: 1,100.

• *Estimated Number of Responses*: 1,100.

• *Average Time per Response*: Thirty minutes.

• *Total Estimated Burden Time*: 550 hours.

• *Frequency*: On Occasion.

• *Obligation To Respond*: Required To Obtain or Retain a Benefit.

We are soliciting public comments to permit the Department to:

• Evaluate whether the proposed information collection is necessary for the proper functions of the Department.

• Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.

• Enhance the quality, utility, and clarity of the information to be collected.

• Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of proposed collection: The information collected is needed to ascertain whether respondents are valid interpreting and/or translating candidates, based on their work history and legal work status in the United States. If candidates successfully become contractors for the U.S. Department of State, Office of Language Services, the information collected is used to initiate security clearance background checks and for processing payment vouchers. Respondents are typically members of the general public with varying degrees of experience in the fields of interpreting and/or translating. The collection is authorized by 5 U.S.C. 3109.

Methodology: OLS makes the "Office of Language Services Contractor Application Form" available via the OLS Internet site. Respondents can submit it via email.

Dated: February 20, 2013.

Thomas F. Hufford,
Director, Office of Language Services,
Department of State.

[FR Doc. 2013-04588 Filed 2-26-13; 8:45 am]

BILLING CODE 4710-09-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Availability of Draft Alaska National Interest Lands Conservation Act (ANILCA) Section 810 Subsistence Evaluation.

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of availability and request for comments.

SUMMARY: The FAA announces the availability and request for comments of a draft ANILCA Section 810 Subsistence Evaluation for proposed improvements to the runway safety areas at the Kodiak Airport, Kodiak, Alaska.

DATES: Comments must be received on or before March 29, 2013.

ADDRESSES: You may submit comments or request for copies or more information by any of the following methods:

1. *Web Site*: Download a copy of the draft Section 810 Subsistence Evaluation or full Draft EIS document at: <http://www.kodiakairporteis.com>

2. *Email*: Leslie.Grey@faa.gov; govmailto:izembek_eis@fws.gov; include "Kodiak Airport EIS ANILCA comments" in the subject line of the message.

3. *Fax*: Attn: Leslie Grey, AAL-614, (907) 271-2851

4. *U.S. Mail*: Leslie Grey—AAL-614, Federal Aviation Administration, Airports Division, 222 West 7th Avenue, Box #14, Anchorage, AK 99513.

5. *In-Person Pickup or Drop-off*: To pick up a copy or drop off comments call or email Leslie Grey in advance.

FOR FURTHER INFORMATION CONTACT: Leslie Grey, AAL-614, Federal Aviation Administration, Alaskan Region, Airports Division, 222 W. 7th Avenue, Box #14, Anchorage, AK 99513. Ms. Grey may be contacted during business hours at (907) 271-5453 (phone) and (907) 271-2851 (Fax) or email Leslie.Grey@faa.gov.

SUPPLEMENTARY INFORMATION: Alternatives proposed as part of the Draft EIS as published in the **Federal Register** of October 23, 2012 (77 FR 64836) would require placement of fill on submerged lands jointly managed by the U.S. Coast Guard Kodiak Base Support Unit and the U.S. Fish and Wildlife Service Alaska Maritime National Wildlife Refuge.

Authority: 16 U.S.C. 3120; 16 U.S.C. 3164.

Issued in Anchorage, Alaska on February 21, 2013.

Annie Aquino-Bernaldo,
Acting Manager, Airports Division, Alaskan Region.

[FR Doc. 2013-04578 Filed 2-26-13; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Meeting: RTCA Special Committee 223, Airport Surface Wireless Communications

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

ACTION: Meeting Notice of RTCA Special Committee 223, Airport Surface Wireless Communications

SUMMARY: The FAA is issuing this notice to advise the public of the meeting of the RTCA Special Committee 223, Airport Surface Wireless Communications.

DATES: The meeting will be held March 19-21, 2013, from 9:00 a.m.—5:00 p.m. daily.

ADDRESSES: The meeting will be held at Booz, Allen, Hamilton Offices, 1201 Maryland Avenue SW., Suite 5140, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: The RTCA Secretariat, 1150 18th Street NW., Suite 910, Washington, DC 20036, or by telephone at (202) 330-0662/(202) 833-9339, fax (202) 833-9434, or Web site at <http://www.rtca.org>.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. No. 92-463, 5 U.S.C., App.), notice is hereby given for a meeting of Special Committee 223. The agenda will include the following:

Tuesday, March 19 Through Thursday, March 21, 2013

- Plenary: Welcome, Introductions, Administrative Remarks.
- Agenda Overview.
- Review and Approve prior Plenary Meeting Summary.
- Profile CCB Status.
- Detailed MOPS Review:
- Convergence Sub-layer.
- Security.
- MAC Layer.
- Physical Layer.
- PICS.
- CRSL.
- Review/Approval of MOPS for FRAC.
- Review of Meeting Summary Report.

- Finalize date of next meeting;
- Adjourn.

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on February 21, 2013.

Paige Williams,

Management Analyst, NextGen, Business Operations Group, Federal Aviation Administration.

[FR Doc. 2013-04562 Filed 2-26-13; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

90th Meeting: RTCA Special Committee 159, Global Positioning Systems (GPS)

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

ACTION: Meeting Notice of RTCA Special Committee 159, RTCA Special Committee 159, Global Positioning Systems (GPS)

SUMMARY: The FAA is issuing this notice to advise the public of the eighty-ninth meeting of the RTCA Special Committee 159, Global Positioning Systems (GPS).

DATES: The meeting will be held March 12-15, 2013 from 9:00 a.m.-4:30 p.m.

ADDRESSES: The meeting will be held at RTCA, Inc., 1150 18th Street NW., Suite 910, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: The RTCA Secretariat, 1150 18th Street NW., Suite 910, Washington, DC 20036, or by telephone at (202) 330-0652/(202) 833-9339, fax at (202) 833-9434, or Web site at <http://www.rtca.org>.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. No. 92-463, 5 U.S.C., App.), notice is hereby given for a meeting of Special Committee 159. The agenda will include the following:

Working Group Sessions

March 12

- Working Group 2, GPS/SBAS, MacIntosh-NBAA Room and Colson Board Room.

March 13

- 9:00 a.m.-12:00 p.m., Working Group 2, GPS/SBAS, A4A Room.
- 1:00 p.m.-5:00 p.m., Working Group 4, Precision Landing Guidance, GPS/GBAS, MacIntosh-NBAA Room and Colson Board Room.

March 14

- Working Group 4, Precision Landing Guidance, GPS/GBAS, MacIntosh-NBAA Room and Colson Board Room.
- 1:00 p.m.-5:00 p.m., Working Group 7, GPS/Antennas, A4A Room.

March 15, 2013

- Chairman's Introductory Remarks.
- Approval of Summary of the Eighty-Ninth Meeting held October 5, 2012.
- Review Working Group (WG) Progress and Identify Issues for Resolution.
- GPS/3rd Civil Frequency (WG-1).
- GPS/WAAS (WG-2).
- GPS/GLONASS (WG-2A).
- GPS/Inertial (WG-2C).
- GPS/Precision Landing Guidance (WG-4).
- GPS/Airport Surface Surveillance (WG-5).
- GPS/Interference (WG-6).
- GPS/Antennas (WG-7).
- Review of EUROCAE Activities.
- Assignment/Review of Future Work.
- Other Business.
- Date and Place of Next Meeting.
- Adjourn.

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on February 21, 2013.

Paige Williams,

Management Analyst, NextGen, Business Operations Group, Federal Aviation Administration.

[FR Doc. 2013-04564 Filed 2-26-13; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. EP 526 (Sub-No. 4)]

Notice of Railroad-Shipper Transportation Advisory Council Vacancy

AGENCY: Surface Transportation Board (Board), Transportation.

ACTION: Notice of vacancies on the Railroad-Shipper Transportation Advisory Council (RSTAC) and solicitation of nominations.

SUMMARY: The Board hereby gives notice of one vacancy on RSTAC for a small shipper representative. The Board is soliciting suggestions for candidates to fill this vacancy.

DATES: Suggestions of candidates for membership on RSTAC are due on March 25, 2013.

ADDRESSES: Suggestions may be submitted either via the Board's e-filing format or in the traditional paper format. Any person using e-filing should attach a document and otherwise comply with the instructions at the E-FILING link on the Board's Web site, at <http://www.stb.dot.gov>. Any person submitting a filing in the traditional paper format should send an original and 10 copies to: Surface Transportation Board, Attn: Docket No. EP 526 (Sub-No. 4), 395 E Street SW., Washington, DC 20423-0001. Please note that submissions will be available to the public at the Board's offices and posted on the Board's Web site under Docket No. EP 526 (Sub-No. 4).

FOR FURTHER INFORMATION CONTACT:

Gabriel Meyer at 202-245-0150. Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1-800-877-8339.

SUPPLEMENTARY INFORMATION: The Board, created by Congress in 1996 to take over many of the functions previously performed by the Interstate Commerce Commission, exercises broad authority over transportation by rail carriers, including regulation of railroad rates and service (49 U.S.C. 10701-10747, 11101-11124), as well as the construction, acquisition, operation, and abandonment of rail lines (49 U.S.C. 10901-10907) and railroad line sales, consolidations, mergers, and common control arrangements (49 U.S.C. 10902, 11323-11327).

RSTAC was established upon the enactment of the ICC Termination Act of 1995 (ICCTA), on December 29, 1995, to advise the Board's Chairman, the Secretary of Transportation, the

Committee on Commerce, Science, and Transportation of the Senate, and the Committee on Transportation and Infrastructure of the House of Representatives with respect to rail transportation policy issues RSTAC considers significant. RSTAC focuses on issues of importance to small shippers and small railroads, including car supply, rates, competition, and procedures for addressing claims. ICCTA directs RSTAC to develop private-sector mechanisms to prevent, or identify and address, obstacles to the most effective and efficient transportation system practicable. The Secretary of Transportation and the members of the Board cooperate with RSTAC in providing research, technical, and other reasonable support. RSTAC also prepares an annual report concerning its activities and recommendations on whatever regulatory or legislative relief it considers appropriate. RSTAC is not subject to the Federal Advisory Committee Act.

RSTAC consists of 19 members. Of this number, 15 members are appointed by the Chairman of the Board, and the remaining 4 members are comprised of the Secretary of Transportation and the Members of the Board, who serve as *ex officio*, nonvoting members. Of the 15 members to be appointed, 9 members are voting members and are appointed from senior executive officers of organizations engaged in the railroad and rail shipping industries. At least 4 of the voting members must be representatives of small shippers as determined by the Chairman, and at least 4 of the voting members must be representatives of Class II or III railroads. The remaining 6 members to be appointed—3 representing Class I railroads and 3 representing large shipper organizations—serve in a nonvoting, advisory capacity, but are entitled to participate in RSTAC deliberations.

RSTAC is required by statute to meet at least semi-annually. In recent years, RSTAC has chosen to meet 4 times a year, with the first meeting each February. Meetings are generally held at the Board's headquarters in Washington, DC, although some may be held in other locations.

RSTAC members receive no compensation for their services and are required to provide for the expenses incidental to their service, including travel expenses, as the Board cannot provide for these expenses. The RSTAC Chairman, however, may request funding from the Department of Transportation to cover travel expenses, subject to certain restrictions in ICCTA.

RSTAC also may solicit and use private funding for its activities, again subject to certain restrictions in ICCTA. RSTAC members currently have elected to submit annual dues to pay for RSTAC expenses.

RSTAC members must be citizens of the United States and represent as broadly as practicable the various segments of the railroad and rail shipper industries. They may not be full-time employees of the United States. Further, RSTAC members appointed or reappointed after June 18, 2010, are prohibited from serving as federally registered lobbyists during their RSTAC term.

The members of RSTAC are appointed for a term of 3 years. A member may serve after the expiration of his or her term until a successor has taken office. No member will be eligible to serve in excess of 2 consecutive terms.

Due to an unanticipated resignation, one vacancy currently exists for a small shipper representative. Upon appointment by the Chairman, the small shipper representative will serve until December 31, 2014. Suggestions for candidates to fill this vacancy should be submitted in letter form, identify the name of the candidate, provide a summary of why the candidate is qualified to serve on RSTAC, and contain a representation that the candidate is willing to serve as a member of RSTAC effective immediately upon appointment and continuing until December 31, 2014. RSTAC candidate suggestions should be filed with the Board by March 25, 2013. Members selected to serve on RSTAC are chosen at the discretion of the Board's Chairman. Please note that submissions will be available to the public at the Board's offices and posted on the Board's Web site under Docket No. EP 526 (Sub-No. 4).

This action will not significantly affect either the quality of the human environment or the conservation of energy resources.

Authority: 49 U.S.C. 726.

Decided: February 21, 2013.

By the Board, Rachel D. Campbell, Office of Proceedings.

Raina White,
Clearance Clerk.

[FR Doc. 2013-04525 Filed 2-26-13; 8:45 am]

BILLING CODE 4915-01-P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

February 22, 2013.

The Department of the Treasury will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, Public Law 104-13, on or after the date of publication of this notice.

DATES: Comments should be received on or before March 29, 2013 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestion for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at OIRA_Submission@OMB.EOP.GOV and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 8140, Washington, DC 20220, or email at PRA@treasury.gov.

FOR FURTHER INFORMATION CONTACT: Copies of the submission(s) may be obtained by calling (202) 927-5331, email at PRA@treasury.gov, or the entire information collection request maybe found at www.reginfo.gov.

Alcohol and Tobacco Tax and Trade Bureau (TTB)

OMB Number: 1513-0032.

Type of Review: Extension.

Title: Inventory—Manufacturer of Tobacco Products, Processed Tobacco, or Cigarette Papers and Tubes.

Form: TTB F 5210.9.

Abstract: This form is necessary to determine the beginning and ending inventories of tobacco products and processed tobacco at the premises of a tobacco products or processed tobacco manufacturer. The information is recorded on this form by the proprietor and is used to determine tax liability, compliance with regulations, and for protection of the revenue.

Affected Public: Private Sector: Businesses or other for-profits.

Estimated Total Burden Hours: 386.

OMB Number: 1513-0033.

Type of Review: Extension.

Title: Report—Manufacturer of Tobacco Products or Cigarette Papers and Tubes and Report—Manufacturer of Processed Tobacco.

Form: TTB F 5250.1, TTB F 5210.5.

Abstract: Manufacturers account for their taxable articles on this report. TTB

uses this information to ensure that taxes have been properly paid, Federal laws and regulations are compiled with, and to prevent diversion.

Affected Public: Private Sector: Businesses or other for-profits.
Estimated Total Burden Hours: 4,632.

OMB Number: 1513-0035.

Type of Review: Extension.

Title: Inventory—Export Warehouse Proprietor.

Form: TTB F 5220.3.

Abstract: TTB F 5220.3 is used by export warehouse proprietors to record inventories that are required by law and regulations.

Affected Public: Private Sector: Businesses or other for-profits.
Estimated Total Burden Hours: 400.

OMB Number: 1513-0052.

Type of Review: Revision.

Title: Alcohol Fuel Plants (AFP) Records, Reports, and Notices (REC 5110/10).

Form: TTB F 5110.75.

Abstract: This information is necessary to determine that persons are qualified to produce alcohol for fuel purposes, and to identify such persons; to account for distilled spirits produced, and verify its proper disposition; to keep registrations current; and to evaluate permissible variations from prescribed procedures.

Affected Public: Private Sector: Businesses or other for-profits; farms.
Estimated Total Burden Hours: 2,784.

OMB Number: 1513-0063.

Type of Review: Extension.

Title: Stills: Notices, Registration, and Records (TTB REC 5150/8).

Abstract: The information collection is used to account for and regulate the distillation of distilled spirits to protect the revenue and to provide for identification of distillers.

Affected Public: Private Sector: Businesses or other for-profits.
Estimated Total Burden Hours: 42.

OMB Number: 1513-0064.

Type of Review: Extension.

Title: Importer's Records and Reports (TTB REC 5170/1).

Abstract: This recordkeeping and reporting requirement concerns the records which must be maintained by the importer as well as the applications and notices required to be submitted to TTB. The records are used by TTB to verify that operations are being conducted in compliance with the law and to ensure that all taxes and duties have been paid on imported spirits, thus protecting the revenue.

Affected Public: Private Sector: Businesses or other for-profits.
Estimated Total Burden Hours: 251.

OMB Number: 1513-0068.

Type of Review: Extension.

Title: Records of Operations—Manufacturer of Tobacco Products or Processed Tobacco TTB REC 5210/1.

Abstract: Tobacco products or processed tobacco manufactures must maintain records that provide accountability over the tobacco products or processed tobacco received and produced. These records ensure that each tobacco products or processed tobacco transaction can be traced, and ensure that tax liabilities are totally satisfied.

Affected Public: Private Sector: Businesses or other for-profits.
Estimated Total Burden Hours: 386.

OMB Number: 1513-0070.

Type of Review: Extension.

Title: Tobacco Export Warehouse—Record of Operations TTB REC 5220/1.

Abstract: Tobacco Export Warehouses store untaxpaid tobacco products and processed tobacco until they are exported. Record is used to maintain accountability over these commodities. These records also allow TTB to verify that all commodities have been exported or tax liabilities are satisfied, protecting tax revenues.

Affected Public: Private Sector: Businesses or other for-profits.
Estimated Total Burden Hours: 1.

OMB Number: 1513-0072.

Type of Review: Extension.

Title: Applications and Notices—Manufacturers of Nonbeverage Products (TTB REC 5530/1).

Abstract: Reports (Letterhead Applications and Notices) are submitted by manufacturers of nonbeverage products who are using distilled spirits on which drawback will be claimed. TTB uses these reports to ensure that operations are in compliance with the law, to prevent spirits from being diverted to beverage use, and to protect the revenue.

Affected Public: Private Sector: Businesses or other for-profits.
Estimated Total Burden Hours: 510.

OMB Number: 1513-0077.

Type of Review: Extension.

Title: Records of Things of Value to Retailers, and Occasional Letter Reports from Industry Members Regarding Information on Sponsorships, Advertisements, Promotions, etc., under the FAA Act—TTB REC 5190/1.

Abstract: These records and occasional letter reports are used to show compliance with the provisions of the Federal Alcohol Administration Act which prevents wholesalers, producers, or importers from giving things of value to retail liquor dealers, and prohibit industry members from conducting certain types of sponsorships, advertisings, promotions, etc.

Affected Public: Private Sector: Businesses or other for-profits; Individuals or Households.

Estimated Total Burden Hours: 2,112.

OMB Number: 1513-0078.

Type of Review: Extension.

Title: Application for a Permit as a Manufacture of Tobacco Products or Processed Tobacco or as an Export Warehouse Proprietor; Application for an Amended Permit as a Manufacture of Tobacco Products or Processed Tobacco or an Export Warehouse, et al.

Form: TTB F 5200.16, TTB F 5200.3, TTB F 5230.4, TTB F 5230.5.

Abstract: These forms are used by the tobacco industry members to obtain and amend permits necessary to engage in business as a manufacturer of tobacco products or processed tobacco, or as an export warehouse proprietor.

Affected Public: Private Sector: Businesses or other for-profits; State, Local and Tribal Governments.
Estimated Total Burden Hours: 2,277.

OMB Number: 1513-0093.

Type of Review: Extension.

Title: Application for Extension of Time for Payment of Tax.

Form: TTB 5600.38.

Abstract: TTB uses the information on the form to determine if a taxpayer is qualified to extend the tax payment based on circumstances beyond the taxpayer's control.

Affected Public: Private Sector: Businesses or other for-profits.
Estimated Total Burden Hours: 3.

OMB Number: 1513-0098.

Type of Review: Extension.

Title: Supporting Data for Nonbeverage Drawback Claims.

Form: TTB F 5154.2.

Abstract: Data required to be submitted by manufacturers of nonbeverage products are used to verify claims for drawback of taxes and hence, to protect the revenue. This form is used to verify that all distilled spirits can be accounted for and that drawback is paid only in the amount prescribed by law.

Affected Public: Private Sector: Businesses or other for-profits.
Estimated Total Burden Hours: 3,422.

OMB Number: 1513-0106.

Type of Review: Extension.

Title: Record of Operations—Importer of Tobacco Products or Processed Tobacco.

Abstract: Importers of tobacco products or processed tobacco are required to maintain records of physical receipts and disposition of tobacco products or processed tobacco to be able to prepare TTB Form 5220.6 (a monthly report). Importers of tobacco products and processed tobacco will consist of both large and small businesses that operate for profit.

Affected Public: Private Sector: Businesses or other for-profits.
Estimated Total Burden Hours: 1.
OMB Number: 1513-0107.
Type of Review: Extension.
Title: Monthly Report—Tobacco Products Importer.
Form: TTB F 5220.6.

Abstract: Reports of the importation and disposition of tobacco products and processed tobacco are necessary to determine whether those issued the permits required by 26 U.S.C. Section 5713 should be allowed to continue their operations or renew their permits. This report is also used to determine if tobacco products or processed tobacco are being diverted for illegal purposes and to ensure that holders of basic permits are engaging in the operations stated on their basic permit.

Affected Public: Private Sector: Businesses or other for-profits.
Estimated Total Burden Hours: 14,064.

OMB Number: 1513-0130.
Type of Review: Extension.
Title: Report of Sale or Transfer of Processed Tobacco.
Form: TTB F 5250.2.

Abstract: TTB believes that unregulated transfers or sales of processed tobacco to persons who do not hold TTB permits could lead to processed tobacco falling into the hands of persons who would be unknown and unaccountable to TTB, including illegal manufacturers. In order to better regulate processed tobacco and prevent diversion, TTB requires the filing of a report covering all such transfers or sales. This report is used to protect the revenue.

Affected Public: Private Sector: Businesses or other for-profits.
Estimated Total Burden Hours: 2,337.

Dawn D. Wolfgang,

Treasury PRA Clearance Officer.

[FR Doc. 2013-04513 Filed 2-26-13; 8:45 am]

BILLING CODE 4810-31-P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

February 21, 2013.

The Department of the Treasury will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, Public Law 104-13, on or after the date of publication of this notice.

DATES: Comments should be received on or before March 29, 2013 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestion for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at OIRA_Submission@OMB.EOP.GOV and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 8140, Washington, DC 20220, or email at PRA@treasury.gov.

FOR FURTHER INFORMATION CONTACT: Copies of the submission(s) may be obtained by calling (202) 927-5331, email at PRA@treasury.gov, or the entire information collection request maybe found at www.reginfo.gov.

Office of Small and Disadvantaged Business Utilization (OSDBU)

OMB Number: 1505-0220.
Type of Review: Extension without change of a currently approved collection.

Title: Electronic Capability Statement.
Abstract: The Electronic Capability Statement will be used by firms that wish to do business with the Department of the Treasury. The form will capture key information such as NAICS, contract and subcontract award information, and past performance. The information will be stored in a database. The database will be used by OSDBU, Treasury Acquisition staff and the Troubled Asset Relief Program to conduct research when searching for small businesses to perform on Treasury contracts.

Affected Public: Private Sector: Businesses or other for-profits.
Estimated Total Burden Hours: 54.

Dawn D. Wolfgang,

Treasury PRA Clearance Officer.

[FR Doc. 2013-04439 Filed 2-26-13; 8:45 am]

BILLING CODE 4810-25-P

DEPARTMENT OF THE TREASURY

Open Meeting of the Federal Advisory Committee on Insurance

AGENCY: Departmental Offices, Treasury.
ACTION: Notice of open meeting.

SUMMARY: This notice announces that the Department of the Treasury's Federal Advisory Committee on Insurance will convene a meeting on Wednesday, March 13, 2013, in Room 4125, 1500 Pennsylvania Avenue NW., Washington, DC, 20220, beginning at 9:00 a.m. Eastern Time. The meeting is open to the public, and the site is

accessible to individuals with disabilities. The Federal Advisory Committee on Insurance will convene its meeting.

DATES: The meeting will be held on Wednesday, March 13, 2013, commencing at 9:00 a.m. Eastern Time.

ADDRESSES: The Federal Advisory Committee on Insurance meeting will be held in the Room 4125, 1500 Pennsylvania Avenue NW., Washington, DC 20220. The meeting will be open to the public. Because the meeting will be held in a secured facility, members of the public who plan to attend the meeting must contact the Federal Insurance Office (Office), at (202) 622-6910, by 5:00 p.m. Eastern Time on Friday, March 8, 2013, to inform the Office of the desire to attend the meeting and to provide the information that will be required to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: James P. Brown, Senior Policy Advisor to the Federal Insurance Office, Room 2100, Department of the Treasury, 1425 New York Avenue NW., Washington, DC 20220, at (202) 622-6910 (this is not a toll-free number). Persons who have difficulty hearing or speaking may access this number via TTY by calling the toll-free Federal Relay Service at (800) 877-8339.

SUPPLEMENTARY INFORMATION: Notice of this meeting is provided in accordance with the Federal Advisory Committee Act, 5 U.S.C. App. II, 10(a)(2), through implementing regulations at 41 CFR 102-3.150.

Public Comment: Members of the public wishing to comment on the business of the Federal Advisory Committee on Insurance are invited to submit written statements by any of the following methods:

Electronic Statements

- Send electronic comments to faci@treasury.gov.

Paper Statements

- Send paper statements in triplicate to the Federal Advisory Committee on Insurance, Room 2100, Department of the Treasury, 1425 New York Avenue NW., Washington, DC 20220. The Department of the Treasury will post all statements on its Web site <http://www.treasury.gov/about/organizational-structure/offices/Pages/Federal-Insurance.aspx> without change, including any business or personal information provided such as names, addresses, email addresses, or telephone numbers. The Department of the Treasury will also make such statements available for public inspection and

copying in the Department of the Treasury's Library, 1500 Pennsylvania Avenue NW., Washington, DC 20220, on official business days between the hours of 10:00 a.m. and 5:00 p.m. Eastern Time. You can make an appointment to inspect statements by telephoning (202) 622-0990. All statements, including attachments and other supporting materials, received are part of the public record and subject to public disclosure. You should submit only information that you wish to make available publicly.

Tentative Agenda/Topics for Discussion: This is a periodic meeting of the Federal Advisory Committee on Insurance. In this meeting, the Federal Advisory Committee on Insurance will discuss topics of interest, international developments, and it will receive and discuss updates from its three subcommittees.

Dated: February 21, 2013.

Rebecca H. Ewing,

Executive Secretary.

[FR Doc. 2013-04533 Filed 2-26-13; 8:45 am]

BILLING CODE 4810-25-P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities; Information Collection Renewal; Comment Request: Disclosure of Financial and Other Information by National Banks

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, 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 a continuing information collection, as required by the Paperwork Reduction Act of 1995.

Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information and to allow 60 days for public comment in response to the notice.

In accordance with the requirements of the PRA, the OCC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number.

The OCC is soliciting comment concerning renewal of its information collection titled, "Disclosure of Financial and Other Information by National Banks."

DATES: Comments must be submitted on or before April 29, 2013.

ADDRESSES: Because paper mail in the Washington, DC area and at the OCC is subject to delay, commenters are encouraged to submit comments by email if possible. Comments may be sent to: Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, Attention: 1557-0182, 400 7th Street SW., Suite 3E-218, Mail Stop 9W-11, Washington, DC 20219. In addition, comments may be sent by fax to (571) 465-4326 or by electronic mail to

regs.comments@occ.treas.gov. You may personally inspect and photocopy comments at the OCC, 400 7th Street SW., Washington, DC 20219. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649-6700. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

All comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not enclose any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

FOR FURTHER INFORMATION CONTACT: You may request additional information or a copy of the collection from Johnny Vilela or Mary H. Gottlieb, OCC Clearance Officers, (202) 649-5490, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 400 7th Street SW., Suite 3E-218, Mail Stop 9W-11, Washington, DC 20219.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information,

including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, the OCC is publishing notice of the proposed collection of information set forth in this document.

Title: Disclosure of Financial and Other Information by National Banks (12 CFR 18).

OMB Control No.: 1557-0182.

Type of Review: Extension, without revision, of a currently approved collection.

Description: The collections of information are found in 12 CFR 18.3, 18.4, and 18.8. Section 18.3 requires the preparation of an annual disclosure statement and specifies how it must be made available to shareholders. Section 18.4 outlines what information the disclosure statement must contain, and provides that a bank may supplement its annual disclosure statement with an optional narrative. Lastly, § 18.8 requires that a national bank promptly furnish its annual disclosure statement upon request.

This program of periodic financial disclosure is needed not only to facilitate informed decision making by existing and potential customers and investors, but also to improve public understanding of, and confidence in, the financial condition of individual national banks and the national banking system. Further, financial disclosure reduces the likelihood that the market will overreact to incomplete information.

Affected Public: Businesses or other for-profit.

Burden Estimates:

Estimated Number of Respondents: 1,338.

Estimated Number of Responses: 1,338.

Estimated Annual Burden: 669 hours.

Frequency of Response: On occasion.

Comments: Comments submitted in response to this notice will be summarized and 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 OCC, including whether the information has practical utility;

(b) The accuracy of the OCC's estimate of the information collection burden;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection 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.

Dated: February 20, 2013.

Michele Meyer,

Assistant Director, Legislative and Regulatory Activities Division.

[FR Doc. 2013-04437 Filed 2-26-13; 8:45 am]

BILLING CODE 4810-33-P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

[OCC Charter Number 705919]

Bank 360, Beresford, South Dakota; Approval of Conversion Application

Notice is hereby given that on December 28, 2012, the Office of the Comptroller of the Currency (OCC) approved the application of Bank 360, Beresford, South Dakota, to convert to the stock form of organization. Copies of the application are available for inspection on the OCC Web site at the FOIA Reading Room <https://foia-pal.occ.gov/palMain.aspx> under Mutual to Stock Conversion Applications. If you have any questions, please call OCC Licensing Activities at (202) 649-6260.

Dated: February 19, 2013

By the Office of the Comptroller of the Currency.

Stephen A. Lybarger,

Deputy Comptroller for Licensing.

[FR Doc. 2013-04440 Filed 2-26-13; 8:45 am]

BILLING CODE 4810-33-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request For Regulation Project

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 certain

transfers of stock or securities by U.S. persons to foreign corporations and related reporting requirements; and stock transfer rules.

DATES: Written comments should be received on or before April 29, 2013 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette Lawrence, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulations should be directed to Katherine Dean, at (202) 622-3186, or at Internal Revenue Service, Room 6242, 1111 Constitution Avenue NW., Washington, DC 20224, or through the internet, at Katherine.b.dean@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: REG-208165-91 (TD 8770), Certain Transfers of Stock or Securities by U.S. Persons to Foreign Corporations and Related Reporting Requirements; and REG-209035-86 (TD 8862), Stock Transfer Rules.

OMB Number: 1545-1271.

Regulation Project Number: REG-208165-91 and REG-209035-86.

Abstract: A United States entity must generally file a gain recognition agreement with the IRS in order to defer gain on a Code section 367(a) transfer of stock to a foreign corporation, and must file a notice with the IRS if it realizes any income in a Code section 367(b) exchange. These regulations provide guidance and reporting requirements related to these transactions to ensure compliance with the respective Code sections.

Current Actions: There is no change to these existing regulations.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 580.

Estimated Time per Respondent: 4 hours, 7 minutes.

Estimated Total Annual Burden Hours: 2,390.

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: February 13, 2013.

Yvette Lawrence,

IRS Reports Clearance Officer.

[FR Doc. 2013-04483 Filed 2-26-13; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8453-PE

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 8453-PE, U.S. Partnership Declaration for an IRS e-file Return.

DATES: Written comments should be received on or before April 29, 2013 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette Lawrence, 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 Katherine Dean,

(202) 622-3186, at Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the Internet at Katherine.b.dean@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: U.S. Partnership Declaration for an IRS e-file Return.

OMB Number: 1545-2034.

Form Number: Form 8453-PE.

Abstract: Form 8453-PE, U.S.

Partnership Declaration for an IRS e-file Return, was developed for Modernized e-file for partnerships. Internal Revenue Code sections 6109 and 6103 necessitate this collection.

Current Actions: The form and instructions have not changed.

Type of Review: Revision of a currently approved collection.

Affected Public: Businesses and other for-profit organizations.

Estimated Number of Respondents: 500.

Estimated Time per Respondent: 3 hours 19 minutes.

Estimated Total Annual Burden Hours: 1660.

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: February 14, 2013.

Yvette Lawrence,

IRS Reports Clearance Officer.

[FR Doc. 2013-04484 Filed 2-26-13; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

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 the election not to apply look-back method in de minimis cases.

DATES: Written comments should be received on or before April 29, 2013 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette Lawrence, Internal Revenue Service, Room 6516, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulation should be directed to R. Katherine Dean, 202-622-3186, Internal Revenue Service, Room 6516, 1111 Constitution Avenue NW., Washington, DC 20224, or through the Internet at Katherine.b.dean@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: Election Not to Apply Look-Back Method in De Minimis Cases.

OMB Number: 1545-1572.

Regulation Project Number: Reg-120200-97.

Abstract: Under Internal Revenue Code section 460(b)(6), a taxpayer may elect not to apply the look-back method to long-term contracts in de minimis cases. The taxpayer is required under the regulation to notify the IRS of its election.

Current Actions: There are no changes being made to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 20,000.

Estimated Time per Respondent: 12 min.

Estimated Total Annual Burden Hours: 4,000.

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: February 13, 2013.

Yvette Lawrence,

IRS Reports Clearance Officer.

[FR Doc. 2013-04486 Filed 2-26-13; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Tip Reporting Alternative Tip Agreement Used in the Cosmetology and Barber Industry

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 tip reporting alternative commitment used in the cosmetology and barber industry.

DATES: Written comments should be received on or before April 29, 2013 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette Lawrence, Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of information collection should be directed to Katherine Dean at Internal Revenue Service, room 6242, 1111 Constitution Avenue NW., Washington, DC 20224, or at (202) 622-3186, or through the Internet at Katherine.b.dean@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: Tip Reporting Alternative Commitment Agreement used in the Cosmetology and Barber Industry.

OMB Number: 1545-1529.

Abstract: Announcement 2000-21, 2000-19 I.R.B. 983, and Announcement 2001-1, #2001-2 I.R.B. p.277 #2001-2, contain information required by the

Internal Revenue Service in its tax compliance efforts to assist employers and their employees in understanding and complying with Internal Revenue Code section 6053(a), which requires employees to report all their tips monthly to their employers.

Current Actions: There is no change to this existing information collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents and/or Recordkeeping: 4,600.

Estimated Average Time per Respondent/Recordkeeper: 9 hr., 22 min.

Estimated Total Annual Reporting and/or Recordkeeping Burden Hours: 43,073.

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: February 14, 2013.

Yvette Lawrence,

IRS Reports Clearance Office.

[FR Doc. 2013-04485 Filed 2-26-13; 8:45 am]

BILLING CODE 4830-01-P



FEDERAL REGISTER

Vol. 78

Wednesday,

No. 39

February 27, 2013

Part II

Department of Health and Human Services

45 CFR Parts 144, 147, 150, et al.

Patient Protection and Affordable Care Act; Health Insurance Market Rules;
Rate Review; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES**45 CFR Parts 144, 147, 150, 154 and 156**

[CMS-9972-F]

RIN 0938-AR40

Patient Protection and Affordable Care Act; Health Insurance Market Rules; Rate Review**AGENCY:** Department of Health and Human Services.**ACTION:** Final rule.

SUMMARY: This final rule implements provisions related to fair health insurance premiums, guaranteed availability, guaranteed renewability, single risk pools, and catastrophic plans, consistent with title I of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, referred to collectively as the Affordable Care Act. The final rule clarifies the approach used to enforce the applicable requirements of the Affordable Care Act with respect to health insurance issuers and group health plans that are non-federal governmental plans. This final rule also amends the standards for health insurance issuers and states regarding reporting, utilization, and collection of data under the federal rate review program, and revises the timeline for states to propose state-specific thresholds for review and approval by the Centers for Medicare & Medicaid Services (CMS).

DATES: *Effective Date.* This rule is effective on April 29, 2013, except 45 CFR 147.103 and the amendments to 45 CFR part 154 are effective on March 29, 2013.

Applicability Dates. The provisions of this final rule generally apply to health insurance coverage for plan or policy years beginning on or after January 1, 2014. The provisions of 45 CFR 147.103 apply on March 29, 2013. The amendments to 45 CFR part 154 apply on April 1, 2013.

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Executive Summary: Beginning in 2014, health insurance issuers will be prohibited from denying coverage to any American because of a pre-existing condition, and from charging individuals and small employers higher premiums based on health status or gender. In addition, health insurance issuers will no longer be able to segment enrollees into separate rating pools in order to charge high-risk individuals more than low-risk individuals. These reforms, combined with other provisions in the Affordable Care Act, will improve the functioning of both the individual and small group markets and make health insurance affordable and accessible to millions of individuals and families who currently lack affordable coverage options.

The Department of Health and Human Services (HHS) published proposed standards to implement the 2014 market reform provisions of the Affordable Care Act and to amend the federal rate review program in a November 26, 2012

Federal Register proposed rule entitled “Patient Protection and Affordable Care Act; Health Insurance Market Rules; Rate Review” (77 FR 70584). These standards apply to health insurance issuers offering non-grandfathered health insurance coverage both inside and outside of the new competitive marketplaces called Affordable Insurance Exchanges, or “Exchanges.”

This final rule: (1) Provides that health insurance issuers may vary the premium rate for health insurance coverage in the individual and small group markets only based on family size, geography, and age and tobacco use within limits; (2) directs health insurance issuers to offer coverage to and accept every employer or individual who applies for coverage in the group and individual market, subject to certain exceptions; (3) directs health insurance issuers to renew or continue in force coverage in the group and individual market, subject to certain exceptions; (4) codifies the requirement that issuers maintain a single risk pool for the individual market and a single risk pool for the small group market (unless a state decides to merge the markets into a single risk pool); and (5) outlines standards for enrollment in catastrophic plans for young adults and people who cannot otherwise afford health insurance.

Finally, this rule amends the standards under the rate review program in 45 CFR part 154. The amendments revise the timeline for states to propose state-specific thresholds for review and approval by CMS. The amendments also direct health insurance issuers to submit data relating to proposed rate increases in a standardized format specified by the Secretary of HHS (the Secretary), and modify criteria and factors for states to have an effective rate review program. These changes are necessary to reflect the new market reform provisions discussed above and to fulfill the statutory requirement beginning in 2014 that the Secretary, in conjunction with the states, monitor premium increases of health insurance coverage offered through an Exchange and outside of an Exchange. The provisions are also designed to streamline data collection for issuers, states, Exchanges, and HHS.

The substantive authority for these final rules is generally sections 2701, 2702, 2703, 2723 and 2794 of the Public Health Service Act (PHS Act) and sections 1302(e), 1312(c), and 1560(c) of the Affordable Care Act. PHS Act section 2792 authorizes rulemaking as necessary or appropriate to carry out the provisions of title XXVII of the PHS Act, including sections 2701, 2702, 2703, 2723, and 2794. Section 1321(a) of the

Affordable Care Act authorizes rulemaking with respect to sections 1302(e), 1312(c), and 1560(c).

I. Background

A. Legislative Overview

The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) was enacted on March 30, 2010. We refer to the two statutes collectively as the “Affordable Care Act” in this final rule.

Subtitles A and C of title I of the Affordable Care Act reorganized, amended, and added to the provisions of part A of title XXVII of the PHS Act relating to health insurance issuers in the group and individual markets and to group health plans that are non-federal governmental plans.¹ As relevant here, these PHS Act provisions include section 2701 (fair health insurance premiums), section 2702 (guaranteed availability of coverage), section 2703 (guaranteed renewability of coverage), and section 2794 (ensuring that consumers get value for their dollars). In addition, subtitle D of title I of the Affordable Care Act includes section 1302(e) (catastrophic plans) and section 1312(c) (single risk pool). These provisions will establish a federal floor that ensures individuals and employers in all states have certain basic protections with respect to the availability and affordability of health insurance coverage.

Section 2701(a)(1) of the PHS Act regarding fair health insurance premiums provides that the premium rate charged by a health insurance issuer for health insurance coverage offered in the individual or small group market may vary with respect to a particular plan or coverage only based on the following factors: (1) Whether the plan or coverage covers an individual or family; (2) rating area; (3) age (within a ratio of 3:1 for adults); and (4) tobacco use (within a ratio of 1.5:1). Section 2701(a)(2) directs each state to establish one or more rating areas and charges the Secretary with reviewing the adequacy of state-established rating areas. If the Secretary determines that a state’s rating areas are not adequate, or that a state

does not establish such areas, the statute authorizes the Secretary to establish rating areas for that state. Section 2701(a)(3) directs the Secretary, in consultation with the National Association of Insurance Commissioners (NAIC), to define permissible age bands for rating purposes. Section 2701(a)(4) provides that, for purposes of family coverage, any rating variation for age and tobacco use must be applied based on the portion of the premium attributable to each family member.

Section 2702 of the PHS Act directs a health insurance issuer offering health insurance coverage in the group or individual market in a state to accept every employer and individual in the state that applies for the coverage, subject to certain exceptions. These exceptions allow issuers to restrict enrollment in coverage: (1) To open and special enrollment periods as described in section 2702(b); (2) to employers with eligible individuals who live, work, or reside in the service area of a network plan as described in section 2702(c)(1)(A); and (3) in certain situations involving limited network capacity and limited financial capacity as described in section 2702(c)(1)(B) and (d).

Section 2703 of the PHS Act requires a health insurance issuer to renew or continue in force any coverage in the group or individual market at the option of the plan sponsor or the individual. Exceptions to this requirement described in section 2703(b) allow the issuer to nonrenew or discontinue coverage for nonpayment of premiums, fraud, or violation of participation or contribution rules under state law. The law also permits an issuer to cease to offer either a particular type of product or all coverage in a particular market, to refuse to renew coverage if all of the plan’s enrollees leave the service area of a network plan, or if group health plan coverage is provided through a bona fide association and the employer’s association membership ends. Finally, an exception outlined in section 2703(d) permits a health insurance issuer, at the time of coverage renewal, to modify the coverage offered to a group health plan in the large group market, or in the small group market if, for coverage that is available in such market other than through one or more bona fide associations, the modification is consistent with state law and effective on a uniform basis among group health plans with that product.²

Section 2701 applies to health insurance issuers offering health insurance coverage in the individual and small group markets, and in the large group market if a state, beginning in 2017, allows health insurance issuers in the large group market to offer qualified health plans (QHPs) in such market through an Exchange pursuant to section 1312(f)(2)(B) of the Affordable Care Act.³ Sections 2702 and 2703 apply to issuers in the individual and group (small and large) markets. These provisions apply to health insurance coverage in the respective markets regardless of whether the coverage is a QHP offered on Exchanges. Section 1255 of the Affordable Care Act provides that sections 2701, 2702, and 2703 of the PHS Act are effective for plan years (in the individual market, policy years) beginning on or after January 1, 2014.⁴ Section 1251(a)(2) of the Affordable Care Act provides that these PHS Act sections do not apply to grandfathered health insurance coverage.

Section 1302 of the Affordable Care Act specifies levels of coverage or “actuarial values” that health plans in the individual and small group markets, both inside and outside of an Exchange, will meet as part of the requirement to cover an essential health benefits (EHB) package beginning in 2014. These plans will provide a bronze, silver, gold, or platinum level of coverage as described in section 1302(d), or a catastrophic plan in the individual market as described in section 1302(e) for young adults and people who cannot otherwise afford health insurance.

Section 1312(c)(1) and (2) of the Affordable Care Act directs a health insurance issuer to consider all enrollees in all health plans (other than grandfathered health plans) offered by such issuer to be members of a single risk pool for a market (the individual market or small group market). Section 1312(c)(3) gives states the option to merge the individual and small group markets within the state into a single risk pool. Section 1312(c) applies to health plans offered both inside and outside of an Exchange for plan years (in the individual market, policy years) beginning on or after January 1, 2014. It does not apply to grandfathered health plans, and explicitly preempts state law

¹ The Affordable Care Act also added section 715(a)(1) to the Employee Retirement Income Security Act of 1974 (ERISA) and section 9815(a)(1) to the Internal Revenue Code (the Code) to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and to make them applicable to group health plans other than non-federal governmental group health plans. The market reform provisions discussed in this final rule apply only to health insurance issuers offering health insurance coverage.

² Section 2742 of the PHS Act provides a corresponding exception for the uniform modification of coverage in the individual market.

³ The applicable definitions for “individual market,” “small group market,” and “large group market” are found in PHS Act section 2791(e) and section 1304(a) of the Affordable Care Act.

⁴ See 45 CFR 144.103 for definitions of “plan year” and “policy year.” These terms are defined differently from “plan year” and “benefit year” as defined in 45 CFR 155.20 with respect to QHPs.

requiring grandfathered health plans to be included in a single risk pool.

Section 1003 of the Affordable Care Act adds a new section 2794 of the PHS Act, which directs the Secretary, in conjunction with the states, to establish a process for the annual review of “unreasonable increases in premiums for health insurance coverage.” The statute provides that health insurance issuers must submit to the Secretary and the applicable state justifications for unreasonable premium increases prior to the implementation of the increases. Section 2794(b)(2) also specifies that in plan years beginning in 2014, the Secretary, in conjunction with the states, shall monitor premium increases of health insurance coverage offered through an Exchange and outside of an Exchange. Section 2794 of the PHS Act does not, by its own terms, apply to grandfathered health insurance coverage or to self-funded plans. Regulations at 45 CFR 154.101(b) further limit the scope of review to small group and individual market coverage.

Section 1563 of the Affordable Care Act amended the Health Insurance Portability and Accountability Act of 1996 (HIPAA) enforcement provision that previously governed group health insurance coverage and non-federal governmental group health plans by expanding its scope to include individual health insurance coverage and by renumbering the provision as section 2723 of the PHS Act.

The preemption provisions of PHS Act section 2724(a)(1) apply so that the requirements of part A of title XXVII of the PHS Act are not to be “construed to supersede any provision of state law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with individual or group health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement” of part A of title XXVII of the PHS Act. Section 1321(d) of the Affordable Care Act applies the same preemption principle to the requirements of title I of the Affordable Care Act.⁵

B. Structure of the Final Rule

The regulations outlined in this final rule are codified in 45 CFR parts 144,

⁵ In addition, section 1252 of the Affordable Care Act provides that any standard or requirement adopted by a state pursuant to title I of the Affordable Care Act (or an amendment made by title I) must be applied uniformly to all health plans in each insurance market to which the standard and requirements apply. Sections 1302(e) and 1312(c) of the Affordable Care Act and the amendments to PHS Act sections 2701, 2702, and 2703 are all found in title I of the Affordable Care Act.

147, 150, 154, and 156. Part 144 outlines standards regarding the basis, scope, and applicability of 45 CFR parts 144 through 148. Part 147 outlines standards for health insurance issuers in the group and individuals markets related to health insurance reforms. Part 150 outlines standards regarding enforcement. Part 154 outlines standards for health insurance issuers in the small group and individual markets with respect to rate increase disclosure and review. Part 156 outlines standards for issuers of QHPs, including with respect to participation in an Exchange.

II. Provisions of the Proposed Rule and Analysis and Responses to Comments

HHS published standards under the statutory provisions discussed in section I.A. of the preamble in a November 26, 2012 **Federal Register** proposed rule entitled “Patient Protection and Affordable Care Act; Health Insurance Market Rules; Rate Review” (77 FR 70584). HHS received approximately 500 comment letters in response to the November 26, 2012 proposed rule. Commenters represented a wide variety of stakeholders, including states, tribal organizations, consumers, health insurance issuers, health care providers, employers, members of the public, and others. Additionally, HHS consulted with the NAIC through its Health Care Reform Actuarial (B) Working Group to define permissible age bands and consulted with and requested formal, written comments from tribal leaders and representatives about the provisions of this rule that impact tribes.

This section summarizes the provisions of the November 26, 2012 proposed rule and discusses and provides responses to the comments.

A. Part 144—Requirements Relating to Health Insurance Coverage

1. Subpart A—General Provisions (§ 144.101 and § 144.102)

HHS proposed technical changes in § 144.101 and § 144.102 to clarify enforcement of the health insurance reform requirements added by the Affordable Care Act and implemented in 45 CFR part 147. In § 144.102(c), HHS also proposed to clarify how to determine whether insurance coverage sold through associations is group or individual coverage under the PHS Act.

Comments received regarding HHS’s enforcement processes and regarding bona fide associations are addressed in other sections of the preamble that we deemed to be more relevant to the substance of the comments.

Comment: Several commenters supported the clarifications proposed in Part 144. In particular, commenters supported the clarifications concerning coverage sold through associations, noting that they would ensure such coverage complies with the market reform protections of the Affordable Care Act.

Response: Based on the comments received, we are finalizing the proposed provisions in § 144.101 and § 144.102 of the proposed rule without modification.

Comment: A few commenters asked for clarification about how to determine whether a group policy should be treated as large group or small group coverage for purposes of applying the PHS Act requirements when employer group size fluctuates between the definition of large employer and small employer.

Response: We intend to issue future guidance on counting employees for determining market size of a group health plan.

B. Part 147—Health Insurance Reform Requirements for the Group and Individual Health Insurance Markets

1. Fair Health Insurance Premiums (§ 147.102)

Section 147.102 of this final rule implements section 2701 the PHS Act, which specifies that the only rating factors that may be used to vary premium rates for health insurance coverage in the individual and small group markets are (1) Family size; (2) geographic rating area; (3) age (within a ratio of 3:1 for adults); and (4) tobacco use (within a ratio of 1.5:1).^{6,7}

Comment: We received several comments requesting flexibility in the application of section 2701. For example, some commenters suggested that we allow states and issuers to phase in the premium rating rules, specifically the 3:1 age rating factor. One commenter recommended issuer flexibility to transition to the new per-member-rating methodology in states without community rating. Further, some commenters noted that small businesses in Massachusetts are permitted to form

⁶ All non-grandfathered health insurance coverage offered through associations and through multiple employer welfare arrangements (MEWAs) is subject to the premium rating rules applicable to the appropriate market, as defined by PHS Act section 2791(e)(1), (3), and (5) (definitions of individual market, large group market, and small group market, respectively).

⁷ The age, tobacco use, and geographic rating factors are multiplicative. For example, the maximum variation for age and tobacco use is 4.5:1 (3 times 1.5:1). The family rate calculation could be additive or multiplicative, depending on whether a per-member- or family-tier-rating methodology is used, as discussed later in this preamble.

group health insurance purchasing cooperatives and receive premium discounts based on other factors that, while permitted by state law, were not explicitly included in the proposed rule.

Response: We do not have the legal authority to permit any rating factors in the final rule other than those explicitly permitted by section 2701 of the PHS Act. Further, we do not have the legal authority to provide for a phase-in of certain rating provisions such as the 3:1 age factor or the per-member-rating methodology.

a. Family Rating

In § 147.102(c)(1), we proposed that issuers develop premiums for family coverage by adding up the rate of each covered family member.⁸ Under this proposal, the rates of no more than the three oldest family members under age 21 would be taken into account in computing the family premium. There would be no cap on the number of family members age 21 and older whose per-member rates would be added into the family premium. We solicited comment on the number of family members that should be included in this rating cap, as well as the appropriate age limit for the cap.

We noted that rating based on specified family tiers, and other family rating practices that fail to apply the age and tobacco use factors proportionately to individual family members, would generally be impermissible pursuant to PHS Act section 2701(a)(4), which requires that any rating variation for age and tobacco use be apportioned to each family member's premium. However, in § 147.102(c)(2), we proposed flexibility for community rated states that do not permit rating based on age or tobacco use to require issuers to use a standard family-tier methodology with corresponding multipliers. We solicited comment on whether instead of permitting such flexibility, states with pure community rating should also use the per-member approach that would be used in states that allow rating for age and tobacco use.

We noted that health insurance issuers currently have flexibility in determining how to set rates for family policies and in defining which family members may be on the same policy, subject to federal and state laws requiring coverage of certain individuals. We solicited comment on

whether to set standards governing the minimum categories of family members that issuers must include in setting rates for family policies or to defer to states and issuers to make this determination. We also solicited comment on the types of individuals who are typically included under family coverage, including types of covered individuals who would not meet the classification of tax dependents under the Code.

Comment: Many commenters remarked on the proposed three-person rating cap for family members under age 21. Several commenters supported the cap, while some commenters expressed concern that it would increase rates for individuals and smaller families. Other commenters believed the cap would increase rates for larger families and requested that no more than two children under age 21 be rated for family coverage. Several commenters recommended clarifying that only the three oldest "dependent children" under age 21 would be taken into account in computing the family premium, so that policyholders and spousal dependents under age 21 would not be counted toward the three-person cap. Other commenters suggested raising the age limit for the cap to age 26, to better align with the rules regarding extension of dependent coverage under section 2714 of the PHS Act.

Response: The final rule maintains the cap at three persons, but clarifies that the cap applies only to the rates of no more than the three oldest "covered children" under age 21. This will mitigate premium increases for larger families accustomed to family tier rating structures and allow for more accurate rating of families with spouses under the age of 21. We maintain age 21 as the age limit for the cap given that the medical risk associated with individuals between age 21 and 26 is higher than the risk associated with individuals under the age of 21. Further, this approach maintains consistency with our approach to child and adult rates for purposes of applying the age rating factor.

Comment: Many commenters supported the proposed per-member-rating methodology and the flexibility for states with community rating to require health insurance issuers to use a standard family-tier methodology with corresponding multipliers. Some commenters suggested that all states should have the option to use a family-tier structure, while other commenters supported applying per-member rating uniformly across all states, including those with community rating. A few commenters requested clarification of

whether there is a limit on the number of family-tier categories permitted in community rated states.

Response: PHS Act section 2701(a)(4) compels per-member rating because the age and tobacco use factors must be attributable to individuals. Thus, only community rated states, which do not allow rating based on age or tobacco use, are able to implement family-tier-rating structures consistent with PHS Act section 2701(a)(4). Those states may require all health insurance issuers in the individual and small group markets to use a standard family-tier methodology with corresponding multipliers and will have the discretion to set the number of tiers in the family-tier structure. If a state has community rating but does not adopt a uniform family-tier structure (with corresponding multipliers), per-member rating will apply in that state.

Comment: Numerous commenters recommended that the final rule defer to the states (and to issuers if permitted by state law) on the categories of family members that must be included on a family policy, noting that state law typically provides the basis for defining familial status. Other commenters urged that HHS adopt a broad definition of family coverage that accounts for all family compositions, including opposite sex and same sex domestic partners; biological, adoptive, step, foster, and grandchildren (if under the care of a grandparent); children under guardianship arrangements; and any other child who would be considered a tax dependent under the Code.

Response: The final rule does not specify the minimum categories of family members that must be rated together on a family policy. We recognize that state laws differ with respect to marriage, adoption, and custody and believe that states are best positioned to make decisions regarding family coverage practices. Accordingly, states have the flexibility to require issuers to include specific types of individuals on a family policy and nothing in these final rules precludes this ability. We note that if an individual is not eligible for family coverage, he or she will be able to purchase individual coverage on a guaranteed availability basis.

b. Small Group Rating

In § 147.102(c)(3), we proposed that issuers in the small group market calculate rates for employee and dependent coverage on a per-member basis, and calculate the group premium by totaling the premiums attributable to each covered individual. States may require issuers to base small group

⁸ Under this approach, the issuer would charge the same per-member premium for all family members of the same age and tobacco use status. The issuer could not charge different rates for family members of the same age and tobacco use status based on their status, for example, as the policyholder, spouse, or dependent.

premiums on an average amount for each employee in the group, provided that the total group premium equals the premium that would be derived through the per-member-rating approach. Furthermore, employers would retain flexibility to decide how to allocate employer contributions to health coverage.

Comments: Many commenters supported applying per-member rating in the small group market, especially in the Small Business Health Options Program (SHOP) where an “employee choice” model would make composite rating difficult to administer. However, some commenters recommended allowing composite rating in the small group market outside the SHOP, and for “employer choice” coverage inside the SHOP where permitted, to minimize disruption in current issuer rating practices. Other comments raised concern that moving to per-member rating may increase premiums for older workers.

Response: The final rule directs that issuers use the per-member-rating methodology in the small group market. As discussed in the November 26, 2012 proposed rule, per-member rating assures compliance with the requirement that age and tobacco rating only be apportioned to an individual family member’s premium, enhances employee choice inside the SHOP, and promotes the accuracy of the risk adjustment methodology. Nothing in these final rules precludes a state from requiring issuers to offer (or a small employer from electing to offer) premiums based on average employee amounts where every employee in the group is charged the same premium. We note that the age bands, as implemented by the per-member-rating methodology, are only generally applicable to health insurance coverage in the individual and small group markets and are consistent with the Age Discrimination in Employment Act of 1967, 29 U.S.C. 621.

c. Geographic Rating

In § 147.102(b), we proposed that each state establish rating areas, which would be presumed adequate if they meet one of the following options: one rating area for the entire state, or no more than seven rating areas based on counties, three-digit zip codes (that is, areas in which all zip codes share the same first three digits), or metropolitan statistical areas (MSAs) and non-MSA geographic divisions.⁹ We proposed that states

would also be permitted to use other actuarially justified geographic divisions, or a number of rating areas greater than seven, with approval from HHS to ensure adequacy. In the event that states do not exercise the option to establish rating areas (or a state’s rating areas were determined to be inadequate), we proposed that the default would be a single rating area for the entire state or one of the other proposed geographic standards as determined by HHS in consultation with the state, local issuers, and other interested stakeholders.

The November 26, 2012 proposed rule requested comment on various aspects concerning the proposed geographic rating area standards, namely comments concerning the use of other geographic divisions or factors; the maximum number of rating areas within a state that would be presumed adequate; whether states with existing rating areas would have to make changes to conform to the proposed standards; whether to establish minimum geographic size and population requirements; and the appropriate schedules and procedures for states to modify their rating areas in the future.

Comment: While some commenters supported the proposed rating area standards, many expressed concern that HHS would not extend a presumption of adequacy if a state established more than seven rating areas. Commenters asserted that the threshold of seven rating areas may not be high enough to reflect actuarially justified differences in health care costs and utilization patterns, particularly in states with large and diverse health care markets, and noted that issuers today use more than seven rating areas in some states. These commenters recommended that states have flexibility to establish rating areas that reflect local market conditions and that minimize disruption. Others commenters were concerned about discrimination against rural, underserved, or high-cost populations.

Response: Following review of the comments submitted on this issue, we have determined that it is appropriate to modify the standards in § 147.102(b) to provide states with additional flexibility to establish rating areas under section 2701 of the PHS Act. The revised standards recognize that in many cases, states established rating areas after an open and transparent dialogue with stakeholders. Further, the revised

standards are intended to provide sufficient flexibility to states to establish rating areas that are responsive to local market conditions, while protecting consumers from potentially discriminatory rating practices.

Section 147.102(b)(3) of this final rule provides that a state’s rating areas must be based on one of the following geographic divisions: Counties, three-digit zip codes, or MSAs and non-MSAs, and will be presumed adequate if they meet either of the following conditions: (1) As of January 1, 2013, the state had established by law, rule, regulation, bulletin, or other executive action uniform geographic rating areas for the entire state; or (2) After January 1, 2013, the state establishes by law, rule, regulation, bulletin, or other executive action for the entire state no more geographic rating areas than the number of MSAs in the state plus one. Under these standards, geographic rating areas may be noncontiguous, but the area encompassed by a geographic rating area must be separate and distinct from areas encompassed by other geographic rating areas. As mentioned, rating areas must be based on counties, three-digit zip codes, or MSAs/non-MSAs. While we proposed the possibility that HHS might approve rating areas based on other existing geographic divisions, we have determined that these are the only geographic boundaries that would be feasible for purposes of implementing the premium tax credit under Code section 36B. We note that if a state had established geographic rating areas on or before January 1, 2013 that did not follow these geographic boundaries, the state would have an opportunity to adjust their proposed rating areas before the default rating area is applied.

We recognize that a greater number of rating areas than the number of MSAs in the state plus one may in some cases be actuarially justified. Therefore, states have the option pursuant to § 147.102(b)(4) of this final rule to seek approval from HHS of a greater number of rating areas as long as the areas are based on counties, three-digit zip codes, or MSAs and non-MSAs. We will review such state proposals to ensure they are actuarially justified and non-discriminatory as discussed below.

Comment: A few commenters requested that HHS specify the criteria it will use to assess the adequacy of state rating area proposals.

Response: As mentioned above, states may seek approval from HHS of a number of geographic rating areas that is greater than the number of MSAs in the state plus one, provided they are based on counties, three-digit zip codes,

⁹MSAs encompass at least one urban core with a population of at least 50,000 people, plus adjacent territory that has a high degree of social and

economic integration with the core. MSAs are always established along county boundaries, but may include counties from more than one state. The 367 MSAs in the United States include approximately one-third of the counties and 83 percent of the population of the United States.

or MSAs/non-MSAs. HHS will review the state proposals pursuant to the criteria described in § 147.102(b)(5) of this final rule. We will determine that a state's rating areas are adequate if they: (1) Are actuarially justified; (2) are not unfairly discriminatory; (3) reflect significant differences in health care unit costs by rating area; (4) lead to stability in rates over time; (5) apply uniformly to all health insurance issuers in a market; and (6) are based on one of the geographic boundaries described above. We believe these are the appropriate criteria to ensure state rating areas are adequate and not designed to isolate high-cost populations of the state.

Comment: One commenter requested clarification as to whether PHS Act section 2701 prevents a state from setting limits on the permissible variation in a rating area factor.

Response: Section 2701 of the PHS Act does not limit the amount by which rates may vary based on geography. Therefore, states and issuers may determine the appropriate variation for the geographic rating area factor. We note, however, that a rating area factor should be actuarially justified to ensure that individuals and employers are not charged excessively high premiums that render meaningless the guaranteed availability protections of section 2702 of the PHS Act.

Comment: A few commenters requested clarification of whether states must apply geographic rating areas uniformly across the individual and small group markets in a state. Other commenters asked whether rating areas may vary by product, noting that provider contracting varies geographically between Preferred Provider Organization (PPO) and Health Maintenance Organization (HMO) plans, and also between broad and narrow networks.

Response: PHS Act section 2701 does not prevent a state from establishing different rating areas for the individual or small group markets. However, to preserve the integrity of the single risk pool requirement, rating areas must apply uniformly within each market and may not vary by product. If a state merges its individual and small group markets pursuant to section 1312(c) of the Affordable Care Act, rating areas will apply uniformly to both the individual and small group markets in the state.

Comment: Several commenters suggested that HHS should not establish minimum geographic size and population standards for rating areas. Commenters noted that geographic differences in health care costs are

based on factors such as price, provider agreements, utilization patterns, and access to care and technology—not based on size or population. By contrast, a few commenters argued minimum geographic size and population requirements were necessary to ensure that rating areas are not excessive in small or sparsely populated states.

Response: This final rule does not establish minimum geographic size or population requirements. We believe the geographic standards and criteria set forth in this final rule provide the appropriate basis for ensuring that state rating areas are actuarially justified and non-discriminatory.

Comment: A few commenters argued that states should have the flexibility to align rating areas with service areas to prevent issuer “cherry-picking” of service areas. Commenters expressed concern that if issuers are able to choose to write business in only the lower cost areas within geographic rating areas, there could be reduced competition and consumer access issues.

Response: While the final rule does not require that geographic rating areas be aligned with service areas, we recommend that states consider aligning both rating and service areas. As we noted in the March 27, 2012 **Federal Register** final rule entitled “Patient Protection and Affordable Care Act; Establishment of Exchange and Qualified Health Plans; Exchange Standards for Employers” (77 FR 18309), herein referred to as the Exchange final rule, Exchanges have flexibility on several elements of the QHP certification process, including the contracting model, so that Exchanges can appropriately adjust to local market conditions and consumer needs. To the extent issuers operate within such uniform service areas or operate statewide, this policy would facilitate consumers' ability to compare health insurance premiums, promoting competition within the market. Furthermore, aligning rating areas with QHP service areas in the Exchange may simplify consumer understanding and Exchange administration of eligibility determinations for premium tax credits, which may be complex if QHP service areas are highly individualized.

Comment: Many commenters expressed concern that applying a single statewide rating area as the default standard would not be appropriate in many states. Commenters suggested various alternatives, such as defaulting to county, three-digit zip code, or MSA boundaries; defaulting to existing state or issuer rating areas; or defaulting to the rating areas of the state's EHB base benchmark plan.

Response: Although the November 26, 2012 proposed rule suggested flexibility in applying either a single statewide rating area or another geographic standard as the default, in response to comments, we are modifying § 147.102(b)(2) to specify that if a state does not establish rating areas (or does not provide information to CMS about such rating areas in accordance with the state reporting requirements discussed in section II.B.2. of the preamble), or a state's rating areas are determined to be inadequate, the default will be one rating area for each MSA in the state and one rating area for all other non-MSA portions of the state, as defined by the Office of Management and Budget (<http://www.census.gov/population/metro/data/def.html>). We believe MSA/non-MSA designations will sufficiently reflect actuarially justified differences in health care unit costs by geography and ensure rating areas are established timely, providing certainty to issuers. We encourage states to establish rating areas as soon as possible but not later than 30 days following publication of this final rule.

Comment: With respect to the process for updating state-established rating areas, several commenters suggested that states have flexibility to periodically review and modify their geographic rating areas (including default rating areas) as necessary or appropriate. Some commenters suggested that rating areas be reviewed on a regular basis, such as annually or biannually, while other commenters suggested less frequent reviews, subject to the discretion of the states. Several commenters noted that insurance products and rates are often developed a year or more in advance and emphasized that issuers must be given adequate time to incorporate any changes to rating areas into their pricing.

Response: As discussed in section II.B.2. of the preamble, § 147.103 of this final rule provides for the Secretary to issue guidance that will establish a process and timeline for states to update their rating areas (including default rating areas). HHS anticipates this process will provide sufficient notice to health insurance issuers in advance of state rate filing deadlines.

d. Age Rating

In 147.102(a)(1)(iii), we proposed that the premium rate charged by a health insurance issuer for non-grandfathered health insurance coverage in the individual or small group market may vary by age, except that such rate may not vary by more than 3:1 for adults, as set forth by the statute. We proposed to

define adults as individuals age 21 and older for purposes of this provision. For individuals under age 21, we proposed that rates must be actuarially justified based on a standard population.

Further, we proposed that an enrollee's age for rating purposes be determined at the time of policy issuance and renewal and requested comment on whether other measurement points, such as birthdays, were appropriate.

After consulting with the NAIC, we proposed the following standard age bands for use in all states and markets subject to section 2701 of the PHS Act:

- Children: A single age band for children ages 0 through 20.
- Adults: One-year age bands for adults ages 21 through 63.
- Older adults: A single age band for adults ages 64 and older.

We solicited comment on the proposed age bands, including comment on whether single or multiple age bands for children were appropriate.

Finally, we proposed that health insurance issuers in a state and market use a uniform age rating curve established by the state, specifying the relative distribution of rates across all age bands. We proposed an HHS standard default age curve that would apply in both the individual and small group markets in states that do not exercise the option to establish their own age curve. We requested comment on the default age rating curve, including comment on the premium impact of the transition from the child age curve to the adult age curve.

Comment: Many commenters supported applying the maximum 3:1 age rating factor to adults defined as individuals age 21 and older. Some commenters, however, recommended defining the adult age as beginning at age 19 to better align with the definition of "pediatric services" in the November 26, 2012 **Federal Register** proposed rule entitled "Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation" (77 FR 70644), herein referred to as the EHB/AV/Accreditation proposed rule. Other commenters recommended that adult rating begin at age 26, consistent with the rules regarding dependent coverage of children to age 26 under section 2714 of the PHS Act.¹⁰ Several commenters suggested we allow issuers to develop rates for individuals age 65 and older outside of the 3:1 age rating factor due to the higher health care costs associated with this population.

Response: We are finalizing the proposed requirement that the

maximum 3:1 ratio for age rating applies to adults age 21 and older. PHS Act section 2701(a)(1)(A)(iii) provides that age rating with respect to adults must be consistent with section 2707(c) relating to child-only plans available to individuals up to age 21. Accordingly, the 3:1 age rating factor applies to all individuals age 21 and older, including those who may be eligible for Medicare based on age. The 3:1 age factor ratio does not apply to individuals under age 21.

Comment: Nearly all commenters expressed support for the proposal to establish single-year age bands for adults age 21 through 63. However, some commenters suggested that multiple age bands for children were necessary to reflect the fact that claims costs for children vary by age, particularly children age 0 to 1, who have much higher health care costs than older children.

Response: The final rule maintains a single age band for children to keep rates level between ages 0 through 1 and ages 2 through 20. This will avoid higher premiums for newborns and provide for easier price comparisons between different plans. A single band for children also simplifies and promotes efficiency of the risk adjustment methodology.

Comment: Most commenters supported determining an enrollee's age for rating purposes once a year at the time of policy issuance or renewal. Commenters stated that such annual determination is generally consistent with current issuer rating practices, helps enrollees to understand and plan for rate increases, and promotes administrative efficiency for issuers. In instances where a family member is added to a family policy or an employee is added to a group health plan outside of policy issuance or renewal, a few commenters requested issuer flexibility to apply an age rating factor based on the new enrollee's age at the time of enrollment.

Response: Based on the comments received, we are finalizing the provision that for rating purposes an enrollee's age be determined at the time of policy issuance or renewal. We clarify that for individuals who are added to the plan or coverage other than on the date of policy issuance or renewal, the enrollee's age may be determined as of the date such individuals are added or enrolled in the coverage.

Comment: A few commenters requested state flexibility to use different age-band structures, such as five-year bands in the small group market. One commenter specifically recommended that states operating their

own risk adjustment programs should have flexibility to establish age bands and to determine whether they must be standardized across a market. Other commenters urged HHS to apply the same age-band structure to both the individual and small group markets to align more closely with per-member rating, minimize rate disruption when individuals move between the two markets, and facilitate states' ability to merge the individual and small group markets into a single risk pool if they determine it appropriate.

Response: The uniform age bands in this final rule apply in all states and markets subject to section 2701 of the PHS Act: the individual and small group markets in all states, and the large group market in states that, beginning in 2017, permit health insurance issuers in the large group market to offer QHPs in such market through an Exchange.

Applying age bands consistently nationwide simplifies identification of the second lowest cost silver plan for calculation of the premium tax credit under Code section 36B. As indicated below, states are welcome to establish their own age rating curve provided the curve incorporates the uniform age bands. A state may establish separate age curves for the individual and small group markets.

Comment: With respect to HHS's proposed default standard age curve, several commenters recommended smoothing the age curve to avoid a significant premium differential between the child age curve at age 20 and the adult age curve at age 21, while another commenter recommended smoothing the age curve for older adults. One commenter suggested that issuers should have flexibility to set their own age curves. Another commenter supported the default age rating curve as proposed, suggesting that it will enhance the transparency, predictability, and accuracy of risk adjustment. A few commenters urged that HHS not make frequent changes to the default age curve and that issuers be provided sufficient time to respond to any updates.

Response: As we stated in the November 26, 2012 proposed rule, the 0.635 age rating factor for children age 0 through 20 is supported by HHS's analysis of data available through HealthCare.gov and an examination of the large group insurance market. Although the shift from the child age curve to the adult age curve could result in a premium differential that is not reflected in current issuer rating practices, we do not believe the differential will result in a significant financial burden on consumers, given

¹⁰ 45 CFR 147.120.

the low premiums for individuals in these age groups, as well as the relative premium stability from ages 21 through 30.

HHS will establish in guidance a default age rating curve that will apply in both the individual and small group markets in states that do not exercise the option to establish their own age curve (or that do not provide information to CMS about their age curve in accordance with the state reporting requirements discussed in section II.B.2. of the preamble). We intend to adopt in guidance the default age curve as proposed in the November 26, 2012 proposed rule for states that allow a maximum 3:1 ratio for age rating. For states that adopt narrower ratios for age rating, the default age curve established by HHS would take into account the permissible rating variation for age under state law. We intend to revise the default age curve periodically, but no more frequently than annually, to reflect market patterns in the individual and small group markets following implementation of the 2014 market reforms.

Comment: One commenter requested clarification of whether issuers may establish their own, actuarially justified child age factor based on a standard population, rather than using the 0.635 child age factor in the HHS default standard age curve.

Response: Health insurance issuers within a market and state must use the uniform age rating curve established by each state or the HHS default standard age curve in instances where a state does not establish a uniform age curve, specifying the relative distribution of rates for all age bands, including the child age band. As discussed in the November 26, 2012 proposed rule, the age factor associated with the child age band must be actuarially justified based on a standard population.

Comment: A few commenters asked HHS to clarify how age rating applies to child-only plans. For example, some commenters requested clarification that the child age band and age curve apply only to dependent children on family policies, not to children enrolled in child-only plans.

Response: The child age band and child age curve apply to child-only plans in the same manner that they apply to all other individual and small group market coverage. Thus, for example, a 10-year-old child would be charged the same rate based on age whether the child was a dependent on a family policy or enrolled in a child-only plan.

e. Tobacco Rating

In § 147.102(a)(1)(iv), we proposed that the premium rate charged by a health insurance issuer for non-grandfathered health insurance coverage offered in the individual or small group market may vary for tobacco use, except that such rate may not vary by more than 1.5:1, as set forth by the statute. States or issuers would have flexibility within these limits to determine the appropriate tobacco rating factor for different age groups (for example, younger enrollees could be charged a lower tobacco use factor than older enrollees provided the tobacco use factor does not exceed 1.5:1 for any age group).

Further, we proposed to coordinate application of the tobacco rating rules of PHS Act section 2701 with the nondiscrimination and wellness program rules of PHS Act section 2705. Specifically, we proposed that a health insurance issuer in the small group market would be required to offer a tobacco user the opportunity to avoid paying the full amount of the tobacco rating factor permitted under PHS Act section 2701 if he or she participates in a wellness program meeting the standards of section 2705 of the PHS Act and its implementing regulations.¹¹ We solicited comment on this proposal and on whether and how the same wellness incentives promoting tobacco cessation could apply in the individual market.

We proposed that the definition of “tobacco use” for purposes of section 2701 be consistent with the approach taken with respect to health-contingent wellness programs designed to prevent or reduce tobacco use under section 2705. We noted that a common definition of “tobacco use” does not currently exist among the states, resulting in wide variation in how health insurance issuers define and assess tobacco use in insurance applications. We solicited comment on how to define “tobacco use” for purposes of both section 2701 and section 2705 and suggested several possible approaches, such as reliance on

¹¹ The Departments of HHS, Labor, and the Treasury published proposed rules under PHS Act section 2705 entitled “Incentives for Nondiscriminatory Wellness Programs in Group Health Plans” in the November 26, 2012 *Federal Register* (77 FR 70620). The rules proposed that the additional increase in the size of the reward for wellness programs designed to prevent or reduce tobacco use would not be limited to the small group market, to provide consistency across markets and to provide large group, self-insured, and grandfathered employment-based plans the same additional flexibility to promote tobacco-free workforces as small, insured non-grandfathered health plans.

self-reporting, a defined amount of tobacco use within a specified look-back period, regular tobacco use, or tobacco use of sufficient frequency so as to be addicted to nicotine. We also solicited comment on use of the single streamlined application under 45 CFR 155.405 to collect information on tobacco use.

Comments: Numerous commenters supported establishing a clear definition and standard application questions to determine tobacco use. Commenters stated that in defining tobacco use, it would be important for HHS to specify the types of tobacco products that would be included, establish a minimum frequency of usage, define the appropriate look-back period, and clarify permissible assessment methods. For example, some commenters recommended a broad definition that includes any form of tobacco use in the past 12 months, while other commenters suggested considering only the most common types of tobacco products used within a 30-day look-back period. Additionally, some commenters recommended relying on self-reporting, while other commenters sought flexibility for issuers to use additional methods to verify accuracy and prevent fraud, such as cotinine testing, attestations, health assessments, and physician affidavits. Several commenters urged HHS to consult with experts and use planned consumer testing of the single streamlined application to develop precise and narrow language and questions about tobacco use. A few commenters representing tribal organizations suggested that a uniform definition of tobacco use include an express exemption for religious and ceremonial uses. One commenter suggested that states have flexibility to determine what constitutes tobacco use.

Response: The National Health Interview Survey, administered by the Centers for Disease Control and Prevention, asks survey respondents if they use tobacco products “every day, some days, or not at all?”¹² In this final rule, we establish a definition of “tobacco use” that is based on the National Health Interview Survey, while setting forth the meaning of “some days” to ensure clarity for issuers and consumers. Specifically, for purposes of this final rule, we define “tobacco use” as use of tobacco on average of four or more times per week within no longer than the past six months. Further,

¹² Centers for Disease Control and Prevention, *Cigarette Smoking Among Adults—United States, 1992, and Changes in the Definition of Current Cigarette Smoking*, *MMWR Weekly* 43(19): 342–346, May 20, 1994.

tobacco use must be defined in terms of when a tobacco product was last used. Tobacco includes all tobacco products. However, religious or ceremonial uses of tobacco (for example, by American Indians and Alaska Natives) are specifically exempt under this final rule. This approach establishes a minimum standard to assure consistency in the individual and small group health insurance markets and simplifies administration of the tobacco rating factor. For example, an individual could be asked the following two questions about tobacco use: (1) Within the past six months, have you used tobacco regularly (four or more times per week on average excluding religious or ceremonial uses)? (2) If yes, when was the last time you used tobacco regularly? Issuers will have flexibility within the federal definition and as permitted by applicable state law to shorten the applicable period of time from the last regular use of tobacco. Because “four or more” as well as “six months” are federal thresholds, states have the ability to define both the frequency of use per week and the look-back period in ways that are more consumer protective (that is, a frequency of more than four times per week and a look-back period of less than six months). This definition is transitional. We intend to consult with experts, use experience with the above definition, and study the interaction effects with the permanent risk adjustment program to develop a more evidenced-based definition of tobacco use through future rulemaking or guidance. We also intend to conduct consumer testing of language and questions about tobacco use.

Comment: Several commenters requested additional consequences for individuals who fail to disclose tobacco use during the application process, such as allowing issuers to collect additional premiums or other penalties, to rescind the policy in the case of intentional misrepresentation or fraud, and to determine the individual to be ineligible for certain enrollment periods. In addition, commenters suggested there should be clear and prominent warnings to applicants about the consequences of failing to answer questions about tobacco use truthfully.

Response: If an enrollee is found to have reported false or incorrect information about their tobacco use, the issuer may retroactively apply the appropriate tobacco use rating factor to the enrollee’s premium as if the correct information had been accurately reported from the beginning of the plan year. However, an issuer must not rescind the coverage on this basis.

Tobacco use is not a material fact for which an issuer may rescind coverage if there is a misrepresentation because these regulations already provide the remedy of recouping the tobacco premium surcharge that should have been paid since the beginning of the plan or policy year. Accordingly, it is the view of the Department of HHS, Labor, and the Treasury (which share interpretative jurisdiction over section 2712 of the PHS Act) that this remedy of recoupment renders any misrepresentation with regard to tobacco use no longer a “material” fact for purposes of rescission under PHS Act section 2712 and its implementing regulations.¹³ Additionally, under guaranteed availability of coverage rules, an issuer may not deny an enrollee or their covered dependents an enrollment period described in this final rule because an enrollee provided false or incorrect information about their tobacco use.

Comments: Several commenters remarked on the proposed rules concerning tobacco rating and wellness programs in the small group market. Some commenters objected to the rules, arguing that participation in a tobacco cessation program does not necessarily result in an actual reduction in the specific financial risk associated with tobacco use, and that issuers need to be able to rate for the higher expected claims costs of tobacco users. Several other commenters supported the proposed link between tobacco rating and wellness programs, noting that tobacco cessation programs are more effective in addressing tobacco use than a premium surcharge, and suggesting that the rules should be expanded to include participation in a broader array of tobacco cessation programs offered outside of one’s workplace, including in the individual market.

Response: We finalize our proposal that a health insurance issuer in the small group market may impose the tobacco rating factor under section 2701 only in connection with a wellness program meeting the requirements under section 2705, allowing a tobacco user the opportunity to avoid paying the full amount of the tobacco rating factor by participating in a wellness program meeting the standards of section 2705(j) and its implementing regulations. We note that wellness rules already apply in the group market. Additionally, the use of tobacco cessation programs may help alleviate underreporting of tobacco use. Pursuant to section 2701(a)(5) of the PHS Act, these rules will apply to

coverage offered in the large group market in a state that, beginning in 2017, allows health insurance issuers to offer QHPs in such market through an Exchange.

Comment: Some commenters supported the proposal allowing issuers to vary tobacco rating by age. Other commenters suggested that tobacco rating should apply only with respect to individuals age 18 and older, the age at which people can begin to legally use tobacco products in most states. Other commenters expressed concern that tobacco rating would disproportionately impact low-income populations and recommended that HHS prohibit tobacco rating altogether.

Response: PHS Act section 2701 permits rating for tobacco use within a ratio of 1.5:1. While we do not have authority to prohibit the imposition of the 1.5:1 tobacco rating factor, we agree that tobacco rating should be limited to legal use of tobacco products under federal and state law, which generally is limited to those 18 years and older. We clarify our interpretation in the final rule. Consistent with these rules and subject to applicable state law, issuers will have the flexibility to vary tobacco rating by age, provided the tobacco use factor does not exceed 1.5:1 for any age band.

Comment: Several commenters sought clarification that states may require a narrower ratio than 1.5:1 for tobacco use or prohibit tobacco rating altogether.

Response: Pursuant to section 2724(a)(1) of the PHS Act, a state law with respect to health insurance issuers is not preempted unless it prevents the application of a federal requirement. Section 2701 provides that the premium rate charged by a health insurance issuer in the individual or small group market cannot vary for tobacco use by more than 1.5:1. Therefore, a state law that prescribes a narrower ratio (for example, 1.25:1) or prohibits varying rates for tobacco use altogether would not be preempted, since such law would not prevent the application of section 2701. Because states may generally impose requirements on health insurance issuers that are more consumer protective than those imposed by federal law, the language in proposed § 147.102(a)(1)(iv) providing that states may use narrower tobacco rating factors is unnecessary, and we remove it from the final rule. (We make parallel revisions in proposed § 147.102(a)(1)(iii) with respect to state laws that use narrower age rating factors).

2. State Reporting (§ 147.103)

In various provisions throughout proposed § 147.102, we proposed that

¹³ 26 CFR 54.9815–2712T, 29 CFR 2590.715–2712, and 45 CFR 147.128.

no later than 30 days after publication of the final rule, states submit certain rating information to CMS generally to support the accuracy of the risk adjustment methodology. This included information about the following, as applicable:

- The use of a narrower age rating ratio than 3:1 for adults age 21 and older.
- The use of a narrower tobacco rating ratio than 1.5:1 for individuals who use tobacco.
- State-established rating areas.
- State-established age rating curves.
- In states with community rating, the use of uniform family tiers and corresponding multipliers.
- A requirement that premiums be based on average enrollee amounts in the small group market.

In addition, in § 156.80(c), we proposed that a state inform CMS of its decision to merge the individual and small group markets in a state into a single risk pool.

We received no comments about the proposed reporting process. Accordingly, we are finalizing the state reporting process as proposed. However, for organization and clarity, we are consolidating these reporting requirements in a new § 147.103 of this final rule. Section 147.103(a) provides that for the 2014 plan or policy year, states will submit information no later than 30 days following publication of the final rule, in a form and manner specified by the Secretary. Section 147.103(b) provides for the Secretary to issue future guidance that would establish a process and timeline for states to submit information for plan or policy years after 2014 (or for updating a state standard that applies in 2014). As described in § 156.80(c), states will follow the same process with respect to a state decision to merge the individual and small group markets in a state into a single risk pool.

3. Guaranteed Availability of Coverage (§ 147.104)

In § 147.104, we proposed that a health insurance issuer offering health insurance coverage in the individual or group market in a state must offer to any individual or employer in the state all of the issuer's products that are approved for sale in the applicable market, and accept any individual or employer that applies for those products.¹⁴ Consistent with other

¹⁴ Other federal laws may restrict the health insurance coverage products available to certain individuals. For example, individuals must meet certain requirements related to residency, citizenship/immigration status, and non-incarceration in order to buy QHPs through an Exchange (45 CFR 155.305(a)).

consumer protection rules under the Affordable Care Act, we proposed that this requirement include non-grandfathered closed blocks of business and solicited comment on our proposal.

We also proposed that issuers establish enrollment periods during which they would allow individuals and employers to purchase health insurance coverage. We proposed to align the initial and annual open enrollment periods outside the Exchanges with those inside the Exchanges. Specifically, we proposed a continuous open enrollment period in the group market and a fixed open enrollment period in the individual market based on a calendar policy year, consistent with the Exchange and SHOP standards outlined in 45 CFR 155.410 and 155.725. Effective dates of coverage would also follow those in the Exchange and SHOP. We solicited comment on how to address the open enrollment needs of individual market enrollees whose coverage renews on a non-calendar year basis.

We proposed that issuers in the individual and group markets establish special enrollment periods for individuals and plan participants and beneficiaries to enroll in coverage outside of the annual open enrollment period as a result of qualifying events triggering eligibility for COBRA continuation coverage under section 603 of ERISA.¹⁵ These special enrollment periods are in addition to those in section 2704(f) of the PHS Act and other federal law.

We proposed that a participant, beneficiary, or enrollee would have 30 calendar days from the date of a qualifying event (generally consistent with the HIPAA standard) to request special enrollment, but invited comment on whether to establish a longer election period, such as 60 calendar days (generally consistent with the Exchange standard). We proposed special enrollment period effective dates that followed the effective dates of coverage for QHP special enrollment periods in § 155.420(b). We noted that a

¹⁵ For employees, COBRA events include a loss of coverage due to voluntary or involuntary termination of employment for reasons other than gross misconduct and reduction in the number of hours of employment. For spouses of covered employees, these events include a loss of coverage due to reasons that would make the employee eligible for COBRA, the employee's becoming entitled to Medicare, divorce or legal separation of the covered employee, and death of the covered employee. For children of covered employees, these events include a loss of coverage due to reasons that would make the employee eligible for COBRA, the employee's becoming entitled to Medicare, divorce or legal separation of the covered employee, death of the covered employee, and loss of dependent child status under plan rules.

notice of special enrollment rights is currently required to be provided to group health plan participants and beneficiaries under HIPAA and solicited comment on whether issuers in the individual market should provide a similar notice to individual market enrollees.

Additionally, we proposed rules governing the circumstances under which issuers are permitted to deny coverage to individuals and employers. These rules would allow issuers to deny coverage to an employer whose eligible individuals do not live, work, or reside in the service area of a network plan (or to an individual who does not live or reside in the service area of a network plan) and in certain situations involving limited network capacity and limited financial capacity.

We also proposed that issuers in the small group market would be permitted to require small employers to satisfy minimum contribution or group participation requirements, to the extent allowed by state law or, in the case of a QHP offered in the SHOP, as permitted by § 156.285(c), and to decline to offer coverage if these standards were not met. This policy was intended to prevent adverse selection. Specifically, we were concerned that a small employer could take advantage of the continuous open enrollment opportunity under the proposed rule to wait to purchase a group policy.

We also addressed the issue of whether there could be an exception from the guaranteed availability requirements allowing coverage sold through bona fide associations to be limited to members of the association. We contrasted the existing provisions in section 2703(b) (which retained a guaranteed renewability exception permitting coverage to be limited to members of a bona fide association) with the provisions in section 2702 (where the exception had not been included in the statute), and proposed that there was no basis for an exception from the guaranteed availability requirement for coverage sold through bona fide associations. We invited comment, however, on whether and how a transition or exception process for bona fide association coverage could be structured to minimize disruption.

To ensure consistency in the marketing of health plans inside and outside of the Exchange and to minimize adverse selection, we proposed to extend to the entire health insurance market the Exchange marketing standard applicable to QHPs under § 156.225. This standard requires that an issuer comply with state marketing standards and not employ

marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs in health insurance coverage.

Finally, we solicited comment about how to prevent potential gaming of guaranteed availability rights and about strategies to minimize the risk of adverse selection.

Comment: Several commenters asked that the term “offer” in section 2702 be interpreted to mean “actively marketed,” so that issuers would not be required to reopen closed blocks of business. Commenters expressed concern about having to develop enrollment materials for closed products. In addition, some commenters were concerned that this requirement would make it difficult for issuers to bring existing products into compliance with the Affordable Care Act in a manner that minimizes consumer confusion, and ultimately prompt some issuers to terminate closed products. Some commenters argued that the requirement is not necessary because starting in 2014, individuals will have choices beyond closed blocks, alleviating many of the concerns about closed blocks in today’s market. Other commenters requested flexibility for states to determine the best policy for addressing closed blocks.

Response: Section 2702 provides that each health insurance issuer that offers health insurance coverage in the group or individual market in a state must accept every employer or individual in the state that applies for such coverage. We have interpreted the term “offer” as used throughout the title XXVII requirements of the PHS Act as added by the Affordable Care Act (which apply to “a health insurance issuer offering health insurance coverage”) to refer to an issuer offering both new as well as existing coverage. Accordingly, this final rule does not interpret the term “offer” in section 2702 to mean “actively marketing.” We note that while this provision requires an issuer to accept any individual or employer that applies for coverage, it does not require closed blocks to be actively marketed. Furthermore, we clarify that only non-grandfathered plans are subject to guaranteed availability.

Comment: Several commenters remarked on the application of the guaranteed availability requirements to coverage sold through bona fide associations.

Response: We refer readers to section II.F.2. of the preamble for discussion of this issue.

Comment: We received a few comments about the proposal that

issuers would be allowed to decline to offer coverage to small employers for failure to satisfy minimum contribution or group participation requirements under state law or the SHOP standards. Several commenters expressed support for the policy and recommended extending it to the large group market. One commenter emphasized that minimum participation and contribution standards must be reasonable and not burdensome to the point that small employers are discouraged from offering coverage.

Response: Upon further consideration of this issue, we have determined that small employers cannot be denied guaranteed availability of coverage for failure to satisfy minimum participation or contribution requirements. As in the case of the bona fide association exception discussed above, while Congress left in place an exception for failure to meet contribution or participation requirements under the guaranteed renewability requirement in section 2703(b), it provided no such exception from the guaranteed availability requirement in section 2702. To the contrary, language in the guaranteed availability provision for group health plans that was in place before the Affordable Care Act was not included in section 2702. Accordingly, the proposed approach would conflict with the guaranteed availability provisions in section 2702 of the PHS Act. Moreover, permitting issuers to deny coverage altogether to a small employer with between 50 and 100 employees based on a failure to meet minimum participation or contribution requirements could subject such employer to a shared responsibility payment under section 4980H of the Code for a failure to offer coverage to its employees.

While section 2702 contains no exception to guaranteed availability based on a failure to meet contribution or minimum participation requirements, section 2702(b)(1) permits an issuer to limit enrollment in coverage to open and special enrollment periods. Under our authority in section 2702(b)(3) to define “open enrollment periods,” we are providing in this final rule that, in the case of a small employer that fails to meet contribution or minimum participation requirements, an issuer may limit its offering of coverage to an annual open enrollment period, which we set forth in this final rule as the period beginning November 15 and extending through December 15 of each year. As such, the group market will have continuous open enrollment, except for small employers that fail to meet contribution or minimum

participation requirements, for which the enrollment period may be limited to the annual enrollment period described above, from November 15 through December 15. This approach addresses concerns about adverse selection in a manner that is consistent with the statutory provisions. We do not extend this provision to the large group market because large employers generally do not present the same adverse selection risk as small employers.

Comment: Several commenters voiced concerns about the potential for individuals with histories of non-payment to game guaranteed availability. Some commenters suggested that we take action to both prevent individuals with histories of non-payment from taking advantage of guaranteed availability and to prevent individuals from dropping in and out of coverage based on medical need. Other commenters, including the NAIC, recommended that states have the flexibility to develop an environment that will discourage adverse selection and suggested that there are a number of tools available to states to limit adverse selection. Some of the tools identified by commenters included: (1) Allowing issuers to require pre-payment of premiums each month; (2) allowing issuers to require payment of all outstanding premiums before enrollees can re-enroll in coverage after termination due to non-payment of premiums; (3) allowing late enrollment penalties or surcharges (similar to those in Medicare Parts B and D); (4) allowing issuers to establish waiting periods or delayed effective dates of coverage; (5) allowing issuers to offset claims payments by the amount of any owed premiums; (6) allowing issuers to prohibit individuals who have canceled coverage or failed to renew from enrolling until the second open enrollment period after their coverage ceased (unless they replace coverage with other creditable coverage); (7) restricting product availability (for example, to a catastrophic, bronze, or silver level plan) outside of enrollment periods to prevent high-risk individuals from enrolling in more generous coverage when medical needs arise; and (8) allowing individuals to move up one metal level each year through the Exchange shopping portal.

Response: We appreciate the various strategies suggested by commenters and agree that states have flexibility to implement policies to address adverse selection. We encourage states to consider approaches to discourage adverse selection while ensuring consumers’ guaranteed availability rights are protected since state policies

that limit guaranteed availability are preempted by this law. We intend to address permissible strategies to limit adverse selection in future guidance.

Comment: Several commenters suggested that the language in proposed § 147.104(e), which prohibits marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs in health insurance coverage, be broadened to apply to all forms of discrimination prohibited by the March 27, 2012 Exchange final rule and section 1557 of the Affordable Care Act, such as discrimination based on age, disability, race, ethnicity, gender, and sexual orientation, not just discrimination against individuals with significant or high cost health care needs. One commenter urged HHS to provide guidance about marketing practices and benefit designs that would be considered discriminatory under this standard. Another commenter asked HHS to remind states of their responsibility to monitor issuer marketing practices.

Response: As noted in the November 26, 2012 proposed rule, discriminatory marketing practices or benefit designs represent a failure by issuers to comply with the guaranteed availability requirements. In response to comments, we revise § 147.104(e) of this final rule to make clear that a health insurance issuer and its officials, employees, agents and representatives must not employ marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals in health insurance coverage based on these factors. This standard will ensure consistency with the prohibition on discrimination with respect to EHB in § 156.125, the non-discrimination standards applicable to QHPs under § 156.200(e), and the marketing standards in § 156.225.

Comment: Numerous commenters expressed support for aligning open enrollment periods inside and outside of the Exchange to promote consistency between markets and minimize the potential for adverse selection. However, some commenters were concerned that establishing open enrollment periods and effective dates of coverage in the individual market based on a calendar policy year would not align with many individual policies, which are currently offered on a non-calendar-year basis. Commenters suggested various approaches to resolving the transition, such as providing to individuals whose coverage renews mid-2014 a one-time special enrollment period to purchase

coverage that complies with 2014 market reform provisions; requiring individuals whose coverage begins on a date other than January 1 to re-enroll during the next open enrollment period; and allowing a rating adjustment for individual health insurance policies covering less than a full year to reflect that fact that enrollees will have less than 12 months to reach the annual deductible. Other commenters recommended that states have flexibility to set their open enrollment periods and effective dates.

Response: We maintain the proposed open enrollment periods in § 147.104(b)(1) of this final rule. We believe that consistent open enrollment periods will help minimize adverse selection between the Exchanges and the outside market, reduce consumer confusion, and allow issuer marketing to be focused on a single enrollment campaign. Rolling open enrollment periods with individual-specific dates, by contrast, would add complexity for families and increase risk selection. We agree with commenters that a one-time open enrollment period will allow individuals with non-calendar year plans to transition to a calendar-year plan upon their renewal date in 2014 and provide for such enrollment opportunity as discussed below. States may wish to consider other strategies to ease the transition, such as directing issuers to pro-rate premiums for policies covering less than a full year, among other transitional measures.

Comment: One commenter noted that his state currently allows individuals to purchase individual health insurance coverage on a guarantee-issue basis at any time during the year and requested clarification as to whether state standards would be preempted by the federal standards. Another commenter urged HHS to ensure that issuers apply consistent rules when offering coverage outside of open enrollment. The commenter expressed concern that some issuers would attempt to employ selective marketing practices designed to attract low-risk individuals (for example, for enrollment in catastrophic plans).

Response: Section 2724(a)(1) of the PHS Act provides that nothing in part A or part C of title XXVII of the PHS Act should be construed to preempt any state law that does not prevent the application of a federal requirement. Therefore, these final rules do not preclude the application of stronger consumer protections provided by state law including, for example, open enrollment periods that allow individuals to purchase coverage more frequently than the federal standards.

We note that if a health insurance issuer in the individual market allows for enrollment outside of an open or special enrollment period, the issuer must still comply with all of the individual market provisions of the PHS Act, including the prohibition against pre-existing condition exclusions and the prohibition against discrimination based on health status. An issuer cannot selectively offer enrollment in a plan to individuals outside of open or special enrollment periods in a manner that discriminates among individuals based on a pre-existing medical condition or health status.

Comment: A number of commenters recommended providing additional special enrollment periods to those described in proposed § 147.104(b)(2), which incorporated the special enrollment periods for COBRA qualifying events under section 603 of ERISA. Specifically, several commenters recommended adding the guaranteed renewability exceptions in § 147.106(b) through (d), for which an enrollee experiences a loss in coverage through no fault of their own, as explicit triggers permitting special enrollment. A few commenters recommended including special enrollment periods for pregnancy. One commenter suggested providing a special enrollment period when individuals permanently move into the issuer's service area, consistent with the Exchange standard.

Response: We agree that it is appropriate to provide additional enrollment opportunities for individuals experiencing certain significant life changes, including several of those suggested by commenters. To provide consistency across the individual market, we believe these events should follow the special enrollment periods for individuals seeking coverage through the Exchanges, as described in the March 27, 2012 Exchange final rule. Because PHS Act section 2702 provides for "special" enrollment periods for "qualifying events" under ERISA, we are providing for additional "limited" open enrollment periods in the individual market under our authority in PHS Act section 2702(b)(3) to promulgate regulations with respect to open enrollment periods. These limited open enrollment periods are equivalent to special enrollment periods in terms of the limited scope and nature of their applicability, and coverage obtained during such limited open enrollment period will become effective consistent with the dates described in § 155.420(b).

Accordingly, in § 147.104(b)(2) of this final rule, we cross-reference the enrollment periods in § 155.420(d) of the March 27, 2012 Exchange final rule

(except as discussed below). Thus, under § 147.104(b)(2), limited open enrollment periods are triggered in the individual market by the following events:

- An individual and any dependents losing minimum essential coverage.
- An individual gaining or becoming a dependent through marriage, birth, adoption, or placement for adoption.
- An individual experiencing an error in enrollment.
- An individual adequately demonstrating that the plan or issuer substantially violated a material provision of the contract in which he or she is enrolled.
- An individual becoming newly eligible or newly ineligible for advance payments of the premium tax credit or experiencing a change in eligibility for cost-sharing reductions.
- New coverage becoming available to an individual or enrollee as a result of a permanent move.

Additionally, the final rule provides that an individual enrolled in a non-calendar year plan is entitled to a limited open enrollment period beginning 30 calendar days prior to the individual's policy renewal date outside the open enrollment period for 2014. This one-time limited open enrollment period will allow individuals with non-calendar year policies in the individual market to transition to a calendar year policy that complies with 2014 market reform requirements of the Affordable Care Act.

We clarify that loss of minimum essential coverage triggering a limited open enrollment period does not include failure to pay premiums on a timely basis, including COBRA premiums prior to expiration of COBRA coverage, or situations allowing for a rescission as specified in 45 CFR 147.128.

We also note that these limited open enrollment periods do not include the events described in paragraphs (d)(3), (d)(8), or (d)(9) of § 155.420 of the March 27, 2012 Exchange final rule (concerning citizenship status, Indians, and exceptional circumstances). The enrollment periods for events described in paragraphs (d)(3) and (d)(8) are related to specific Exchange eligibility criteria and therefore are not appropriate for the broader market. The enrollment periods in paragraph (d)(9) arising from exceptional circumstances are not similar enough to those discussed in the November 26, 2012 proposed rule for HHS to include in the final rule. We would initiate future rulemaking if we were to establish a limited open enrollment period based on the triggering event in paragraph

(d)(9) of § 155.420. With the exception of these triggering events, limited open enrollment periods are the same inside and outside the Exchange in the individual and the small group market. We note that states may create special enrollment periods or limited open enrollment periods in addition to those established by this final rule.

Comment: Many commenters supported establishing 60-day special enrollment periods, consistent with those in the Exchange, to reduce consumer confusion, facilitate orderly enrollment, and ease the administrative burden on states and issuers. One commenter recommended 30-day special enrollment periods, consistent with the HIPAA standard. A few commenters recommended a 63-day election period. Other commenters recommended that individuals be permitted to begin the special enrollment process 30 days prior to a known qualifying event.

Response: We agree that 60-day enrollment periods will promote consistency with the Exchanges and will give consumers the time they need to explore coverage options following a change in life circumstances. Therefore, we provide a 60-day election period for the special and limited open enrollment periods in the individual market. However, to avoid inconsistency with the statutory requirement in PHS Act section 2704(f)(1) that individuals losing group health coverage must request special enrollment not later than 30 days after the loss of coverage, we maintain 30-day special enrollment periods for the group market. We note that the March 27, 2012 Exchange final rule (§ 155.725(a)(3)) currently provides for 60-day special enrollment periods with respect to the SHOP. We intend to revise the SHOP special enrollment periods to be consistent with the election period in group market under PHS Act section 2704(f)(1) and this final rule. We also note that we will monitor the effects the 60-day election period has on the individual market and whether or not it is necessary to move to a 30-day election period to be consistent with the group market.

Comment: In response to our request for comment, many commenters supported a requirement that issuers in the individual market provide a notice of special enrollment rights to individual market enrollees, similar to what is provided to group health plan participants and beneficiaries under HIPAA.

Response: Following review of the comments submitted on this issue and further consideration of the additional burden that would be imposed on QHP

issuers, we do not in this final rule require a notice of special enrollment in the individual market. QHP issuers are already subject to various notice requirements through the Exchange which will allow enrollees to make timely and informed coverage decisions. Furthermore, to ensure consistency with Exchanges and to avoid confusion, we do not extend a notice requirement to the broader individual market.

Comment: One commenter recommended that special enrollment periods not apply to individual family members who do not otherwise qualify for special enrollment. The commenter stated, for example, that an individual who loses minimum essential coverage should be allowed to obtain new coverage, but should not be allowed to obtain coverage for other dependents that were not covered on the previous policy.

Response: If an individual experiences an event that triggers a limited open or special enrollment right pursuant to § 147.104(b)(2) or (b)(3) of this final rule, the individual has the option to choose any family coverage offered in the individual market to cover members of his or her family. Pursuant to existing HIPAA regulations at § 146.117, this right already exists in the group market.

Comment: Some commenters recommended that issuers offering individual health insurance coverage be required to offer family coverage, while one commenter recommended clarifying that offering family coverage is not required under the guaranteed availability provisions.

Response: The final rule does not require an issuer to offer family coverage. While issuers are required to offer all products that are approved for sale in a market, an issuer is not required to offer a family coverage option with every policy form.

4. Guaranteed Renewability of Coverage (§ 147.106)

In § 147.106, we proposed to implement the guaranteed renewability provisions of section 2703 of the PHS Act. We proposed that an issuer offering health insurance coverage in the group or individual market must renew or continue in force such coverage at the option of the plan sponsor or individual. The exceptions to this requirement include: (1) Nonpayment of premiums; (2) fraud; (3) violation of minimum employer participation or contribution rules, as permitted under applicable state law; (4) termination of a particular type of product or all coverage in a market; (5) enrollees' movement outside the service area of a

network plan; and (6) for coverage provided through a bona fide association, an employer's loss of membership in the association.¹⁶ We noted that under the March 27, 2012 Exchange final rule at § 155.430, QHP issuers are permitted to terminate coverage in additional circumstances (for example, decertification of the QHP in the Exchange) and requested comment on whether issuers in such circumstances should be required to renew coverage on a non-QHP basis outside the Exchange.

We also proposed standards governing the discontinuance of a particular product or all health insurance coverage in the group or individual market, consistent with the statute.

Finally, we proposed that issuers in the group market may uniformly modify coverage at the time of coverage renewal and noted that parallel provisions in section 2742 of the PHS Act allow for the uniform modification of coverage in the individual market. We stated that the uniform modification of coverage provisions would allow issuers to make cost-sharing adjustments and benefit design changes to come into compliance with the requirements of the Affordable Care Act that become effective in 2014 and requested comment on whether such interpretation should be incorporated explicitly into regulation text.

Comment: Many commenters supported allowing enrollees in a QHP that terminates or is decertified in the Exchange to elect to renew coverage on a non-QHP basis outside the Exchange. Some commenters supported applying such standard with respect to all QHP termination events. Other commenters suggested enrollees should be notified in such instances that continuing coverage outside of the Exchange will affect their eligibility for advance payments of the premium tax credit and cost-sharing reductions. One commenter asserted that renewing coverage on a non-QHP basis may be unnecessary, since an enrollee's loss of coverage in a QHP will in most instances trigger a special enrollment right, and argued that decisions about coverage renewal are best left to the states.

Response: As discussed above, if an individual loses minimum essential coverage because, for example, a QHP is decertified, individuals enrolled in the QHP will have a limited open enrollment right for any policy in the

individual market, including any product being offered by the same issuer that offered the QHP.

Comment: A few commenters recommended clarifying that coverage may be non-renewed for loss of eligibility. For example, commenters suggested that for consistency with § 156.155 regarding catastrophic plans, a non-renewal provision would apply at the end of the policy year in which the person was no longer eligible for coverage.

Response: Individuals may only qualify for enrollment in some plans (for example, catastrophic plans or QHPs in the Exchange) if they meet certain eligibility criteria. While we do not include this clarification explicitly in § 147.106 of the final rule, we note that issuers are not required to renew coverage if an individual is not otherwise eligible for such coverage.

Comment: One commenter recommended that issuers be permitted to non-renew coverage when an enrollee becomes covered by other minimum essential coverage to prevent individuals from over-insuring.

Response: Consistent with PHS Act section 2703, the final rule does not include enrollment in other coverage as an exception for guaranteed renewability. We note that state coordination of benefit laws may apply in instances where individuals are enrolled in more than one type of coverage.

Comment: With respect to the discontinuation of coverage provisions in § 147.106(d)(1), one commenter suggested that HHS recognize the large group and small group segments of the group market so that an issuer is not required to exit both segments of the group market when exercising the option to discontinue all coverage in a market.

Response: PHS Act section 2703(c)(2)(A) permits an issuer to non-renew or discontinue coverage if the issuer discontinues offering all health insurance coverage in the "group market." Thus, the issuer must withdraw from the entire group market in order to satisfy this exception to guaranteed renewability. The final rule implements the statute without modification.

Comment: Several commenters noted that the guaranteed renewability laws in some states would prevent issuers from making plan design changes and cost-sharing adjustments necessary to bring existing, non-grandfathered coverage into compliance with the requirements of the Affordable Care Act that become effective in 2014. Commenters urged HHS to incorporate language into

regulation text explicitly permitting issuers to discontinue or uniformly modify coverage at renewal, even if such discontinuance or modification is not permitted under applicable state law.

Response: State laws that prevent issuers from uniformly modifying coverage, as permitted by sections 2703 and 2742 of the PHS Act, to comply with federal standards in title XXVII of the PHS Act would, in effect, prevent the application of such standards and, therefore, be preempted under section 2724(a)(1) of the PHS Act.

C. Part 150—CMS Enforcement in Group and Individual Insurance Market

We proposed technical changes in 45 CFR part 150 to reflect that the HIPAA enforcement standard, as originally codified in PHS Act section 2722 and redesignated as section 2723 by the Affordable Care Act, applies to the market reform provisions of the PHS Act created by the Affordable Care Act. Pursuant to section 2723, states have the primary enforcement authority with respect to health insurance issuers in the group and individual markets. HHS has secondary enforcement authority and will enforce a provision in a state only if the state advises us that it does not have authority to enforce the provision or if the state fails to substantially enforce a provision.

Comment: Several commenters requested a safe harbor from enforcement, at least for the first year of implementation, as long as issuers are making good faith efforts to comply and implement the new requirements. Special concern was raised in the instance where state law conflicts with federal law.

Response: As stated in previous Affordable Care Act guidance, our approach to implementation is marked by an emphasis on assisting (rather than imposing penalties on) issuers and others that are working diligently and in good faith to understand and comply with the law.¹⁷ While the final rule does not provide an enforcement safe harbor for the market reform provisions, HHS will continue to work closely with issuers and states in the implementation of these provisions.

Comment: One commenter questioned HHS's authority to extend this enforcement standard to the provisions of the Affordable Care Act including the market reform provisions.

Response: Title I of the Affordable Care Act amends title XXVII of the PHS

¹⁶ Section 2742(b)(5) of the PHS Act provides an exception to guaranteed renewability for an individual market enrollee's loss of membership in a bona fide association.

¹⁷ See, for example, Affordable Care Act Implementation FAQs—Set 1 Q1, available at http://cciio.cms.gov/resources/factsheets/aca_implementation_faqs.html.

Act. Specifically, the market reform provisions are enumerated in sections 2701, 2702, and 2703 of title XXVII of the PHS Act, which are subject to the enforcement provisions of PHS Act section 2723.

Comment: One commenter requested clarification regarding the process HHS uses to determine that a state is not substantially enforcing a provision of title XXVII of the PHS Act.

Response: We refer readers to 45 CFR 150.203, *et. seq.* for regulations describing HHS's enforcement processes.

D. Part 154—Health Insurance Issuer Rate Increases: Disclosure and Review

1. Subpart B—Disclosure and Review Provisions

a. State-specific Thresholds (§ 154.200)

In § 154.200(a)(2) and (b), we proposed that states seeking state-specific thresholds submit proposals to CMS by August 1 of each year. The Secretary would publish a **Federal Register** notice not later than September 1 of each year concerning whether a state-specific threshold applies in a state. If approved, a state-specific threshold would become effective on January 1 of the year following the Secretary's notice.

Comment: A few commenters were concerned that proposed timeline would not give issuers sufficient time to file rates before January 1.

Response: We are finalizing the revised timeline in § 154.200(a)(2) and (b) as proposed because the new dates increase consistency inside and outside of the Exchange. We are working to align the market with the QHP submission schedule and with the 2014 market reforms. Since QHP filings are due April 30 of each year, moving the state-specific threshold application date to August 1 will give states the appropriate amount of time to analyze the QHP information they receive and to request a state-specific threshold if they believe one is necessary. We will be moving the state-specific threshold determination deadline from June 1 to September 1, with any potential state-specific threshold going into effect January 1 of the following year. Under the May 23, 2011 rate review final rule (76 FR 29964), the Secretary was to publish a notice about state-specific thresholds by June 1, and the effective date of any state-specific threshold was September 1 of the same year. Under this final rule, issuers will still have three months to prepare to file rates under any potential state-specific threshold. Therefore, we are shifting the entire timeline forward three months to

enable states to have enough information to assess their markets appropriately. We note that the January 1 effective date for state-specific thresholds only means that rate filings submitted on or after January 1 will be subject to any potential state-specific threshold and not necessarily rate increases that are effective January 1.

b. Submission of Rate Filing Justification (§ 154.215)

Section 2794(b)(2)(A) of the PHS Act directs that beginning in 2014, the Secretary, in conjunction with the states, shall monitor premium increases of health insurance coverage offered through an Exchange and outside an Exchange. To enable the Secretary to carry out this new monitoring function and to streamline data collection for programs beginning in 2014, we proposed revisions in § 154.215 that would direct health insurance issuers to submit data and documentation regarding rate increases on a standardized form determined by the Secretary. We also proposed that the rate review standards be modified by extending the requirement that health insurance issuers report information about rate increases to all rate increases, not just those above the review threshold. States would continue to have the authority to collect additional information above this baseline to conduct more thorough reviews or rate monitoring. Furthermore, the review threshold in § 154.200 would continue to be used to determine which rates must be reviewed rather than just reported.

Under the Paperwork Reduction Act of 1995 (PRA) process (44 U.S.C. chapter 35), we proposed a “unified rate review” template for health insurance issuers to use for submitting data for rate increases. In this final rule, we have revised the text of § 154.215 to reflect the “unified rate review” terminology. We also have added language explicitly reflecting the fact that the premium rates subject to rate review reporting are shaped by the premium rating standards implemented under the single risk pool requirement and the applicability of the guaranteed availability and renewability requirements. We clarify that states are not specifically required to use the unified rate review template in order to have an effective rate review program.

Comment: Several commenters remarked on the proposal to expand reporting of all rate increases using the unified rate review template. Some commenters supported the expanded reporting requirement, while other commenters were concerned about the administrative burden on issuers. One

commenter suggested that the proposal would allow both CMS and states to monitor rate trends and identify patterns that could indicate market disruption.

Response: Section 2794(b)(2)(A) of the PHS Act, as added by the Affordable Care Act, requires the Secretary to monitor premium increases of health insurance coverage offered both inside and outside an Exchange, for plan years beginning in 2014. Accordingly, we proposed that issuers offering health insurance coverage in the small group or individual markets report information about all rate increases. We believe that standardizing the reporting process will reduce administrative burden and duplication over time and enable both states and CMS to evaluate information about the single risk pool, actuarial value, essential health benefits, and other market reforms beginning in 2014. This reporting will also assist states and CMS in monitoring the market inside and outside the Exchange for adverse selection. Therefore, we are finalizing the requirement to report all rate increases in § 154.215 as proposed. We note that when new business is included in the unified rate review template, the issuer must demonstrate all premium and claims projections for the new products and plans as provided in guidance. Historical experience is only required for existing product/plan combinations represented on the unified rate review template. We also note that, in response to comments received through the PRA process, we have made changes to the uniform rate review template to both remove data elements and to make some optional in the first two years of applicability. As discussed in more detail in section V. of the preamble, we estimate that these changes reduce the number of required data elements by approximately 45 percent.

Comment: Several commenters remarked on the content of the proposed unified rate review template.

Response: We address these comments in section V. of the preamble regarding collection of information requirements. As mentioned above, we have made changes to the template in response to comments to ensure streamlined and efficient data collection.

2. Subpart C—Effective Rate Review Programs

a. Determination of Effective Rate Review Programs (§ 154.301)

To account for the market reform changes in 2014, we proposed to modify the standards in § 154.301(a)(3) for

states to have an effective rate review program with respect to rate filings subject to review. Specifically, we proposed that a state with an effective rate review program review the following additional elements as part of its rate review process: (1) the reasonableness of assumptions used by an issuer to estimate the rate impact of the reinsurance and risk adjustment programs; and (2) issuer data related to implementation and ongoing utilization of a market-wide single risk pool, essential health benefits, actuarial values, and other market reform provisions of the Affordable Care Act. We did not propose to modify the 10 percent subject to review threshold as finalized in § 154.200.

We also proposed to revise § 154.301(a)(4) by adding additional factors that states would take into consideration when conducting their examinations, including (1) in reviewing the impact of cost-sharing changes, the impact on the actuarial value of the health plan in light of the requirement under section 1302(d) of the Affordable Care Act that a plan meet one of the AV levels; and (2) in reviewing benefit changes to a plan, the impact of the changes on the plan's essential health benefits and non-essential health benefits.

Additionally, we proposed that states take into account, to the extent possible, the following additional factors when conducting an examination of a rate review filing:

- Other standardized ratio tests (in addition to the medical loss ratio) recommended or required by statute, regulation, or best practices;
- The impact of geographic factors and variations;
- The impact of changes within a single risk pool to all products or plans within the risk pool; and
- The impact of reinsurance and risk adjustment payments and charges.

Finally, we proposed revisions in § 154.301(b) to ensure that a state with an effective rate review program make available on its Web site, at a minimum, the same amount of information in Parts I, II, and III of each Rate Filing Justification that CMS makes available on its Web site. We proposed that a state may, instead of providing access to the information contained in Parts I, II, and III of each Rate Filing Justification, provide a link to CMS's Web site where consumers can find such information.

Comment: Several commenters remarked on the proposed additional criteria for states to have an effective rate review program. Some commenters supported the additional criteria, while others suggested that states with

effective rate review programs should have flexibility to use either the unified rate review template or their own templates and formats for collecting information from issuers. One commenter suggested that CMS should accept state regulators' attestations that they are reviewing the required information, but not necessarily require that states incorporate the unified rate review template into their review process.

Response: We finalize the proposed amendments in § 154.301 except that, in order to limit additional factors to only those that reflect the 2014 market reforms, we do not require states to consider "other standardized ratio tests recommended or required by statute, regulation, or best practices" to have an effective rate review program. Although states will likely consider these ratio tests as part of their review processes, we intend to minimize the criteria and factors for states to have an effective rate review program in order to give states the maximum flexibility to conduct reviews. Further, this final rule does not require states to incorporate the unified rate review template into their review process. States will retain the flexibility to use other collection tools, provided they collect the information necessary to conduct effective reviews. States cannot rely on issuer attestation alone in conducting these reviews. Issuers in all states, including those with effective rate review programs, must still under this final rule submit information to CMS using the unified rate review template. We note that states and issuers will have an incentive to use the collection tools provided by CMS to ensure streamlined and efficient data collection.

This approach strikes the appropriate balance between maintaining state flexibility and allowing CMS to carry out functions related to: (1) The monitoring of premium increases of health insurance coverage offered through an Exchange and outside an Exchange as required by section 2794(b)(2)(A) of the PHS Act; (2) Exchanges such as QHP certification and premium tax credit and cost-sharing reduction verification; and (3) the risk adjustment and reinsurance programs. We note that even without the administrative efficiencies associated with using the information collected through rate review authority for the second and third functions listed above, the same data would be needed and collected to carry out the first function by itself. We also clarify that we will use the information collected only for these specified purposes and will initiate

future rulemaking if we intend to use the data for any other purpose.

Comment: Some commenters expressed concern about the public release of information. Commenters recommended disclosing only a minimal amount of information and that such disclosure not include confidential or proprietary information.

Response: As mentioned in the preamble of the November 26, 2012 proposed rule, we will release only information collected that is determined not to include trade secrets and is approved for release under the Freedom of Information Act (FOIA). In general, all information collected by HHS is subject to FOIA. In accordance with the HHS's FOIA implementing regulations at 45 CFR 5.65(c), health insurance issuers may designate part or all of the information submitted as exempt from disclosure under Exemption 4 of the FOIA if the issuer believes the information is commercial or financial information that is confidential or privileged. If there is a FOIA request, we will follow the pre-disclosure notification procedures found at 45 CFR 5.65(d) through (e) to seek issuer input on the applicability of Exemption 4 before disclosure is made. If the information has previously been published or made generally available to the public, it will not be considered confidential or privileged for purposes of Exemption 4. In addition, as discussed in section II.E.1.a. of the preamble, issuers will set their index rates and plan-specific pricing once per year upon filing their rates with state insurance departments, and information would only be released after the QHP submission process is concluded. Accordingly, we believe that public disclosure of certain rate review information will not undermine competitive market dynamics.

b. Rate Filing Justification (§ 154.225 and § 154.330)

We proposed to amend § 154.225 and § 154.330 by replacing the term "Preliminary Justification" with the term "Rate Filing Justification," to reflect more appropriately the rate filing information that would be reported. We received no comments regarding this proposed change. Accordingly, we are finalizing proposed § 154.225 and § 154.330 without modification.

E. Part 156—Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges

1. Subpart A—General Provisions

a. Single Risk Pool (§ 156.80)

In § 156.80, we proposed standards to implement the requirement in section 1312(c) of the Affordable Care Act that an issuer use a single risk pool for a market (the individual market, small group market, or merged market) when developing rates and premiums for coverage effective beginning in 2014.

We proposed that an issuer develop a market-wide index rate (average rate) based on the total combined EHB claims experience of all enrollees in all non-grandfathered plans in the risk pool. After setting the index rate, the issuer would make a market-wide adjustment based on the expected aggregated payments and charges under the risk adjustment and reinsurance programs in a state. The premium rate for any given plan could not vary from the resulting adjusted market-wide index rate, except for the following factors: The actuarial value and cost-sharing structure of the plan; the plan's provider network, delivery system characteristics, and utilization management practices; plan benefits in addition to EHB; and with respect to catastrophic plans, the expected impact of specific eligibility categories for those plans. The index rate, the market-wide adjustment to the index rate, and the plan-specific adjustments would have to be actuarially justified and implemented transparently, consistent with federal and state rate review processes.

We invited comment on the set of allowable plan-specific adjustments and whether to allow flexibility in product pricing in 2016 after issuers had gained sufficient experience with the reformed market. Additionally, in the "HHS Notice of Benefit and Payment Parameters for 2014" proposed rule (77 FR 73118), we solicited comment on whether Exchange user fees or other administrative costs should be spread across all plans in a market as a market-wide adjustment to the index rate.

Comment: Several commenters suggested that issuers should be allowed to reflect distribution costs and other administrative costs associated with different products in their premiums to promote administrative efficiency. One commenter recommended allowing a market-wide adjustment to the index rate for Exchange user fees, as well as distribution costs, agent and broker commissions, and all administrative costs, to spread these costs evenly

across the market and protect against adverse selection. Other commenters urged that any flexibility in product pricing not result in de facto experience rating based on health status. A few commenters opposed our proposal to pool Exchange user fees across all plans in a market within a state because they believed that this would unfairly increase costs for members that are not enrolled in the Exchange. Other commenters supported the proposal to pool Exchange user fees across all of an issuer's plans in a relevant market within a state.

Response: We agree with commenters urging the pooling of Exchange user fees across the market as these costs are not related to the unique efficiencies or designs of a particular plan. Accordingly, the final rule directs issuers to make a market-wide adjustment to the index rate for Exchange user fees. This will ensure that Exchange user fees are spread evenly across the market, creating a level playing field inside and outside the Exchange, and further protecting against adverse selection. Further, this policy is consistent with the treatment of Exchange user fees for medical loss ratio (MLR) and rebate calculations under 45 CFR 158.161(a).¹⁸

As for distribution costs and other administrative costs (other than Exchange user fees), we believe that issuers should be allowed to make actuarially justified adjustments to the market-wide index rate at the individual plan level for those costs. This will allow pricing to vary among individual plans by administrative costs reasonably allocable to those plans, ensuring that administrative efficiencies are priced accurately and promoting market competition. The final rule therefore includes administrative costs (other than Exchange user fees) as an additional factor that issuers may use to modify the market-wide index rate at the individual plan level.

Comment: Several commenters requested issuer flexibility in product pricing to adequately adjust for the risk of their enrollees. Commenters opposed any restriction to making actuarially justified adjustments to the index rate for new and renewing businesses during the course of the year. Other commenters suggested issuers adjust the index rate on a consistent, annual basis.

Response: Issuers in the individual or combined markets (in states that have merged the individual and small group

markets) should set their index rates and plan-specific pricing once per year, upon filing their rates with the state's department of insurance. Permitting changes in these markets to the index rate throughout the year could effectively lead to premium pricing in violation of the rules described above. We believe that these rates should apply to new and renewing enrollees during the course of the year.

Comment: Several commenters requested clarification on whether adjustments to the index rate could reflect differences in health status. Some commenters also requested that issuers be permitted to make an adjustment to the index rate to account for induced utilization. Other commenters requested that HHS enforce the single risk pool requirement so that the index rate and plan-specific rates set by issuers do not reflect differences in enrollee health status.

Response: As indicated in the preamble of the November 26, 2012 proposed rule, we believe that the purpose of the single risk pool is to prevent issuers from segregating enrollees into separate rating pools based on health status. In this final rule, we confirm that plan-specific adjustments to the market-wide index rate must not reflect differences in health status or risk selection. In addition, we exclude induced demand from the index rate adjustments because of the actuarial difficulty of measuring whether differences in total plan expenditures are due to risk selection or induced demand.

Comment: Several commenters requested clarification on whether the term "actuarial value" for the purpose of the individual plan adjustment to the index rate has the same meaning as the term "actuarial value" in the Actuarial Value (AV) calculator in the November 26, 2012 EHB/AV/Accreditation proposed rule. Several commenters also requested clarification on the method for applying plan-specific premium factors, particularly whether issuers may adjust the index rate for anticipated difference in utilization, risk adjustment payments and reinsurance payments through plan design, and the allowable adjustment for catastrophic plans.

Response: The calculation of the actuarial value through the AV calculator is based on data sets provided by HHS reflecting a standard population, utilization, and unit prices. For the purpose of developing an adjustment to the market-wide index rate for individual plans, we would expect health insurance issuers to utilize pooled allowable claims data as a basis for calculating the plan-specific

¹⁸ CCHIO Technical Guidance (CCHIO 2012–002): Questions and Answers Regarding the Medical Loss Ratio Regulation, Q&A #34 (Apr. 20, 2012), available at <http://cciio.cms.gov/resources/files/mlr-qa-04202012.pdf>.

actuarial value. By using the claims data of their pooled population, issuers can develop more accurate adjustments to the index rate for individual plans. In the absence of data, issuers of new plans would have the option of calculating pooled allowable claims using actuarially reasonable projections.

Additionally, we would expect issuers to proportionally allocate anticipated reinsurance and risk adjustment payments and charges based on plan premium by applying the risk adjustment/reinsurance adjustment factor as a constant multiplicative factor across plans. We believe that this modification would prevent issuers from differentially allocating risk adjustment and reinsurance payments and charges across plans in a manner that would reintroduce risk selection differences into plan premiums.

Finally, with respect to catastrophic plans, we clarify that issuers may make a plan-specific adjustment to the market-wide index rate that accounts for differences between catastrophic and non-catastrophic plans in expected average enrollee gross spending and expected average risk adjustment payment transfers. This plan-specific adjustment would be uniform across all of an issuer's catastrophic plans (that is, risk across all catastrophic plans must be pooled). This adjustment for catastrophic plans should not include plan liability differences due to actuarial value, because actuarial value differences should be accounted for in the actuarial value adjustment.

Comment: A few commenters requested flexibility in the claims data that could be used to determine the index rate for the initial years of Exchange operation. One commenter specifically recommended that issuers be permitted to use the claims experience from grandfathered books of business when developing initial rates.

Response: We recognize that lack of robust EHB claims experience may create challenges for issuers in setting rates in the initial years of implementation. We clarify that in the absence of applicable claims data, an issuer may use any reasonable source of claims data, including claims experience from grandfathered books of business or claims data from actuarial rate manuals (to the extent available), to establish its index rate, as long as those data are used to actuarially estimate the portion of claims data associated with providing coverage for EHB as required to establish the index rate.

Comment: A few commenters expressed concern that merging the individual and small group markets could cause market disruption and

affect the rating methodology. Other commenters requested clarification about how the single risk pool would apply if a state elected to merge its individual and small group markets.

Response: If a state exercises the option to merge its individual and small group markets, an issuer must, in accordance with § 156.80(d) of this final rule, calculate the market-wide index rate and plan-specific adjustments based on the merged market. As only non-grandfathered individual market plans are eligible for payments under the transitional reinsurance program, in a merged market, the pooled reinsurance adjustment should be based only on the portion of the issuer's individual market business eligible for reinsurance payments.

Comment: Numerous commenters requested clarification of whether the single risk pool is to be maintained at the holding company level or at the individual licensee level.

Response: Section 1312(c) of the Affordable Care Act requires a health insurance issuer to maintain a single risk pool in the individual market and a single risk pool in the small group market (unless a state requires both pools to be merged). Section 1301(b)(2) of the Affordable Care Act provides that the term "health insurance issuer" has the meaning given the term in section 2791(b) of the PHS Act, which defines a health insurance issuer as an entity that is licensed to conduct the business of insurance in a state. Accordingly, the single risk pool is to be maintained at the licensed entity level.

2. Subpart B—Standards for Essential Health Benefits, Actuarial Value, and Cost Sharing

a. Enrollment in Catastrophic Plans (§ 156.155)

In § 156.155, we proposed standards for catastrophic plans offered in the individual market, consistent with section 1302(e) of the Affordable Care Act. Specifically, we proposed that a health plan is a catastrophic plan if it: (1) Meets all applicable requirements for health insurance coverage in the individual market; (2) does not offer coverage at the bronze, silver, gold, or platinum levels of coverage described in section 1302(d) of the Affordable Care Act; (3) does not provide coverage of essential health benefits until the enrolled individual reaches the annual limitation in cost sharing in section 1302(c)(1) of the Affordable Care Act; and (4) covers at least three primary care visits per year before reaching the deductible. Further, we proposed that a catastrophic plan may not impose any

cost-sharing requirements for preventive services identified in section 2713 of the PHS Act.

We also proposed to codify the statutory criteria identified in section 1302(e)(2) of the Affordable Care Act listing the two categories of individuals eligible to enroll in a catastrophic plan. The first category includes individuals who are younger than age 30 before the beginning of the plan year. The second category includes individuals who have been certified as exempt from the individual responsibility payment because they cannot afford minimum essential coverage or because they are eligible for a hardship exemption. Finally, we proposed that if a catastrophic plan covers more than one person (such as a catastrophic family plan), each individual enrolled must satisfy at least one of these two eligibility criteria.

Comment: A few commenters requested clarification as to whether the provisions regarding catastrophic plans apply only to coverage offered through an Exchange.

Response: Section 1301(a)(1)(B) of the Affordable Care Act directs a QHP to provide the EHB package described in section 1302(a) that, subject to section 1302(e), meets the actuarial value (AV) levels described in section 1302(d) (bronze, silver, gold, or platinum levels of coverage). Section 1302(e) describes an exception to the AV requirements for catastrophic plans. These provisions are incorporated by reference in section 2707(a) of the PHS Act, which extends coverage of the EHB package required under section 1302(a) to health insurance issuers offering non-grandfathered coverage in the individual and small group markets. Accordingly, the provisions regarding catastrophic plans apply to coverage offered both inside and outside of an Exchange.

Comment: One commenter recommended clarifying that individuals are eligible for enrollment in a catastrophic plan (offered through or outside the Exchange) if they have obtained from the Exchange a hardship exemption based on inability to afford or obtain coverage.

Response: As discussed in the February 1, 2013 **Federal Register** proposed rule entitled "Patient Protection and Affordable Care Act; Exchange Functions: Eligibility for Exemptions; Miscellaneous Minimum Essential Coverage Provisions" (78 FR 7348), herein referred to as the Minimum Essential Coverage proposed rule, only the Exchange may issue certificates of exemption based on hardship. Under the Minimum Essential

Coverage proposed rule, there are several situations where an Exchange would grant a certificate of exemption for hardship based on an inability to afford or obtain coverage. One category of the hardship exemption is based on the Exchange determining that an applicant, or another individual in the applicant's family, is unable to afford coverage for a calendar year based on the applicant's projected household income. This specific category would allow individuals to receive a hardship exemption in lieu of the statutory unaffordability exemption based on the individual's actual household income. We agree that, consistent with the above discussion of section 2707(a) of the PHS Act, individuals granted a certificate of exemption from the Exchange based on hardship may use such exemption determination to establish eligibility to purchase a catastrophic plan outside of the Exchange.

Comment: One commenter stated that with respect to a catastrophic family plan, only one member of a family should have to meet the eligibility criteria rather than all family members.

Response: Section 1302(e)(1)(A) of the Affordable Care Act provides that the only individuals who are eligible to enroll in a catastrophic plan are those individuals who meet specific eligibility criteria described in section 1302(e)(2). Therefore, we do not accept the commenter's suggestion that all members of a family may enroll in a catastrophic plan if only one family member is eligible to enroll.

Comment: We received several comments about the requirement that catastrophic plans must provide coverage for at least three primary care visits before reaching the annual deductible. Some commenters recommended clarifying that issuers must cover at least three primary care visits in addition to the preventive services required to be covered without cost sharing under section 2713 of the PHS Act, and that issuers may not impose any cost-sharing requirements for these visits. Other commenters recommended clarifying that primary care visits include visits to obstetrical or gynecological providers.

Response: Health insurance issuers providing catastrophic coverage must fully comply with PHS Act section 2713 and its implementing regulations in addition to providing coverage for at least three primary care visits. The classification of who is a primary care provider for the purpose of the primary care visits is determined by the terms of the health plan or by state law.

F. Applicability to Special Plan Types

1. Student Health Insurance Coverage (§ 147.145)

Section 1560(c) of the Affordable Care Act provides that nothing in title I of the Affordable Care Act, or an amendment made by title I, "shall be construed to prohibit an institution of higher education (as such term is defined for purposes of the Higher Education Act of 1965) from offering a student health insurance plan, to the extent that such requirement is otherwise permitted under applicable federal, state, or local law." HHS has interpreted section 1560(c) to mean that if particular requirements of the Affordable Care Act would have, as a practical matter, the effect of prohibiting an institution of higher education from offering a student health plan otherwise permitted under federal, state, or local law, these requirements would be inapplicable pursuant to section 1560(c).

HHS published a final rule in the March 21, 2012 **Federal Register** entitled "Student Health Insurance Coverage" (77 FR 16453), which clarified that for purposes of federal law, student health insurance coverage is defined as a type of individual health insurance coverage and therefore generally subject to the individual market requirements of title XXVII of the PHS Act and title I of the Affordable Care Act. However, pursuant to section 1560(c) of the Affordable Care Act, the March 21, 2012 final rule exempted student health insurance coverage from the guaranteed availability and guaranteed renewability requirements of PHS Act sections 2741(e)(1) and 2742(b)(5) added by HIPAA.

Consistent with that policy, the November 26, 2012 proposed rule outlined similar exemptions for student health insurance coverage from the guaranteed availability and guaranteed renewability requirements of PHS Act sections 2702 and 2703 added by the Affordable Care Act to ensure that enrollment in student health insurance plans may be limited only to students and their dependents. Further, we solicited comment on whether issuers should be permitted to maintain a separate risk pool for student health insurance coverage and whether different premium rating rules should apply.

Comment: While some commenters recommended including student health insurance coverage in the general individual market risk pool, many commenters urged HHS to recognize the unique characteristics of student health insurance plans by allowing separate risk pooling of such coverage.

Commenters expressed concern that pooling the risk of student enrollees with other individual market enrollees could increase student health insurance premiums and potentially discourage some universities from offering student health insurance plans. Commenters also noted that student health insurance issuers typically do not underwrite students on an individual basis, but rather offer coverage to institutions of higher education at a group community rate. These commenters requested flexibility with respect to the premium rating rules of PHS Act section 2701 so that issuers may continue to consider characteristics such as the educational institution's claims experience, enrollment method, demographics, and availability of on-campus services when developing rates and premiums for student health insurance coverage.

Response: We recognize that student health insurance coverage generally is rated and administered differently than other forms of individual health insurance coverage. Issuers of student health insurance coverage typically contract with a college or university to issue a "blanket" health insurance policy, from which students can buy coverage, and the policy is generally rated on a group basis based on the total expected claims experience of the college's or university's students enrolled in the plan. Accordingly, under HHS's authority in section 1560(c) of the Affordable Care Act to ensure that the law's requirements would not effectively prohibit the offering of a student health insurance plan otherwise permitted under federal, state, or local law, and to minimize market disruption in the initial transition to the reformed market, this final rule provides that non-grandfathered student health insurance coverage is not subject to the single risk pool requirement of section 1312(c) of the Affordable Care Act.

Student health insurance is subject under these final rules to the premium rating requirements of section 2701 of the PHS Act. We note, however, that given the exemption from single risk pool requirement, the premium rate charged by an issuer offering student health insurance coverage may be based on a school-specific group community rate if, consistent with section 2701, the issuer offers the coverage without rating for age or tobacco use. This provides flexibility to student health insurance issuers with respect to the per-member-rating provisions of PHS Act section 2701(a)(4) and § 147.102(c)(1), while ensuring that student enrollees and their dependents are not charge more based on their health status or gender.

The treatment of student health insurance coverage under these final rules will serve as a transitional policy. We intend to monitor student health insurance coverage as the insurance market transitions to the 2014 market reforms and revisit this policy in the future.

Comment: Several commenters supported the proposal to exempt student health insurance coverage from the guaranteed availability and renewability requirements of the Affordable Care Act. One commenter specifically recommended with respect to the guaranteed availability provisions of the November 26, 2012 proposed rule that open enrollment periods for student health insurance plans be permitted to coincide with college and university enrollment periods.

Response: In this final rule, we finalize our proposal to exempt student health insurance coverage from the guaranteed availability requirements under PHS Act section 2702 and the guaranteed renewability requirements under PHS Act section 2703. Therefore, the special and open enrollment periods under section 2702 do not apply to issuers of student health insurance coverage. Student health insurance issuers may work with colleges and universities to determine appropriate enrollment periods for student enrollees and their dependents.

2. Bona Fide Association Coverage

As mentioned above, we proposed, consistent with PHS Act section 2702, that non-grandfathered health insurance coverage made available in the individual or group market through a bona fide association must be guaranteed available to all individuals or employers in a state and market. These proposed rules represented a change from existing law permitting coverage sold through bona fide associations to be limited only to association members; therefore, we invited comment on whether and how a transition or exception process for bona fide association coverage could be structured to minimize disruption.

Comment: Several commenters noted that the Affordable Care Act preserved an exception for coverage sold through bona fide associations from the guaranteed renewability provisions of sections 2703 and 2742 of the PHS Act and urged HHS to recognize a similar exception for bona fide associations from the guaranteed availability provisions of section 2702. Some commenters recommended providing a transition period during which issuers could close association coverage to new enrollment, while other commenters

cautioned that as long as issuers offering coverage through bona fide associations are able to limit coverage to association members, they effectively will be able to select healthy applicants and refuse applicants with high health care costs.

Response: Section 1563 of the Affordable Care Act deleted the exception contained in section 2711(f) of the PHS Act that existed prior to the amendments made by the Affordable Care Act, which exempted small group coverage sold through bona fide associations from having to guarantee issue policies to anyone other than members of the association. Therefore, the final rule implements the Affordable Care Act, which does not recognize an exception from guaranteed availability for bona fide association coverage. We note that while starting in 2014, health insurance issuers may not limit coverage sold through associations only to association members, nothing prevents an issuer from renewing existing association coverage. Furthermore, as discussed in the November 26, 2012 proposed rule, the exception for limited network capacity could provide a basis for limiting enrollment in certain products to bona fide association members.

3. Expatriate Plans

Comment: A few commenters urged HHS to exempt expatriate coverage from the market reform provisions of the Affordable Care Act, including the guaranteed availability, guaranteed renewability, premium rating, and rate review provisions, arguing that expatriate plans face special circumstances and considerations in complying with these provisions of federal law. For example, commenters stated that expatriate policies are designed to meet the unique coverage needs of employees while working outside of the United States (and their dependents). Commenters also noted that the rates for expatriate policies must accommodate the regulatory requirements and health care costs of other countries; reflect benefits that are particularly important to expatriates (such as medical evacuation coverage, war risk coverage, and currency fluctuation); and maintain global competitiveness with non-U.S. issuers offering expatriate coverage. Accordingly, commenters recommended that enrollment in expatriate policies be limited to expatriate employees and their dependents, and that the rules reflect the unique rating requirements faced by expatriate plans.

Response: We plan to issue future guidance on the applicability of the market reform provisions of the

Affordable Care Act, including these final rules, to expatriate policies.

4. State High Risk Pools

Comment: We received several comments as to whether states may continue their high risk pools beyond 2014. Many commenters supported state flexibility to transition high risk pools as a means of minimizing premium disruption and promoting continuity of care. A few commenters noted that high risk pool enrollees will have a right to guaranteed availability and stated such individuals must not be prohibited from enrolling in other coverage offered in the individual market, particularly through the Exchange. Some commenters suggested that enrollees who maintain high risk pool coverage should be eligible for premium tax credits and cost-sharing reductions and notified about new coverage options. Other commenters requested clarification about whether state high risk pools are subject to the market reform provisions of the Affordable Care Act.

Response: Many states currently have high risk insurance pools as their state alternative mechanism to provide insurance coverage for individuals who meet enrollment criteria and who do not otherwise have access to group or individual health insurance coverage. Since state high risk pool coverage is not provided through insurance and is not group health plan coverage, state high risk pool coverage is not subject to title XXVII of the PHS Act. However, some states, as their state alternative mechanism, require issuers (or certain issuers of last resort) to guarantee the availability of a product or specific benefit design. If the state alternative mechanism is individual market insurance coverage, it is subject to title XXVII of the PHS Act. Individuals enrolled in state high risk pools will have the same rights as others to guaranteed availability for any products offered inside and outside of the state Exchange, and states may not prevent individuals from moving to other products or to a state's Exchange. States will continue to have the discretion to determine whether each state continues to have a high risk pool in order to ease the transition of enrollees to other products, consistent with the February 1, 2013 Minimum Essential Coverage proposed rule, which proposed to designate state high risk pools as minimum essential coverage for a period of time to be determined by the Secretary.¹⁹

¹⁹ 78 FR 7348.

III. Modification of Effective Date for Certain Provisions

The Congressional Review Act, 5 U.S.C. 801(a)(3), ordinarily requires that the effective date of a “major rule” such as this final rule be at least 60 days from the date of publication. However, 5 U.S.C. 808(2) permits the federal agency promulgating the rule to determine an effective date, notwithstanding this otherwise applicable 60-day requirement, when an agency “for good cause finds (and incorporates the finding and a brief statement of reasons therefore in the rule issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.” While this final rule is generally effective 60 days from the date of publication, we have determined for 45 CFR 147.103, which specifies the timing for state reporting of rating factors, and the amendments to 45 CFR part 154 governing rate review, an effective date 30 days from the date of publication of this rule.

Section 147.103 directs states to report to HHS within 30 days after publication of this rule certain rating factors required by § 147.102, including but not limited to: the age rating ratio if a state adopts a ratio narrower than 3:1 for adults; the tobacco rating ratio if a state adopts a ratio narrower than 1.5 to 1; a uniform age rating curve if a state adopts any; and geographical rating areas if the state establishes any. It is imperative that HHS receive these data from the states within 30 days of publication of this final rule in order to implement timely the risk adjustment methodology set forth in section 1343 of the Affordable Care Act and its implementing regulations. Should these data not be received within 30 days of publication of this final rule, HHS’s risk adjustment scores for use on January 1, 2014 would have to be calculated using assumed rating factors based on the limitations set forth in this final rule, which could result in inaccurate risk adjustment payments to health insurance issuers in states that have developed different rating factors. This may in turn lead to imbalance in the insurance markets in those states with different rating factors. Furthermore, health insurance issuers are required to submit their applications by April 30, 2013 to the Exchanges to be certified as QHPs in 2014. In order to submit accurate information on their applications, the issuers will need to know what rating factors in a state will be effective starting January 1, 2014.

The amendments to 45 CFR part 154 revise the timeline for states to propose state-specific thresholds for review and

approval by HHS. The amendments also direct health insurance issuers to submit data relating to proposed rate increases in a standardized format specified by the Secretary of HHS, and modify criteria and factors for states to have an effective rate review program. These changes are necessary to reflect the new market reform provisions and to fulfill the statutory requirement beginning in 2014 that the Secretary, in conjunction with the states, monitor premium increases of health insurance coverage offered through an Exchange and outside of an Exchange. The provisions are also designed to streamline data collection for issuers, states, Exchanges, and HHS. Since health insurance issuers will be submitting their 2014 rate filings in states starting April 1, 2013, these amendments must be effective at that point for consumers to experience the full benefits in 2014 of the rate review process both inside and outside the Exchanges.

Furthermore, HHS and the states must have the ability to collect, beginning April 1, 2013, rate data from health insurance issuers relating to the 2014 market reforms to ensure effective implementation of the market reforms starting January 1, 2014. For example, if the data submission requirement for all rate increases is not in place by April 1, 2013, states and HHS will have very little ability to gauge whether issuers have combined all of their products into a single risk pool in either the individual or small group markets. Issuers could, therefore, implement different index rates and allowable modifiers without fear of being observed by a regulator for some time, which would have the potential effect of issuers continuing to rate for health status in 2014.

Accordingly, for the reasons stated above, 45 CFR 147.103 of this final rule and the amendments to 45 CFR part 154 are effective 30 days after publication of this final rule.

IV. Provisions of the Final Regulations

For the most part, this final rule incorporates the provisions of the proposed rule. Those provisions of this final rule that differ from the proposed rule are as follows:

Changes to § 147.102 (Fair health insurance premiums)

- Clarifies that tobacco use means use of tobacco on average four or more times per week within no longer than the past six months, including all tobacco products but excluding religious and ceremonial uses of tobacco. Further, tobacco use must be defined in terms of when a tobacco product was last used.

Additionally, clarifies that issuers may vary rates for tobacco use only with respect to individuals who may legally use tobacco under federal and state law.

- Gives states additional flexibility to establish geographic rating areas that would be presumed adequate.
- Modifies the default rating area standard such that there would be one rating area for each metropolitan statistical area and one rating area comprising all non-metropolitan statistical areas in the state.
- Clarifies the criteria that HHS will use to determine whether proposed state rating areas are adequate.
- Clarifies that the cap on the number of individuals under age 21 taken into account when computing the family premium applies to the three oldest “covered children” under age 21.
- Deletes language in paragraphs (a)(1)(iii) and (a)(1)(iv) providing that states may use narrower age and tobacco use factors to avoid confusion.
- Consolidates state reporting requirements in a new § 147.103.

Changes to § 147.104 (Guaranteed availability of coverage)

- Adds events triggering limited open enrollment periods in the individual market, consistent with Exchange special enrollment periods, as well as a one-time limited open enrollment period for the 2014 calendar year for individuals with non-calendar year individual policies.
- Establishes 60-day special and limited open enrollment periods in the individual market; maintains 30-day special enrollment periods in the group market.
- Ensures consistency of the prohibition against employing discriminatory marketing practices and benefit designs with the prohibition on discrimination with respect to EHB in § 156.125 and the non-discrimination standards applicable to QHPs under § 156.200(e).

Changes to § 147.145 (Student health insurance coverage)

- Exempts student health insurance coverage from the single risk pool requirements of Affordable Care Act section 1312(c).

Changes to § 154.215 (Submission of Rate Filing Justification)

- Clarifies that if any product is subject to a rate increase, an issuer must submit a Rate Filing Justification for all products in the single risk pool, including new or discontinuing products.
- Replaces the term “standardized data template” with “unified rate review template” each place it appears.

Changes to § 156.80 (Single risk pool)

- Clarifies that the index rate for the single risk pool must be adjusted on a market-wide basis for Exchange user fees and may be adjusted at the plan-level for distribution costs and other administrative costs.

Changes to § 156.155 (Enrollment in catastrophic plans)

- Makes a technical correction in paragraph (c) of this section that each enrolled individual in the case of a catastrophic plan covering multiple individuals must meet the eligibility criteria outlined in paragraph “(a)(5)” of this section.

V. Collection of Information Requirements

In the November 26, 2012 proposed rule (77 FR 70584), we solicited public comments on each of the sections identified as containing information collection requirements (ICRs). In this final rule, we are restating our summary of the information collection requirements and providing summaries of the comments received and our responses to those comments. Regarding wage data, we generally used data from the Bureau of Labor Statistics to derive average labor costs (including fringe benefits) for estimating the burden associated with the ICRs.

A. ICRs Regarding State Disclosures (§ 147.102(b), § 147.102(e), § 147.103, § 156.80(c))

The final rule directs states to submit to CMS certain information as applicable about their rating and risk pooling requirements. A state will inform CMS if it adopts a narrower age rating ratio than 3:1 or adopts a narrower rating ratio for tobacco use than 1.5:1. A state will also submit information to CMS regarding state-established geographic rating areas and state-established uniform age rating curves. A state with pure community rating will submit information to CMS about its uniform family tiers and corresponding multipliers, if any. A state will also inform CMS if it requires premiums to be based on average enrollee amounts in the small group market (§ 147.103). Finally, a state will inform CMS if it elects to merge its individual and small group market risk pools (§ 156.80(c)). Because we do not know how many states will choose to establish their own geographical rating areas, age rating curves, and family tier structures; adopt narrower age or tobacco rating factors; require premiums to be based on average enrollee amounts in the small group market; or merge their individual and small group market

risk pools, we have estimated the burden for one state.

The burden associated with this requirement is the time involved for states to provide to CMS information on the rating factors and requirements applicable to their small group and individual markets. If a state adopts narrower rating ratios for age or tobacco use, or chooses to merge their individual and small group market risk pools, the state will inform CMS. We estimate that it will take 20 minutes for a state to prepare and submit a report to CMS for each of these disclosures, for a total burden of one hour and a cost of approximately \$31 for all three reports combined.

This final rule provides that a state's rating areas must be based on the geographic divisions of counties, three-digit zip codes, or MSAs and non-MSAs and will be presumed adequate if either of the following conditions are met: (1) As of January 1, 2013, the state had established by law, rule, regulation, bulletin, or other executive action uniform geographic rating areas for the entire state; or (2) After January 1, 2013, the state establishes by law, rule, regulation, bulletin, or other executive action for the entire state no more geographic rating areas than the number of MSAs in the state plus one. We anticipate that states that currently have geographical rating areas will retain them. For states that establish rating areas, we estimate that it will take one hour for a state to prepare and submit a report to CMS on its geographical rating areas, for a burden of one hour and a cost of approximately \$31.

If a state develops an age rating curve, the state will report the state's age rating curve to CMS. We anticipate that HHS's default standard age rating curve will apply in most states. Only one state commented that it would establish its own age rating curve. For states that designate their own curve, we estimate that it will take three hours for each state to prepare and submit a report on its age rating curve, for a burden of three hours and a cost of \$93.

If a state is community rated and designates a uniform family tier structure with corresponding multipliers, the state will report family tier structure information to CMS. We estimate that very few states will designate family tier structures and that it will take one hour to prepare and submit a report to CMS. The burden for reporting family tier structure information is estimated to be one hour, and a cost of approximately \$31.

If a state requires premiums in the small group market to be based on average enrollee amounts, it will submit

that information to CMS. We estimate that it will take one hour for a state to prepare and submit the report on small group market premiums to CMS, for a burden of one hour and a cost of approximately \$31.

We assume that each report will be prepared by clerical staff (at a cost of approximately \$31 per hour) and will be reviewed by a senior manager (using 1 hour of labor at approximately \$65 per hour) prior to submission to CMS. The total burden for all disclosures is eight hours (seven by clerical staff and one by a senior manager) and approximately \$279 per state, if a state needs to prepare and submit a report in all of these areas.

We expect that states that already have established a narrower age or tobacco rating ratio, family tier structure and requirements for small group market premiums to be based on average enrollee amounts, will retain them and simply incur the burden of reporting them. Based on our interactions with state officials and review of publicly available studies prepared by actuarial firms on the impact of the Affordable Care Act on the health insurance market in various states, we believe that many states have already studied the issue of merging their individual and small group market risk pools and would only incur the burden of reporting. We anticipate that few states will choose to establish their own age rating curve or establish new geographical rating areas and incur related administrative costs. If a state chooses to establish its own age rating curve (§ 147.102(e)), it is likely to engage an actuarial consultant. We estimate that it will require approximately 100 hours of effort by an actuary (at a cost of \$225 per hour) and 23 hours of combined labor by state actuaries (10 hours at a cost of approximately \$50 per hour) and senior management (13 hours at a cost of approximately \$65 an hour) to establish an age curve. The total burden will be 123 hours and approximately \$24,000. If a state chooses to establish geographical rating areas (§ 147.102(b)), if they haven't already done so, staff actuaries are likely to conduct an analysis and prepare a report for management (30 hours at a cost of approximately \$50 per hour) and senior management will review the reports and make a decision (2 hours at a cost of approximately \$65 an hour). The total burden would be 32 hours and approximately \$1,600.

B. ICRs Regarding Rate Increase Disclosure and Review (§ 154.215, § 154.301)

This final rule directs that health insurance issuers use a unified rate review template, as specified by the

Secretary, to report information about a proposed rate increase to CMS. States with effective rate review programs have the option to incorporate this template into their rate review process. The existing information collection requirement (OMB Control Number 0938-1141) includes a standardized template that is currently used by issuers seeking rate increases to submit data to CMS. CMS published an updated rate review template for public comment, in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35).

Health insurance issuers seeking rate increases will submit data using the unified rate review template and will incur administrative costs to prepare and submit the data. Based on CMS's experience with the 2011 MLR reporting year, there are 2,010 health insurance issuers (company/state combinations, including territories) offering coverage in the individual market in all states and 1,050 issuers offering coverage in the small group market in all states, while there are 2,294 unique issuers offering products in one or both markets. Most issuers already have to provide this information to their respective states. We anticipate a total of 7,650 submissions for rate review increases annually in both markets. Based on past experience, we anticipate that approximately 1,200 of these submissions will be for rate increases at or above the subject to review threshold and the remaining 6,450 submissions will be for rate increases below the review threshold. We assume that each submission will require 11 hours of work by an actuary (at a cost of \$225 per hour), including minimal time required for recordkeeping. The total cost for all submissions will be approximately \$19 million. Therefore, the increase in administrative costs for all issuers

seeking rate increases below the review threshold will be approximately \$16 million, with an average of \$7,000 per issuer. It should be noted that there are administrative efficiencies gained by helping issuers to avoid significant duplication of effort for filings subject to review by using the same standardized template for all issuers offering health insurance coverage in the small group or individual markets across all states, and because the vast majority of states currently require all rate increases to be filed. These efficiencies are not quantified in this rule.

A few commenters remarked that the costs related to rate review template submission have been underestimated. An industry group also provided estimates of the number of submissions and related costs. According to industry feedback received by CMS, the current rate review template being used requires only one to four hours of actuarial labor to complete. The unified rate review template includes more data and we estimate that it would take an actuary 11 hours, on average, to complete. Issuers will have to submit only one consolidated report for all their products in a market, unlike the current template in use which requires a separate submission for each product.

Additionally, issuers seeking rate increases may need to adjust their systems to provide the data required in the unified rate review template and incur one-time costs. One commenter provided a range of anticipated costs obtained from an industry survey. However, we do not expect many issuers to undertake major systems changes to prepare the rate review submissions. Most of the data elements specified in the new template are currently captured by issuers and most of the changes will involve categorizing the data into new categories and aggregating the information to the

market level. We estimate that an issuer would need, on average, 40 hours of work by a programmer (at a cost of approximately \$50 per hour) to develop a program that will extract the necessary data from its systems. The total one-time cost to all issuers for developing a program to extract the necessary data will be approximately \$4.6 million, with an average cost of approximately \$2,000 per issuer.

For filings subject to review, states with effective rate review programs may use the data submissions in their reviews; however, this is not expected to increase review costs.

Based on comments received and discussions with issuers and states, we have made changes to the proposed template to address concerns that have been raised. We have both removed data elements from the uniform rate review template and identified information that will be optional in the first two years of applicability. We estimate that through these changes we have reduced the number of required data elements by approximately 45 percent. States may collect additional information above this baseline. We expect that the unified rate review template will not significantly increase the burden on states or industry; rather, the data requested in the template will assist states and industry in complying with the market rules.

In addition, the final rule gives states with effective rate review programs the discretion to choose whether to incorporate the unified rate review template in their rate review processes or whether to use their own rate review templates. Issuers in states with effective rate review programs that do not require the federal template will still be required to submit information about all rate increases to CMS on the template.

TABLE V.1—ANNUAL REPORTING, RECORDKEEPING AND DISCLOSURE BURDEN*

Regulation Section(s)	Number of respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting (\$)	Total labor cost of reporting (\$)	Total capital/maintenance costs (\$)	Total cost (\$)
Age Ratio, Tobacco Ratio, Rating areas, Family Tier, Small Group Market Premium, Age rating curve: § 147.103; Risk Pool Merger: § 156.80 (c)	1	8	1	8	35	279	0	279
Age curve (§ 147.102(e)) ...	1	1	123	123	194	24,000	0	24,000

TABLE V.1—ANNUAL REPORTING, RECORDKEEPING AND DISCLOSURE BURDEN*—Continued

Regulation Section(s)	Number of respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting (\$)	Total labor cost of reporting (\$)	Total capital/maintenance costs (\$)	Total cost (\$)
Geographical Rating Area (§ 147.102(b)) ...	1	1	32	32	51	1,600	0	1,600
Rate Increase Disclosure and Review (§ 154.215, § 154.301)**	2,294	7,650	11	84,150	225	19,000,000	0	19,000,000
Total				84,313		19,025,879		19,025,879

* Not included in this table is a 4.6 million upfront burden related to rate increase disclosures.
 ** Of the \$19 million labor cost of reporting, only \$16.3 million is attributable to this rule.

We have submitted an information collection request to OMB for review and approval of the ICRs contained in this final rule. The requirements are not effective until approved by OMB and assigned a valid OMB control number.

VI. Regulatory Impact Analysis

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

A. Summary

As stated earlier in this preamble, this final rule implements the Affordable Care Act’s requirements on health insurance coverage related to fair health insurance premiums, guaranteed availability, guaranteed renewability, single risk pools, and catastrophic plans. These provisions are generally effective for plan or policy years beginning on or after January 1, 2014. In addition, this final rule amends the standards for health insurance issuers and states regarding reporting, utilization, and collection of data under the rate review program.

CMS has crafted this final rule to implement the protections intended by Congress in an economically efficient manner. We have examined the effects of this final rule as required by Executive Order 13563 (76 FR 3821, January 21, 2011), Executive Order 12866 (58 FR 51735, September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), 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)). In accordance with OMB Circular A–4, CMS has quantified the benefits, costs, and transfers where possible, and has also provided a qualitative discussion of the benefits,

costs, and transfers that may stem from this final rule.

B. Executive Orders 13563 and 12866

Executive Order 12866 (58 FR 51735) 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). Executive Order 13563 (76 FR 3821, January 21, 2011) is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866.

Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a final rule—(1) Having an annual effect on the economy of \$100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects (for example, \$100 million or more in any 1 year), and a “significant” regulatory action is subject to review by the OMB. OMB has designated this final rule as a

“significant regulatory action.” Even though it is uncertain whether it is likely to have economic impacts of \$100 million or more in any one year, CMS has provided an assessment of the potential costs, benefits, and transfers associated with this final regulation.

1. Need for Regulatory Action

Sections 1302(e) and 1312(c) of the Patient Protection and Affordable Care Act (Affordable Care Act), and sections 2701, 2702, and 2703 of the Public Health Service Act (PHS Act), as added and amended by the Affordable Care Act, create certain standards related to fair health insurance premiums, guaranteed availability, guaranteed renewability, risk pools, and catastrophic plans applicable to non-grandfathered health insurance coverage starting in 2014. These final regulations provide the necessary guidance to implement these important consumer protections. The current individual and small group health insurance markets generally are viewed as dysfunctional, placing consumers at a disadvantage due to the high cost of health insurance coverage, resulting from factors such as lack of competition, adverse selection, and limited transparency. In addition to affordability concerns, many people have difficulty finding and enrolling in coverage options. If employer-based coverage is not available, a person may find that affordable individual market coverage is not available due to medical underwriting. The provisions of this final rule, combined with other provisions in the Affordable Care Act, will improve the functioning of both the individual and the small group markets and make insurance affordable and accessible to millions of Americans who currently do not have affordable options available to them. In addition, this final rule would amend the existing rate review standards to reflect the new market conditions in 2014.

2. Summary of Impacts

In accordance with OMB Circular A-4, Table VI.1 below depicts an accounting statement summarizing CMS’s assessment of the benefits, costs, and transfers associated with this regulatory action. The period covered by the RIA is 2013–2017.

CMS anticipates that the provisions of these final regulations would ensure increased access and improve affordability of health insurance coverage in the individual and small

group markets. Individuals who are currently unable to obtain affordable coverage because of their medical history, health status, gender, or age will be able to obtain such coverage under these final rules, along with other provisions of the Affordable Care Act, leading to an increase in the number of people with health insurance. Newly insured individuals and individuals with expanded coverage will have increased access to health care, improving utilization of preventive care

and health outcomes and protection from the risk of catastrophic medical expenditures, leading to financial security. In addition, an issuer seeking a rate increase will submit data and documentation about the rate increase using a unified rate review template, which will provide CMS the data necessary for monitoring rate increases. In accordance with Executive Order 12866, CMS expects that the benefits of this final regulatory action justify the costs.

TABLE VI.1—ACCOUNTING TABLE

Qualitative: Benefits:					
* Increase in enrollment in the individual and small group market leading to improved access to health care for the previously uninsured, especially individuals with medical conditions, which will result in improved health and protection from the risk of catastrophic medical expenditures					
* A common marketing standard covering the entire insurance market, reducing adverse selection, improving market oversight and competition and reducing search costs for consumers.					
* Decrease in administrative costs for issuers due to elimination of medical underwriting and coverage exclusions.					
* Prevent duplication of effort for rate review filings subject to review by setting forth a unified rate review template for all issuers offering health insurance coverage in the small group or individual markets.					
* Provide state departments of insurance with more capacity to conduct meaningful rate review and approval of products sold inside and outside an Exchange by using a unified rate review template.					
* Extend the availability and affordability of student health coverage as a transitional policy.					
Costs	Estimate	Year dollar	Discount rate	Period covered	
Annualized Monetized (\$/year)	\$ 17.3 million	2012	7%	2013–2017	
	\$17.3 million	2012	3%	2013–2017	

Administrative costs related to submission of data by issuers seeking rate increases below the rate review threshold, one-time fixed costs to issuers related to rate review data extraction, disclosure of state rating requirements and costs incurred by states choosing to establish rating areas and age rating curves.

Qualitative:

- * Additional costs incurred by issuers to comply with provisions in the final rule.
- * Costs related to possible increases in utilization of health care for the newly insured.
- * Costs incurred by states for disclosure of rate increases, if applicable.

Transfers:

Qualitative:

- * Lower rates for individuals in the individual and small group market who are older and/or in relatively poor health, and women; and potentially higher rates for some young men which will be mitigated by provisions such as premium tax credits, risk stabilization programs, access to catastrophic plans, and the minimum essential coverage provision.
- * Reduction in uncompensated care for providers who treat the uninsured and increase in payments from issuers.
- * Decrease in out-of-pocket expenditures by the newly insured and increase in health care spending by issuers, which may be more than offset by an increase in premium revenue.

3. Anticipated Benefits, Costs and Transfers

In developing this final rule, CMS carefully considered its potential effects including both costs and benefits. One commenter suggested providing additional quantitative estimates of benefits, costs and transfers. Because of data limitations, CMS did not attempt to quantify all of the benefits, costs, and transfers resulting from this final rule. Nonetheless, CMS was able to identify several potential impacts which are discussed qualitatively below.

There are diverse state laws and industry practices currently in place

that result in wide variation in premium rates (henceforth referred to as “rates”) and coverage for individual and group health insurance markets. Regarding the individual market, only five states have both guaranteed availability for at least some products and modified or pure community rating requirements, while in other states, issuers can deny health insurance coverage or charge higher premiums to people with medical conditions.²⁰ Currently, 11 states and

the District of Columbia have rate bands, which allow issuers to vary rates only within a certain range of the average rate, two states prohibit rating based on age, and five states prohibit rating based on tobacco use in the individual market.²¹ In the small group market, 36 states and the District of Columbia have rate bands, 12 states have community rating requirements, two states do not allow rating based on age and 16 do not allow rating based on tobacco use. In many states, women are

²⁰ GAO, Private Health Insurance: Estimates of Individuals with Preexisting Conditions Range from 36 Million to 122 Million, GAO-12-439, March 2012.

²¹ Kaiser Family Foundation, Focus on Health Reform: Health Insurance Market Reforms: Rate Restrictions, June 2012.

charged higher premiums than men: Only 14 states prohibit gender rating in the individual market while 15 states do not allow gender rating in the small group market. Of the states that prohibit gender rating in the individual market, only three of those states require maternity coverage in all policies, meaning that women in the other states can be charged additional premiums for maternity coverage.

Currently, only five states have guaranteed availability in the individual market. Studies show that 48 states require guaranteed renewability in the small group market while all 50 states provide some level of guaranteed renewability in the individual market. In addition, HIPAA already provides guaranteed renewability of coverage to individuals and employers, irrespective of state law. Therefore, this provision is not expected to have any significant effect in that regard.

Starting in 2014, issuers in the individual and small group markets will only be allowed to vary rates based on age and tobacco use within specified ranges, family size, and geography (the fair health insurance premium requirement). Issuers generally will accept every individual and employer that applies for health insurance coverage (the guaranteed availability requirement), and, subject to certain exceptions, must also renew or continue health insurance coverage at the option of the plan sponsor or individual (the guaranteed renewability requirement). In addition, issuers must have single risk pools for each of the individual and small group markets, or a single merged risk pool, if a state so elects, which will include all individuals enrolled in non-grandfathered plans in the applicable market (the single risk pool requirement).

The provisions of the final rule will affect the characteristics of enrollees, enrollment, and premium rates in the individual and small group markets. In addition, several other related provisions of the Affordable Care Act that will be effective in 2014, such as establishment of the Exchanges, premium tax credits, and the minimum essential coverage provision, will improve access to and affordability of health insurance coverage. The Congressional Budget Office (CBO) estimates that, by 2017, the number of uninsured will be reduced by 27 million.²² Therefore, it is appropriate to take into consideration the effect of all these provisions in this analysis, even

though not all of them are the focus of this final rule. It should be noted that the impact of these provisions may vary between states, because of the differences in current regulatory frameworks.

A few commenters referred to actuarial studies that include estimates of premium changes in different states and markets.²³ Actuarial studies that conclude that premiums will increase for certain markets or age groups generally do not take into account all the provisions of the Affordable Care Act and factors that would affect premiums and also assume that the risk pool will worsen as a result of these provisions. However, we, along with CBO, anticipate that the risk pool will improve. Different provisions of the Affordable Care Act can have opposing effects on premiums. Some of the other provisions, in addition to the ones mentioned above, that will also affect premiums are essential health benefits, medical loss ratio requirements, risk adjustment, temporary risk corridors and the transitional reinsurance programs. There are also factors such as benefit improvements; competition among issuers in the Exchanges to be the second lowest cost silver plan; migration of current membership to more efficient, lower premium plans due to increased transparency; new plan design offerings such as Accountable Care Organizations and issuers re-contracting with providers to obtain lower unit prices due to reduction in uncompensated or charity care. In addition, studies that focus on premiums do not take into account the decrease in out-of-pocket costs for consumers. According to a study, in 2010, 49 million working-age adults spent at least 10 percent of their income on health insurance premiums and out-of-pocket costs and 20 million working-age adults' out-of-pocket costs were so high compared to their income that they were effectively underinsured.²⁴ Increased access will lead to a decrease in out-of-pocket costs for these individuals.

This final rule directs that health insurance issuers use a unified rate review template, as specified by the Secretary, to report information about a

²³ For example, studies on the Alaska Individual Market by Lewis & Ellis, Indiana Individual Market by Milliman, Maine Small Group Market by Jonathan Gruber & Gorman Actuarial, LLC and Wisconsin Small Group Market by Jonathan Gruber & Gorman Actuarial, LLC.

²⁴ Sara R. Collins, *Invited Testimony: Premium Tax Credits Under The Affordable Care Act: How They Will Help Millions Of Uninsured And Underinsured Americans Gain Affordable, Comprehensive Health Insurance*, The Commonwealth Fund, October 27, 2011.

proposed rate increase to CMS. States will continue to have the authority to collect additional information above this baseline to conduct more thorough reviews or rate monitoring.

a. Benefits

In 2011, 48.6 million people in the United States were uninsured.²⁵ In addition, an estimated 29 million adults were underinsured in 2010.²⁶ Studies have shown that people without health insurance have reduced access to health care, higher out-of-pocket costs, higher mortality rates and receive less preventive care.²⁷ Uninsured and underinsured people are also more likely to be unable to pay their medical bills, have medical debt, and experience financial difficulties.

The provisions of this final rule and other changes implemented by the Affordable Care Act will increase enrollment in the individual and small group markets. According to CBO, there will be approximately 26 million enrollees in Exchange coverage by 2017. CBO estimates that, by 2017, the number of uninsured will be reduced by 27 million.²⁸ Access to catastrophic plans is likely to further increase the number of insured. The provisions of this final rule will also preserve affordability and availability of student health insurance coverage. Newly insured individuals and individuals with expanded coverage will have

²⁵ Source: U.S. Census Bureau, *Current Population Survey, 2012 Annual Social and Economic Supplement*, Table HI01. Health Insurance Coverage Status and Type of Coverage by Selected Characteristics: 2011.

²⁶ Cathy Schoen, Michelle M. Doty, Ruth H. Robertson and Sara R. Collins, *Affordable Care Act Reforms Could Reduce The Number Of Underinsured US Adults by 70 Percent*, Health Affairs, 30, no.9 (2011):1762-1771.

²⁷ The Henry J. Kaiser Family Foundation, *The Uninsured: A Primer, Key Facts About Americans Without Health Insurance*, Washington, DC, 2011, citing a number of studies on the effects of being uninsured; ASPE, *The Value of Health Insurance: Few of the Uninsured Have Adequate Resources to Pay Potential Hospital Bills*, 2011 (<http://aspe.hhs.gov/health/reports/2011/valueofinsurance/rb.shtml>); Sara R. Collins, Ruth Robertson, Tracy Garber, and Michelle M. Doty, *The Income Divide in Health Care: How the Affordable Care Act Will Help Restore Fairness to the U.S. Health System*, The Commonwealth Fund, February 2012; J. Doyle, *Health Insurance, Treatment and Outcomes: Using Auto Accidents as Health Shocks*, *Review of Economics and Statistics*, 87(2): 256-270, 2005; S. Dorn, *Uninsured and Dying Because of It: Updating the Institute of Medicine Analysis on the Impact of Uninsurance on Mortality*, Urban Institute, 2008; Cathy Schoen, Michelle M. Doty, Ruth H. Robertson and Sara R. Collins, *Affordable Care Act Reforms Could Reduce The Number Of Underinsured US Adults by 70 Percent*, Health Affairs, 30, no.9 (2011):1762-1771.

²⁸ "CBO's February 2013 Estimate of the Effects of the Affordable Care Act on Health Insurance Coverage," Congressional Budget Office, February 2013.

²² "CBO's February 2013 Estimate of the Effects of the Affordable Care Act on Health Insurance," Congressional Budget Office, February 2013.

access to better health care and experience a reduction in out-of-pocket costs. Ample research demonstrates that access to insurance coverage improves utilization of preventive care, improves health outcomes, and creates less financial debt, which would lead to better financial security.²⁹ The State of Massachusetts passed similar health reforms in 2006, and now has the lowest uninsured rate in the country. In 2011, only 3.4 percent of Massachusetts residents were uninsured.³⁰ This has resulted in increased access to health care, including preventive care and fewer individuals with high out-of-pocket spending.³¹

Research shows that individuals in relatively poor health experience difficulty obtaining health insurance coverage. This results in lack of adequate access to health care and higher out-of-pocket expenses for these individuals. According to a recent study by U.S. Government Accountability Office (GAO), between 36 million and 122 million adults age 19 to 64 years old (or between 20 and 66 percent of the adult population) have medical conditions that could result in issuers denying them coverage or charging higher premiums.³² Of these, an estimated 88 to 89 percent live in states that do not have insurance protections provided by the fair health insurance

premium and guaranteed availability provisions of the Affordable Care Act. The GAO study estimated that health care expenditures for adults with medical conditions are, on average, between \$1,504 and \$4,844 more per year than for other adults. Similarly, a study by HHS found that there are between 50 million and 129 million non-elderly individuals with a medical condition, including between 4 and 17 million children under age 18, and up to 25 million of these adults and children are uninsured.³³ A study found that, in 2010, 35 percent of nonelderly adults who shopped for health insurance coverage in the individual market were denied coverage or received coverage exclusions for medical conditions.³⁴ The Affordable Care Act's provision on guaranteed availability will prohibit issuers from denying coverage to individuals based on their health status or any other factor, and the provision on fair insurance premiums will prevent issuers from charging a higher premium to individuals based on health status. The final rule will ensure that individuals who would have been denied coverage or charged excessively high premium rates, for reasons such as medical conditions or high expected medical costs, will now be able to obtain health insurance at an affordable cost. In addition, young adults and people for whom coverage would otherwise be unaffordable will have access to a catastrophic plan that will have a lower premium, protect against high out-of-pocket costs, and cover recommended preventive services without cost sharing.

The provisions of this final rule and other changes implemented by the Affordable Care Act will increase enrollment in the individual market. An analysis by CBO and the staff of the Joint Committee on Taxation (JCT)³⁵ estimated that the characteristics of enrollees in the individual market will be significantly different, especially due to the addition of people who would have been uninsured in the absence of the Affordable Care Act. CBO and JCT

estimated that relatively more new enrollees in the individual market would be younger and healthier and likely to use less medical care, and the addition of new enrollees would result in average premium rates in the market being 7 to 10 percent lower in 2016 compared to what they would have been in the absence of the Affordable Care Act, all else held constant. According to CBO and JCT, the characteristics of people in the small group market would change slightly, and projected premium rate changes could decrease up to 1 percent.

Currently, health insurance issuers may maintain several blocks of business, or "pools," for their individual and small group market business. Most states place some restrictions on the number of small group blocks of business. However, the individual market generally has not been subject to similar restrictions. In the past, some issuers used separate pools to segment risks, resulting in large rate increases for less-healthy enrollees. A single risk pool will tend to lower rates for relatively unhealthy participants in the individual market by including younger, healthier individuals in the pool and ensuring that newer and more long-term policyholders are pooled together. In the small group market, a single risk pool will stabilize rates.

The guaranteed availability provision may result in some adverse selection—individuals with poor health who would have been denied coverage before in some states will now be able to obtain health insurance. However, according to CBO and JCT,³⁶ adverse selection will be mitigated principally by the minimum essential coverage provision and the availability of premium tax credits, which will make insurance affordable for millions of Americans for whom it is currently unaffordable. Other factors such as fixed open enrollment periods will also help to mitigate adverse selection. The Affordable Care Act also establishes a transitional reinsurance program, a temporary risk corridor program, and a permanent risk adjustment program, which will provide payments to issuers providing coverage to high-risk individuals, to mitigate the potential effects of adverse selection. These programs will provide payment stability to issuers and reduce uncertainty in insurance risk in the individual market and in the small

²⁹T. Gross and Notowidigdo, Health Insurance and the Consumer Bankruptcy Decision: Evidence from Expansions of Medicaid, *Journal of Public Economics*, 95(7–8):767–778, 2011; J. Doyle, Health Insurance, Treatment and Outcomes: Using Auto Accidents as Health Shocks, *Review of Economics and Statistics*, 87(2): 256–270, 2005; Amy Finkelstein, et al., The Oregon Health Insurance Experiment: Evidence from the First Year, National Bureau of Economic Research Working Paper No. 17190, July 2011; Institute of Medicine, Care without coverage: Too little, too late, National Academies Press, 2002; J. Ayanian et al., Unmet Health Needs of Uninsured Adults in the United States, *JAMA* 284(16):2061–9, 2000; Andrew P. Wilper, et al., Health Insurance and Mortality in US Adults, *American Journal of Public Health*, 99(12) 2289–2295, 2009; S. Dorn, Uninsured and Dying Because of It: Updating the Institute of Medicine Analysis on the Impact of Uninsurance on Mortality, Urban Institute, 2008; Jack Hadley, Insurance Coverage, Medical Care Use, and Short-term Health Changes Following an Unintentional Injury or the Onset of a Chronic Condition, *JAMA*. 2007;297(10):1073–1084. doi: 10.1001/jama.297.10.1073; K. Cook et al., Does major illness cause financial catastrophe?, *Health Services Research* 45, no. 2, 2010.

³⁰Source: U.S. Census Bureau, Current Population Survey, 2012 Annual Social and Economic Supplement, Table HI06. Health Insurance Coverage Status by State for All People: 2011.

³¹Kaiser Family Foundation, Focus on Health Reform: Massachusetts Health Care Reform: Six Years Later, June 2012.

³²GAO, Private Health Insurance: Estimates of Individuals with Preexisting Conditions Range from 36 Million to 122 Million. GAO–12–439, March 2012.

³³ASPE, At Risk: Preexisting Conditions Could Affect 1 in 2 Americans: 129 Million People Could Be Denied Affordable Coverage Without Health Reform, November 2011.

³⁴Sara R. Collins, Invited Testimony: Premium Tax Credits Under The Affordable Care Act: How They Will Help Millions Of Uninsured And Underinsured Americans Gain Affordable, Comprehensive Health Insurance, The Commonwealth Fund, October 27, 2011.

³⁵Congressional Budget Office, Letter to Honorable Evan Bayh, providing an Analysis of Health Insurance Premiums Under the Patient Protection and Affordable Care Act, November 30, 2009.

³⁶Congressional Budget Office, Letter to Honorable Evan Bayh providing An Analysis of Health Insurance Premiums Under the Patient Protection and Affordable Care Act, November 30, 2009.

group market, in the case of the permanent risk adjustment program.

Administrative costs for issuers will be lowered because of the elimination of medical underwriting and the ban on coverage exclusions. Costs should decrease for processing new applications for coverage and implementing the coverage exclusions in the individual and small group markets. This, in turn, could contribute to lower premium rates.

The final rule also requires all health insurance issuers marketing group or individual health insurance coverage to comply with the same marketing standards as issuers offering QHPs within the Exchanges. This minimizes the potential for the adverse selection that could result if plans sold through Exchanges were subject to different marketing standards from plans sold outside of the Exchanges. A common standard covering the entire insurance market will also ensure consistency in market oversight, increase competition, and reduce search costs for consumers.³⁷

The amendments to the rate review standards will help avoid significant issuer duplication of effort for filings subject to review by using the same standardized template for all issuers offering health insurance coverage in the small group or individual markets. Additionally, the use of the unified rate review template will provide the necessary information to conduct the review and approval of products sold inside and outside an Exchange, monitor rates to detect patterns that could signal market disruption, and oversee the market-wide rules.

b. Costs

Under the final rule, issuers will likely incur some one-time, fixed costs in order to comply with the provisions of this final rule, including administrative expenditures for systems and software updates and changes in marketing. In addition, states may incur costs in order to establish geographic rating areas and uniform age rating curves. We do not anticipate that many states will establish their own age curve: Only one state has indicated that it would establish its own age rating curve. As discussed in section V. of the preamble, we estimate that a state would incur approximately \$24,000 in costs to establish its own age curve. The final rule provides that a state's rating areas must be based on the geographic

divisions of counties, three-digit zip codes, or MSAs and non-MSAs and will be presumed adequate if either of the following conditions are met: (1) As of January 1, 2013, the state had established by law, rule, regulation, bulletin, or other executive action uniform geographic rating areas for the entire state; or (2) After January 1, 2013, the state establishes by law, rule, regulation, bulletin, or other executive action for the entire state no more geographic rating areas than the number of MSAs in the state plus one. States have the option to seek approval from CMS of a greater number of rating areas as long as the areas are based on counties, three-digit zip codes, or MSAs and non-MSAs. We anticipate that few states will incur costs related to establishing rating areas and estimate that related costs will be approximately \$1,600 each for those that do.

In addition to these administrative costs, insurance coverage can lead to increased utilization of health services for individuals who become newly insured. While a portion of this increased utilization may be economically inefficient, studies that estimated the effects of Medicare found that the cost of this inefficiency is likely more than offset by the benefit of risk reduction.^{38 39}

The final rule also directs states to provide information to CMS about their rating and risk pooling practices in several key areas, as applicable. They include: Age and tobacco rating factors, age rating curves, family tier structure, composite rating in the small group market, geographical rating areas, and combined individual and small group market risk pools. As discussed in section V. of the preamble, we estimate a total burden of approximately \$279 for a state to submit information in all seven areas. This estimate does not include the costs of establishing age curves and geographical rating areas, which are discussed above.

Health insurance issuers seeking rate increases below the subject to review threshold will submit data using the unified rate review template and incur administrative costs to prepare and submit the data. As discussed in section V. of the preamble, we estimate that the increase in administrative costs for all issuers seeking rate increases below the review threshold will be approximately

\$16 million, with an average of \$7,000 per issuer. It should be noted that the vast majority of states currently require all rate increases to be filed and that administrative efficiencies can be gained by avoiding significant issuer duplication of effort for filings subject to review by using the same standardized template for all issuers offering health insurance coverage in the small group or individual markets across all states, and because the vast majority of states currently require all rate increases to be filed. These efficiencies are not quantified in this rule.

Additionally, issuers seeking rate increases may need to adjust their systems to provide the data required in the standardized template format. The total one-time cost to all issuers for developing a program to extract the necessary data from their systems is estimated at approximately \$4.6 million, with an average cost of approximately \$2,000 per issuer.

For filings subject to review, states with effective rate review programs may use the data submissions in their reviews; however, it is not expected to increase review costs.

c. Transfers

As discussed elsewhere in the preamble, most aspects of rating methodologies today are left to the discretion of health insurance issuers, subject to oversight by the states. In most states, issuers may vary premium rates based on a number of factors such as age, health status, and gender. In 2010, 60 percent of non-elderly adults who shopped for insurance coverage in the individual market had difficulty finding affordable coverage.⁴⁰ Also, as a result of current gender rating, premium rates for women are significantly higher than those for men. According to a study by the National Women's Law Center, 92 percent of best-selling plans currently practice gender rating.⁴¹ The provision of fair premiums will allow issuers to vary rates based on only a limited number of factors and within specified ranges. Since rating based on gender and health will no longer be

³⁷ Sara R. Collins, Invited Testimony: Premium Tax Credits Under The Affordable Care Act: How They Will Help Millions Of Uninsured And Underinsured Americans Gain Affordable, Comprehensive Health Insurance, The Commonwealth Fund, October 27, 2011.

⁴⁰ National Women's Law Center, Turning to Fairness: Insurance discrimination against women today and the Affordable Care Act, Washington, DC, March 2012.

³⁷ R. Cebul et al., Unhealthy Insurance Markets: Search Frictions and the Cost and Quality of Health Insurance, *American Economic Review* 101(5): 1842–1847, 2011.

³⁸ Finkelstein, A, McKnight R: "What Did Medicare Do? The Initial Impact of Medicare on Mortality and Out Of Pocket Medical Spending " *Journal of Public Economics* 2008, 92:1644–1668.

³⁹ Finkelstein, A., "The Aggregate Effects of Health Insurance: Evidence from the Introduction of Medicare," *National Bureau of Economic Research Working Paper No. 11619*, Sept, 2005.

allowed, rates for some older, less healthy adults and women may decrease. While these rules could increase rates for younger, healthier adults and for some men, other factors will mitigate the effects of reformed rating practices, such as choices of and competition among plans on Exchanges, greater pooling of risks through the Exchanges, premium tax credits, the risk stabilization programs, access to catastrophic plans, and the minimum essential coverage provision.

As people who were previously uninsured obtain coverage, their out-of-pocket expenses are expected to decrease while the issuers' spending will increase, which is expected to be mitigated by an increase in premium collections. Expansion in health insurance coverage will also reduce the amount of uncompensated care for providers that treat the uninsured. Millions of people without health insurance now use health care services for which they do not fully pay, shifting the uncompensated cost of their care to health care providers, people who do have insurance (in the form of higher premiums), and state and local governments.⁴² Providers of uncompensated care try to recover the money by increasing the amounts charged to insurance companies, which results in higher premiums for individuals with private insurance. The cost of uncompensated care for the previously uninsured will be transferred from the providers (for example, hospitals and physicians), governmental programs and charitable organizations to the individuals and issuers of their health insurance coverage. Reduction in the number of uninsured would reduce the amount of uncompensated care and could lead, all else held equal, to a decrease in private health insurance rates.

C. Regulatory Alternatives

Under Executive Order 12866, CMS is required to consider alternatives to issuing rules and alternative regulatory approaches.

Under the final rule, all issuers in a state and market will use a uniform age rating curve. CMS considered the alternative of allowing issuers to set their own rating curve. Under the alternative, issuers would have more flexibility and might incur lower upfront, fixed costs (for example, systems and software updates) to comply with the final rule. A uniform

age rating curve, however, improves the accuracy of risk adjustment, provides for easier price comparisons between different plans, and simplifies identification of the second lowest cost silver plan for purposes of determining premium tax credits.

CMS also considered the alternatives of including a tobacco component for the rating curve and keeping the rating factor for tobacco use separate from the wellness program rules. These alternatives would reduce flexibility for the issuers with respect to rating for tobacco use and would provide no alternative to the tobacco surcharge which could discourage disclosure of tobacco use. Under the final rule, a health insurance issuer in the small group market may implement the tobacco use surcharge only in connection with a wellness program that effectively allows tobacco users to reduce their premiums to the level of non-tobacco users by participating in a tobacco cessation program or satisfying another reasonable alternative. This provision will help to alleviate underreporting of tobacco use and promote tobacco cessation strategies that improve health and reduce health care costs.

CMS believes that the provisions of this final rule strike the best balance of extending protections of the Affordable Care Act to consumers while preserving the availability of such coverage and minimizing market disruptions to the extent possible.

D. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires agencies that issue a rule to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. The RFA generally defines a "small entity" as—(1) A proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a nonprofit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000 (states and individuals are not included in the definition of "small entity"). CMS uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 to 5 percent.

As discussed in the Web Portal final rule published on May 5, 2010 (75 FR 24481), CMS examined the health insurance industry in depth in the Regulatory Impact Analysis we prepared for the final rule on establishment of the Medicare Advantage program (69 FR 46866, August 3, 2004). In that analysis

it was determined that there were few, if any, insurance firms underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) that fell below the size thresholds for "small" business established by the SBA (currently \$7 million in annual receipts for health issuers).⁴³

In addition, CMS used the data from Medical Loss Ratio (MLR) annual report submissions for the 2011 MLR reporting year to develop an estimate of the number of small entities that offer comprehensive major medical coverage. These estimates may overstate the actual number of small health insurance issuers that would be affected, since they do not include receipts from these companies' other lines of business. It is estimated that there are 22 small entities each with less than \$7 million in earned premiums that offer individual or group health insurance coverage and would therefore be subject to the requirements of this final regulation. These small entities account for less than five percent of the estimated 466 companies offering health insurance coverage in the individual or group markets in different states that would be affected by the provisions of this rule. Thirty six percent of these small entities belong to holding groups, and many if not all of these small entities are likely to have other lines of business that would result in their revenues exceeding \$7 million. For these reasons, CMS expects that this final rule will not affect small issuers.

The requirements in this final rule may affect health insurance premiums in the small group market. We expect that many employers that purchase health insurance coverage in the small group market would meet the SBA standard for small entities. As mentioned earlier in the impact analysis, the impact on premiums is likely to be small and may even lead to lower rates in the small group market. CMS will monitor premium changes in the small group market through the rate review program.

E. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act (UMRA) of 1995 requires that agencies assess anticipated costs and benefits before issuing any final rule that includes a federal mandate that could result in any expenditure in any one year by state, local or tribal governments, in the

⁴² Families USA, Hidden Health Tax: Americans Pay a Premium (Washington, DC: Families USA, 2009) (<http://familiesusa2.org/assets/pdfs/hidden-health-tax.pdf>).

⁴³ Table of Small Business Size Standards Matched to North American Industry Classification System Codes, effective March 26, 2012, U.S. Small Business Administration, available at www.sba.gov.

aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. In early 2013, that threshold level is approximately \$139 million.

UMRA does not address the total cost of a final rule. Rather, it focuses on certain categories of cost, mainly those “federal mandate” costs resulting from—(1) imposing enforceable duties on state, local, or tribal governments, or on the private sector; or (2) increasing the stringency of conditions in, or decreasing the funding of, state, local, or tribal governments under entitlement programs.

This final rule gives state governments the option to establish rating areas within the state and uniform age rating curves. There are no mandates on local or tribal governments. State governments may incur administrative cost related to the option of establishing rating areas and uniform age rating curves. However, if the state government does not act, CMS will establish the rating areas and uniform age rating curve in that state. State governments will also incur administrative costs related to disclosure of rating and pooling requirements to CMS, which are estimated to be \$279 per state. The private sector (for example, health insurance issuers) will incur administrative costs related to the implementation of the provisions in this final rule. This final rule does not impose an unfunded mandate on local or tribal governments. However, consistent with policy embodied in UMRA, this final rule has been designed to be low-burden alternative for state, local and tribal governments, and the private sector while achieving the objectives of the Affordable Care Act.

F. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications.

As discussed earlier in the preamble, states are the primary regulators of health insurance coverage. States will continue to apply state laws regarding health insurance coverage. However, if any state law or requirement prevents the application of a federal standard, then that particular state law or requirement would be preempted. If CMS determines that a state does not meet the criteria for an effective rate review program, then CMS will review a rate increase subject to review to determine whether it is unreasonable. If

a state does meet the criteria, then CMS will adopt that state’s determination of whether a rate increase is unreasonable. States will continue to apply state law requirements regarding rate and policy filings. State requirements that are more stringent than the federal requirements would be not be preempted by this final rule. Accordingly, states have significant latitude to impose requirements with respect to health insurance coverage that are more restrictive than the federal law.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have Federalism implications or limit the policymaking discretion of the states, CMS has engaged in efforts to consult with and work cooperatively with affected states, including consulting with National Association of Insurance Commissioners.

Throughout the process of developing this final rule, CMS has attempted to balance the states’ interests in regulating health insurance issuers and Congress’s intent to provide uniform protections to consumers in every state. By doing so, it is CMS’s view that it has complied with the requirements of Executive Order 13132. Under the requirements set forth in section 8(a) of Executive Order 13132, and by the signatures affixed to this rule, HHS certifies that the CMS Center for Consumer Information and Insurance Oversight has complied with the requirements of Executive Order 13132 for the attached final rule in a meaningful and timely manner.

G. Congressional Review Act

This final rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801, *et seq.*), which specifies that before a rule can take effect, the federal agency promulgating the rule shall submit to each House of the Congress and to the Comptroller General a report containing a copy of the rule along with other specified information, and has been transmitted to Congress and the Comptroller General for review.

List of Subjects

45 CFR Part 144

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, and State regulation of health insurance.

45 CFR Part 150

Administrative practice and procedure, Health care, Health insurance, Penalties, Reporting and recordkeeping requirements.

45 CFR Part 154

Administrative practice and procedure, Claims, Health care, Health insurance, Health plans, Penalties, Reporting and recordkeeping requirements.

45 CFR Part 156

Administrative practice and procedure, Advertising, Advisory committees, Brokers, Conflict of interest, Consumer protection, Grant programs-health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Loan programs-health, Organization and functions (Government agencies), Medicaid, Public assistance programs, Reporting and recordkeeping requirements, Safety, State and local governments, Sunshine Act, Technical Assistance, Women, and Youth.

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR parts 144, 147, 150, 154, and 156 as set forth below:

PART 144—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

■ 1. The authority citation for part 144 continues to read as follows:

Authority: Secs. 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg-63, 300gg-91, and 300gg-92).

■ 2. Amend § 144.101 by revising paragraphs (d)(1) and (d)(2) to read as follows:

§ 144.101 Basis and Purpose.

* * * * *
(d) * * *

(1) States that fail to substantially enforce one or more provisions of part 146 concerning group health insurance, one or more provisions of part 147 concerning group or individual health insurance, or the requirements of part 148 of this subchapter concerning individual health insurance.

(2) Insurance issuers in States described in paragraph (d)(1) of this section.

* * * * *

■ 3. Revise § 144.102 to read as follows:

§ 144.102 Scope and applicability.

(a) For purposes of 45 CFR parts 144 through 148, all health insurance coverage is generally divided into two markets—the group market and the individual market. The group market is further divided into the large group market and the small group market.

(b) The protections afforded under 45 CFR parts 144 through 148 to individuals and employers (and other sponsors of health insurance offered in connection with a group health plan) are determined by whether the coverage involved is obtained in the small group market, the large group market, or the individual market.

(c) Coverage that is provided to associations, but not related to employment, and sold to individuals is not considered group coverage under 45 CFR parts 144 through 148. If the coverage is offered to an association member other than in connection with a group health plan, or is offered to an association's employer-member that is maintaining a group health plan that has fewer than two participants who are current employees on the first day of the plan year, the coverage is considered individual health insurance coverage for purposes of 45 CFR parts 144 through 148. The coverage is considered coverage in the individual market, regardless of whether it is considered group coverage under state law. If the health insurance coverage is offered in connection with a group health plan as defined at 45 CFR 144.103, it is considered group health insurance coverage for purposes of 45 CFR parts 144 through 148.

(d) Provisions relating to CMS enforcement of parts 146, 147, and 148 are contained in part 150 of this subchapter.

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 4. The authority citation for part 147 continues to read as follows:

Authority: Secs. 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg-63, 300gg-91, and 300gg-92), as amended.

■ 5. A new § 147.102 is added to part 147 to read as follows:

§ 147.102 Fair health insurance premiums.

(a) *In general.* With respect to the premium rate charged by a health insurance issuer for health insurance coverage offered in the individual or small group market—

(1) The rate may vary with respect to the particular plan or coverage involved only by determining the following:

(i) Whether the plan or coverage covers an individual or family.

(ii) Rating area, as established in accordance with paragraph (b) of this section.

(iii) Age, except that the rate may not vary by more than 3:1 for like individuals of different age who are age 21 and older and that the variation in rate must be actuarially justified for individuals under age 21, consistent with the uniform age rating curve under paragraph (e) of this section. For purposes of identifying the appropriate age adjustment under this paragraph and the age band under paragraph (d) of this section applicable to a specific enrollee, the enrollee's age as of the date of policy issuance or renewal must be used.

(iv) Subject to section 2705 of the Public Health Service Act and its implementing regulations (related to prohibiting discrimination based on health status and programs of health promotion or disease prevention) as applicable, tobacco use, except that such rate may not vary by more than 1.5:1 and may only be applied with respect to individuals who may legally use tobacco under federal and state law. For purposes of this section, tobacco use means use of tobacco on average four or more times per week within no longer than the past 6 months. This includes all tobacco products, except that tobacco use does not include religious or ceremonial use of tobacco. Further, tobacco use must be defined in terms of when a tobacco product was last used.

(2) The rate must not vary with respect to the particular plan or coverage involved by any other factor not described in paragraph (a)(1) of this section.

(b) *Rating area.* (1) A state may establish one or more rating areas within that state, as provided in paragraphs (b)(3) and (b)(4) of this section, for purposes of applying this section and the requirements of title XXVII the Public Health Service Act and title I of the Patient Protection and Affordable Care Act.

(2) If a state does not establish rating areas as provided in paragraphs (b)(3) and (b)(4) of this section or provide information on such rating areas in accordance with § 147.103, or CMS determines in accordance with paragraph (b)(5) of this section that a state's rating areas under paragraph (b)(4) of this section are not adequate, the default will be one rating area for each metropolitan statistical area in the state and one rating area comprising all

non-metropolitan statistical areas in the state, as defined by the Office of Management and Budget.

(3) A state's rating areas must be based on the following geographic boundaries: Counties, three-digit zip codes, or metropolitan statistical areas and non-metropolitan statistical areas, as defined by the Office of Management and Budget, and will be presumed adequate if either of the following conditions are satisfied:

(i) The state established by law, rule, regulation, bulletin, or other executive action uniform rating areas for the entire state as of January 1, 2013.

(ii) The state establishes by law, rule, regulation, bulletin, or other executive action after January 1, 2013 uniform rating areas for the entire state that are no greater in number than the number of metropolitan statistical areas in the state plus one.

(4) Notwithstanding paragraph (b)(3) of this section, a state may propose to CMS for approval a number of rating areas that is greater than the number described in paragraph (b)(3)(ii) of this section, provided such rating areas are based on the geographic boundaries specified in paragraph (b)(3) of this section.

(5) In determining whether the rating areas established by each state under paragraph (b)(4) of this section are adequate, CMS will consider whether the state's rating areas are actuarially justified, are not unfairly discriminatory, reflect significant differences in health care unit costs, lead to stability in rates over time, apply uniformly to all issuers in a market, and are based on the geographic boundaries of counties, three-digit zip codes, or metropolitan statistical areas and non-metropolitan statistical areas.

(c) *Application of variations based on age or tobacco use.* With respect to family coverage under health insurance coverage, the rating variations permitted under paragraphs (a)(1)(iii) and (a)(1)(iv) of this section must be applied based on the portion of the premium attributable to each family member covered under the coverage.

(1) *Per-member rating.* The total premium for family coverage must be determined by summing the premiums for each individual family member. With respect to family members under the age of 21, the premiums for no more than the three oldest covered children must be taken into account in determining the total family premium.

(2) *Family tiers under community rating.* If a state does not permit any rating variation for the factors described in paragraphs (a)(1)(iii) and (a)(1)(iv) of this section, the state may require that

premiums for family coverage be determined by using uniform family tiers and the corresponding multipliers established by the state. If a state does not establish uniform family tiers and the corresponding multipliers, the per-member-rating methodology under paragraph (c)(1) of this section will apply in that state.

(3) *Application to small group market.* In the case of the small group market, the total premium charged to the group is determined by summing the premiums of covered participants and beneficiaries in accordance with paragraph (c)(1) or (c)(2) of this section, as applicable. Nothing in this section precludes a state from requiring issuers to offer, or an issuer from voluntarily offering, to a group premiums that are based on average enrollee amounts, provided that the total group premium is the same total amount derived in accordance with paragraph (c)(1) or (c)(2) of this section, as applicable.

(d) *Uniform age bands.* The following uniform age bands apply for rating purposes under paragraph (a)(1)(iii) of this section:

(1) *Child age bands.* A single age band for individuals age 0 through 20.

(2) *Adult age bands.* One-year age bands for individuals age 21 through 63.

(3) *Older adult age bands.* A single age band for individuals age 64 and older.

(e) *Uniform age rating curves.* Each state may establish a uniform age rating curve in the individual or small group market, or both markets, for rating purposes under paragraph (a)(1)(iii) of this section. If a state does not establish a uniform age rating curve or provide information on such age curve in accordance with § 147.103, a default uniform age rating curve specified in guidance by the Secretary will apply in that state which takes into account the rating variation permitted for age under state law.

(f) *Special rule for large group market.* If a state permits health insurance issuers that offer coverage in the large group market in the state to offer such coverage through an Exchange starting in 2017, the provisions of this section applicable to coverage in the small group market apply to all coverage offered in the large group market in the state.

(g) *Applicability date.* The provisions of this section apply for plan years (in the individual market, policy years) beginning on or after January 1, 2014.

(h) *Grandfathered health plans.* This section does not apply to grandfathered health plans in accordance with § 147.140.

■ 6. A new § 147.103 is added to part 147 to read as follows:

§ 147.103 State reporting.

(a) 2014. If a state has adopted or intends to adopt for the 2014 plan or policy year a standard or requirement described in this paragraph, the state must submit to CMS information about such standard or requirement in a form and manner specified in guidance by the Secretary no later than March 29, 2013. A state standard or requirement is described in this paragraph if it includes any of the following:

(1) A ratio narrower than 3:1 in connection with establishing rates for individuals who are age 21 and older, pursuant to § 147.102(a)(1)(iii).

(2) A ratio narrower than 1.5:1 in connection with establishing rates for individuals who use tobacco legally, pursuant to § 147.102(a)(1)(iv).

(3) Geographic rating areas, pursuant to § 147.102(b).

(4) In states that do not permit rating based on age or tobacco use, uniform family tiers and corresponding multipliers, pursuant to § 147.102(c)(2).

(5) A requirement that issuers in the small group market offer to a group premiums that are based on average enrollee amounts, pursuant to paragraph § 147.102(c)(3).

(6) A uniform age rating curve, pursuant to § 147.102(e).

(b) *Updates.* If a state adopts a standard or requirement described in paragraph (a) of this section for any plan or policy year beginning after the 2014 plan or policy year (or updates a standard or requirement that applies for the 2014 plan or policy year), the state must submit to CMS information about such standard in a form and manner specified in guidance by the Secretary.

(c) *Applicability date.* The provisions of this section apply on March 29, 2013.

■ 7. A new § 147.104 is added to part 147 to read as follows:

§ 147.104 Guaranteed availability of coverage.

(a) *Guaranteed availability of coverage in the individual and group market.* Subject to paragraphs (b) through (d) of this section, a health insurance issuer that offers health insurance coverage in the individual or group market in a state must offer to any individual or employer in the state all products that are approved for sale in the applicable market, and must accept any individual or employer that applies for any of those products.

(b) *Enrollment periods.* A health insurance issuer may restrict enrollment in health insurance coverage to open or special enrollment periods.

(1) *Open enrollment periods—(i) Group market.* A health insurance issuer in the group market must allow an employer to purchase health insurance coverage for a group health plan at any point during the year. In the case of health insurance coverage offered in the small group market, a health insurance issuer may limit the availability of coverage to an annual enrollment period that begins November 15 and extends through December 15 of each year in the case of a plan sponsor that is unable to comply with a material plan provision relating to employer contribution or group participation rules as defined in § 147.106(b)(3), pursuant to applicable state law and, in the case of a QHP offered in the SHOP, as permitted by § 156.285(c) of this subchapter. With respect to coverage in the small group market, and in the large group market if such coverage is offered in a Small Business Health Options Program (SHOP) in a state, coverage must become effective consistent with the dates described in § 155.725(h) of this subchapter.

(ii) *Individual market.* A health insurance issuer in the individual market must allow an individual to purchase health insurance coverage during the initial and annual open enrollment periods described in § 155.410(b) and (e) of this subchapter. Coverage must become effective consistent with the dates described in § 155.410(c) and (f) of this subchapter.

(2) *Limited open enrollment periods.* A health insurance issuer in the individual market must provide a limited open enrollment period for the events described in § 155.420(d) of this subchapter, excluding paragraphs (d)(3) (concerning citizenship status), (d)(8) (concerning Indians), and (d)(9) (concerning exceptional circumstances). In addition, a health insurance issuer in the individual market must provide, with respect to individuals enrolled in non-calendar year individual health insurance policies, a limited open enrollment period beginning on the date that is 30 calendar days prior to the date the policy year ends in 2014.

(3) *Special enrollment periods.* A health insurance issuer in the group and individual market must establish special enrollment periods for qualifying events as defined under section 603 of the Employee Retirement Income Security Act of 1974, as amended. These special enrollment periods are in addition to any other special enrollment periods that are required under federal and state law.

(4) *Length of enrollment periods.* With respect to the group market, enrollees must be provided 30 calendar days after

the date of the qualifying event described in paragraph (b)(3) of this section to elect coverage. With respect to the individual market, enrollees must be provided 60 calendar days after the date of an event described in paragraph (b)(2) and (b)(3) of this section to elect coverage.

(5) *Effective date of coverage for limited open and special enrollment periods.* With respect to an election made under paragraph (b)(2) or (b)(3) of this section, coverage must become effective consistent with the dates described in § 155.420(b) of this subchapter.

(c) *Special rules for network plans.* (1) In the case of a health insurance issuer that offers health insurance coverage in the group and individual market through a network plan, the issuer may do the following:

(i) Limit the employers that may apply for the coverage to those with eligible individuals in the group market who live, work, or reside in the service area for the network plan, and limit the individuals who may apply for the coverage in the individual market to those who live or reside in the service area for the network plan.

(ii) Within the service area of the plan, deny coverage to employers and individuals if the issuer has demonstrated to the applicable state authority (if required by the state authority) the following:

(A) It will not have the capacity to deliver services adequately to enrollees of any additional groups or any additional individuals because of its obligations to existing group contract holders and enrollees.

(B) It is applying paragraph (c)(1) of this section uniformly to all employers and individuals without regard to the claims experience of those individuals, employers and their employees (and their dependents) or any health status-related factor relating to such individuals, employees, and dependents.

(2) An issuer that denies health insurance coverage to an individual or an employer in any service area, in accordance with paragraph (c)(1)(ii) of this section, may not offer coverage in the individual or group market, as applicable, within the service area to any individual or employer, as applicable, for a period of 180 calendar days after the date the coverage is denied. This paragraph (c)(2) does not limit the issuer's ability to renew coverage already in force or relieve the issuer of the responsibility to renew that coverage.

(3) Coverage offered within a service area after the 180-day period specified

in paragraph (c)(2) of this section is subject to the requirements of this section.

(d) *Application of financial capacity limits.* (1) A health insurance issuer may deny health insurance coverage in the group or individual market if the issuer has demonstrated to the applicable state authority (if required by the state authority) the following:

(i) It does not have the financial reserves necessary to offer additional coverage.

(ii) It is applying this paragraph (d)(1) uniformly to all employers or individuals in the group or individual market, as applicable, in the state consistent with applicable state law and without regard to the claims experience of those individuals, employers and their employees (and their dependents) or any health status-related factor relating to such individuals, employees, and dependents.

(2) An issuer that denies health insurance coverage to any employer or individual in a state under paragraph (d)(1) of this section may not offer coverage in the group or individual market, as applicable, in the state before the later of either of the following dates:

(i) The 181st day after the date the issuer denies coverage.

(ii) The date the issuer demonstrates to the applicable state authority, if required under applicable state law, that the issuer has sufficient financial reserves to underwrite additional coverage.

(3) Paragraph (d)(2) of this section does not limit the issuer's ability to renew coverage already in force or relieve the issuer of the responsibility to renew that coverage.

(4) Coverage offered after the 180-day period specified in paragraph (d)(2) of this section is subject to the requirements of this section.

(5) An applicable state authority may provide for the application of this paragraph (d) on a service-area-specific basis.

(e) *Marketing.* A health insurance issuer and its officials, employees, agents and representatives must comply with any applicable state laws and regulations regarding marketing by health insurance issuers and cannot employ marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs in health insurance coverage or discriminate based on an individual's race, color, national origin, present or predicted disability, age, sex, gender identity, sexual orientation, expected length of life, degree of medical

dependency, quality of life, or other health conditions.

(f) *Applicability date.* The provisions of this section apply for plan years (in the individual market, policy years) beginning on or after January 1, 2014.

(g) *Grandfathered health plans.* This section does not apply to grandfathered health plans in accordance with § 147.140.

■ 8. A new § 147.106 is added to part 147 to read as follows:

§ 147.106 Guaranteed renewability of coverage.

(a) *General rule.* Subject to paragraphs (b) through (d) of this section, a health insurance issuer offering health insurance coverage in the individual or group market is required to renew or continue in force the coverage at the option of the plan sponsor or the individual, as applicable.

(b) *Exceptions.* An issuer may nonrenew or discontinue health insurance coverage offered in the group or individual market based only on one or more of the following:

(1) *Nonpayment of premiums.* The plan sponsor or individual, as applicable, has failed to pay premiums or contributions in accordance with the terms of the health insurance coverage, including any timeliness requirements.

(2) *Fraud.* The plan sponsor or individual, as applicable, has performed an act or practice that constitutes fraud or made an intentional misrepresentation of material fact in connection with the coverage.

(3) *Violation of participation or contribution rules.* In the case of group health insurance coverage, the plan sponsor has failed to comply with a material plan provision relating to employer contribution or group participation rules, pursuant to applicable state law. For purposes of this paragraph the following apply:

(i) The term "employer contribution rule" means a requirement relating to the minimum level or amount of employer contribution toward the premium for enrollment of participants and beneficiaries.

(ii) The term "group participation rule" means a requirement relating to the minimum number of participants or beneficiaries that must be enrolled in relation to a specified percentage or number of eligible individuals or employees of an employer.

(4) *Termination of plan.* The issuer is ceasing to offer coverage in the market in accordance with paragraph (c) or (d) of this section and applicable state law.

(5) *Enrollees' movement outside service area.* For network plans, there is no longer any enrollee under the plan

who lives, resides, or works in the service area of the issuer (or in the area for which the issuer is authorized to do business); and in the case of the small group market, the issuer applies the same criteria it would apply in denying enrollment in the plan under § 147.104(c)(1)(i).

(6) *Association membership ceases.* For coverage made available in the small or large group market only through one or more bona fide associations, if the employer's membership in the bona fide association ceases, but only if the coverage is terminated uniformly without regard to any health status-related factor relating to any covered individual.

(c) *Discontinuing a particular product.* In any case in which an issuer decides to discontinue offering a particular product offered in the group or individual market, that product may be discontinued by the issuer in accordance with applicable state law in the applicable market only if the following occurs:

(1) The issuer provides notice in writing to each plan sponsor or individual, as applicable, provided that particular product in that market (and to all participants and beneficiaries covered under such coverage) of the discontinuation at least 90 calendar days before the date the coverage will be discontinued.

(2) The issuer offers to each plan sponsor or individual, as applicable, provided that particular product the option, on a guaranteed availability basis, to purchase all (or, in the case of the large group market, any) other health insurance coverage currently being offered by the issuer to a group health plan or individual health insurance coverage in that market.

(3) In exercising the option to discontinue that product and in offering the option of coverage under paragraph (c)(2) of this section, the issuer acts uniformly without regard to the claims experience of those sponsors or individuals, as applicable, or any health status-related factor relating to any participants or beneficiaries covered or new participants or beneficiaries who may become eligible for such coverage.

(d) *Discontinuing all coverage.* (1) An issuer may elect to discontinue offering all health insurance coverage in the individual or group market, or all markets, in a state in accordance with applicable state law only if—

(i) The issuer provides notice in writing to the applicable state authority and to each plan sponsor or individual, as applicable, (and all participants and beneficiaries covered under the coverage) of the discontinuation at least

180 calendar days prior to the date the coverage will be discontinued; and

(ii) All health insurance policies issued or delivered for issuance in the state in the applicable market (or markets) are discontinued and not renewed.

(2) An issuer that elects to discontinue offering all health insurance coverage in a market (or markets) in a state as described in this paragraph (d) may not issue coverage in the applicable market (or markets) and state involved during the 5-year period beginning on the date of discontinuation of the last coverage not renewed.

(e) *Exception for uniform modification of coverage.* Only at the time of coverage renewal may issuers modify the health insurance coverage for a product offered to a group health plan in the following:

(1) Large group market.

(2) Small group market if, for coverage available in this market (other than only through one or more bona fide associations), the modification is consistent with state law and is effective uniformly among group health plans with that product.

(f) *Application to coverage offered only through associations.* In the case of health insurance coverage that is made available by a health insurance issuer in the small or large group market to employers only through one or more associations, the reference to “plan sponsor” is deemed, with respect to coverage provided to an employer member of the association, to include a reference to the employer.

(g) *Applicability date.* The provisions of this section apply for plan years (in the individual market, policy years) beginning on or after January 1, 2014.

(h) *Grandfathered health plans.* This section does not apply to grandfathered health plans in accordance with § 147.140.

■ 9. Amend § 147.145 by revising paragraph (b)(1) and adding paragraph (b)(3) to read as follows:

§ 147.145 Student health insurance coverage.

* * * * *

(b) *Exemptions from the Public Health Service Act and the Affordable Care Act*—(1) *Guaranteed availability and guaranteed renewability*—(i) For purposes of sections 2741(e)(1) and 2742(b)(5) of the Public Health Service Act, student health insurance coverage is deemed to be available only through a bona fide association.

(ii) For purposes of section 2702(a) of the Public Health Service Act, a health insurance issuer that offers student health insurance coverage is not

required to accept individuals who are not students or dependents of students in such coverage.

(iii) For purposes of section 2703(a) of the Public Health Service Act, a health insurance issuer that offers student health insurance coverage is not required to renew or continue in force coverage for individuals who are no longer students or dependents of students.

* * * * *

(3) *Single risk pool.* Student health insurance coverage is not subject to the requirements of section 1312(c) of the Affordable Care Act.

* * * * *

PART 150—CMS ENFORCEMENT IN GROUP AND INDIVIDUAL INSURANCE MARKETS

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

Authority: Secs. 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

■ 11. Amend § 150.101 by revising paragraphs (a) and (b)(2) to read as follows:

§ 150.101 Basis and scope.

(a) *Basis.* CMS's enforcement authority under sections 2723 and 2761 of the PHS Act and its rulemaking authority under section 2792 of the PHS Act provides the basis for issuing regulations under this part 150.

(b) * * *

(2) *Enforcement with respect to health insurance issuers.* The states have primary enforcement authority with respect to the requirements of title XXVII of the PHS Act that apply to health insurance issuers offering coverage in the group or individual health insurance market. If CMS determines under subpart B of this part that a state is not substantially enforcing title XXVII of the PHS Act, including the implementing regulations in parts 146, 147, and 148 of this subchapter, CMS enforces them under subpart C of this part.

■ 12. Amend § 150.103 as follows:

■ a. Remove the definition of “HIPAA requirements;”

■ b. Revise the definition of “Individual health insurance policy or individual policy;” and

■ c. Add the definition of “PHS Act requirements” in alphabetical order.

The revision and addition read as follows:

§ 150.103 Definitions.

* * * * *

Individual health insurance policy or individual policy means the legal document or contract issued by the issuer to an individual that contains the conditions and terms of the insurance. Any association or trust arrangement that is not a group health plan as defined in § 144.103 of this subchapter or does not provide coverage in connection with one or more group health plans is individual coverage subject to the requirements of parts 147 and 148 of this subchapter. The term “individual health insurance policy” includes a policy that is—

(1) Issued to an association that makes coverage available to individuals other than in connection with one or more group health plans; or

(2) Administered, or placed in a trust, and is not sold in connection with a group health plan subject to the provisions of parts 146 and 147 of this subchapter.

PHS Act requirements means the requirements of title XXVII of the PHS Act and its implementing regulations in parts 146, 147, and 148 of this subchapter.

* * * * *

■ 13. In part 150, remove the words “HIPAA requirement” or “HIPAA requirements,” and add in their place “PHS Act requirement” or “PHS Act requirements,” respectively, wherever they appear in the following places:

■ a. Section 150.103, in the definition of “Complaint”.

■ b. In the heading of subpart B of part 150.

■ c. Section 150.201.

■ d. Section 150.203, in the introductory text and paragraphs (a) and (b).

■ e. Section 150.205(d) and (e)(1).

■ f. Section 150.207, in the section heading and text.

■ g. Section 150.209.

■ h. Section 150.211, in the introductory text.

■ i. Section 150.213(b) and (c).

■ j. Section 150.217, in the introductory text.

■ k. Section 150.219(a).

■ l. Section 150.221(a).

■ m. Section 150.301.

■ n. Section 150.303(a) introductory text, (a)(3), and (b).

■ o. Section 150.305(a)(1), (b)(2), and (c)(2).

■ p. Section 150.309.

■ q. Section 150.311, in the introductory text and paragraphs (d), (f) introductory text, (f)(3), and (g).

■ r. Section 150.313(a) and (e)(3)(iv).

■ s. Section 150.317(a)(1) and (a)(3).

■ t. Section 150.319(b)(1) introductory text, (b)(1)(ii), and (b)(1)(iii).

■ u. Section 150.343(a).

■ v. Section 150.465(c).

PART 154—HEALTH INSURANCE ISSUER RATE INCREASES: DISCLOSURE AND REVIEW REQUIREMENTS

■ 14. The authority citation for part 154 continues to read as follows:

Authority: Section 2794 of the Public Health Service Act (42 U.S.C. 300gg–94).

■ 15. In § 154.200, revise the third sentence and add a fourth sentence to paragraph (a)(2) and paragraph (b) to read as follows:

§ 154.200 Rate increases subject to review.

(a) * * *

(2) * * * A state-specific threshold shall be based on factors impacting rate increases in a state to the extent that the data relating to such state-specific factors is available by August 1. States interested in proposing a state-specific threshold for approval are required to submit a proposal to the Secretary by August 1.

(b) The Secretary will publish a notice no later than September 1 of each year, to be effective on January 1 of the following year, concerning whether a threshold under paragraph (a)(1) or (a)(2) of this section applies to the state; except that, with respect to the 12-month period that begins on September 1, 2011, the threshold under paragraph (a)(1) of this section applies.

* * * * *

■ 16. Revise § 154.215 to read as follows:

§ 154.215 Submission of rate filing justification.

(a) If any product is subject to a rate increase, a health insurance issuer must submit a Rate Filing Justification for all products in the single risk pool, including new or discontinuing products, on a form and in a manner prescribed by the Secretary.

(b) The Rate Filing Justification must consist of the following Parts:

(1) Unified rate review template (Part I), as described in paragraph (d) of this section.

(2) Written description justifying the rate increase (Part II), as described in paragraph (e) of this section.

(3) Rating filing documentation (Part III), as described in paragraph (f) of this section.

(c) A health insurance issuer must complete and submit Parts I and III of the Rate Filing Justification described in paragraphs (b)(1) and (b)(3) of this section to CMS and, as long as the applicable state accepts such

submissions, to the applicable state. If a rate increase is subject to review, then the health insurance issuer must also complete and submit to CMS and, if applicable, the state Part II of the Rate Filing Justification described in paragraph (b)(2) of this section.

(d) Content of unified rate review template (Part I): The unified rate review template must include the following as determined appropriate by the Secretary:

(1) Historical and projected claims experience.

(2) Trend projections related to utilization, and service or unit cost.

(3) Any claims assumptions related to benefit changes.

(4) Allocation of the overall rate increase to claims and non-claims costs.

(5) Per enrollee per month allocation of current and projected premium.

(6) Three year history of rate increases for the product associated with the rate increase.

(e) Content of written description justifying the rate increase (Part II): The written description of the rate increase must include a simple and brief narrative describing the data and assumptions that were used to develop the rate increase and including the following:

(1) Explanation of the most significant factors causing the rate increase, including a brief description of the relevant claims and non-claims expense increases reported in the rate increase summary.

(2) Brief description of the overall experience of the policy, including historical and projected expenses, and loss ratios.

(f) Content of rate filing documentation (Part III): The rate filing documentation must include an actuarial memorandum that contains the reasoning and assumptions supporting the data contained in Part I of the Rate Filing Justification. Parts I and III must be sufficient to conduct an examination satisfying the requirements of § 154.301(a)(3) and (4) and determine whether the rate increase is an unreasonable increase. Instructions concerning the requirements for the rate filing documentation will be provided in guidance issued by CMS.

(g) If the level of detail provided by the issuer for the information under paragraphs (d) and (f) of this section does not provide sufficient basis for CMS to determine whether the rate increase is an unreasonable rate increase when CMS reviews a rate increase subject to review under § 154.210(a), CMS will request the additional information necessary to make its determination. The health insurance

issuer must provide the requested information to CMS within 10 business days following its receipt of the request.

(h) Posting of the disclosure on the CMS Web site:

(1) CMS promptly will make available to the public on its Web site the information contained in Part II of each Rate Filing Justification.

(2) CMS will make available to the public on its Web site the information contained in Parts I and III of each Rate Filing Justification that is not a trade secret or confidential commercial or financial information as defined in HHS's Freedom of Information Act regulations, 45 CFR 5.65.

(3) CMS will include a disclaimer on its Web site with the information made available to the public that explains the purpose and role of the Rate Filing Justification.

(4) CMS will include information on its Web site concerning how the public can submit comments on the proposed rate increases that CMS reviews.

■ 17. Revise § 154.220 to read as follows:

§ 154.220 Timing of providing the rate filing justification.

A health insurance issuer must submit a Rate Filing Justification for all rate increases that are filed in a state on or after April 1, 2013, or effective on or after January 1, 2014 in a state that does not require the rate increase to be filed, as follows:

(a) If a state requires that a proposed rate increase be filed with the state prior to the implementation of the rate, the health insurance issuer must submit to CMS and the applicable state the Rate Filing Justification on the date on which the health insurance issuer submits the proposed rate increase to the state.

(b) For all other states, the health insurance issuer must submit to CMS and the state the Rate Filing Justification prior to the implementation of the rate increase.

§ 154.225 [Amended]

■ 18a. In § 154.225(a), introductory text, remove the words "Preliminary Justification" and add in their place "Rate Filing Justification."

§ 154.230 [Amended]

■ 18b. In § 154.230(b) and (c)(1), remove the words "Preliminary Justification" and add in their place "Rate Filing Justification."

■ 19. Amend § 154.301 as follows:

■ a. Amend paragraphs (a)(3)(i) and (a)(3)(xi) by removing "; and" and adding in its place a period.

■ b. Amend paragraphs (a)(4)(i), (a)(4)(ii), and (a)(4)(vi) through (a)(4)(x)

by removing the semicolons and replacing them with periods.

■ c. Revise paragraphs (a)(4)(iii) through (a)(4)(v), and (b).

■ d. Add new paragraphs (a)(3)(iii), (a)(3)(iv), and (a)(4)(xiii) through (a)(4)(xv). The revisions and additions read as follows:

§ 154.301 CMS's determinations of effective rate review programs.

(a) * * *

(3) * * *

(iii) The reasonableness of assumptions used by the health insurance issuer to estimate the rate impact of the reinsurance and risk adjustment programs under sections 1341 and 1343 of the Affordable Care Act.

(iv) The health insurance issuer's data related to implementation and ongoing utilization of a market-wide single risk pool, essential health benefits, actuarial values and other market reform rules as required by the Affordable Care Act.

(4) * * *

(iii) The impact of cost-sharing changes by major service categories, including actuarial values.

(iv) The impact of benefit changes, including essential health benefits and non-essential health benefits.

(v) The impact of changes in enrollee risk profile and pricing, including rating limitations for age and tobacco use under section 2701 of the Public Health Service Act.

* * * * *

(xiii) The impacts of geographic factors and variations.

(xiv) The impact of changes within a single risk pool to all products or plans within the risk pool.

(xv) The impact of reinsurance and risk adjustment payments and charges under sections 1341 and 1343 of the Affordable Care Act.

* * * * *

(b) *Public disclosure and input.* In addition to satisfying the provisions in paragraph (a) of this section, a state with an effective rate review program must provide, for the rate increases it reviews, access from its Web site to at least the information contained in Parts I, II, and III of the Rate Filing Justification that CMS makes available on its Web site (or provide CMS's Web address for such information) and have a mechanism for receiving public comments on those proposed rate increases.

* * * * *

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ 20. The authority citation for part 156 continues to read as follows:

Authority: Title I of the Affordable Care Act, sections 1301–1304, 1311–1312, 1321, 1322, 1324, 1334, 1342–1343, and 1401–1402, Pub. L. 111–148, 124 Stat. 119 (42 U.S.C. 18042).

■ 21. A new § 156.80 is added to subpart A to read as follows:

§ 156.80 Single risk pool.

(a) *Individual market.* A health insurance issuer must consider the claims experience of all enrollees in all health plans (other than grandfathered health plans) subject to section 2701 of the Public Health Service Act and offered by such issuer in the individual market in a state, including those enrollees who do not enroll in such plans through the Exchange, to be members of a single risk pool.

(b) *Small group market.* A health insurance issuer must consider the claims experience of all enrollees in all health plans (other than grandfathered health plans) subject to section 2701 of the Public Health Service Act and offered by such issuer in the small group market in a state, including those enrollees who do not enroll in such plans through the Exchange, to be members of a single risk pool.

(c) *Merger of the individual and small group markets.* A state may require the individual and small group insurance markets within a state to be merged into a single risk pool if the state determines appropriate. A state that requires such merger must submit to CMS information on its election in accordance with the procedures described in § 147.103 of this subchapter.

(d) *Index rate—(1) In general.* Each plan year or policy year, as applicable, a health insurance issuer must establish an index rate for a state market described in paragraphs (a) through (c) of this section based on the total combined claims costs for providing essential health benefits within the single risk pool of that state market. The index rate must be adjusted on a market-wide basis based on the total expected market-wide payments and charges under the risk adjustment and reinsurance programs in the state and Exchange user fees. The premium rate for all of the health insurance issuer's plans in the relevant state market must use the applicable market-wide adjusted index rate, subject only to the plan-level

adjustments permitted in paragraph (d)(2) of this section.

(2) *Permitted plan-level adjustments to the index rate.* For plan years or policy years beginning on or after January 1, 2014, a health insurance issuer may vary premium rates for a particular plan from its market-wide index rate for a relevant state market based only on the following actuarially justified plan-specific factors:

(i) The actuarial value and cost-sharing design of the plan.

(ii) The plan's provider network, delivery system characteristics, and utilization management practices.

(iii) The benefits provided under the plan that are in addition to the essential health benefits. These additional benefits must be pooled with similar benefits within the single risk pool and the claims experience from those benefits must be utilized to determine rate variations for plans that offer those benefits in addition to essential health benefits.

(iv) Administrative costs, excluding Exchange user fees.

(v) With respect to catastrophic plans, the expected impact of the specific eligibility categories for those plans.

(e) *Grandfathered health plans in the individual and small group market.* A state law requiring grandfathered health plans described in § 147.140 of this subchapter to be included in a single

risk pool described in paragraphs (a) through (c) of this section does not apply.

(f) *Applicability date.* The provisions of this section apply for plan years (as that term is defined in § 144.103 of this subchapter) in the group market, and for policy years (as that term is defined in § 144.103 of this subchapter) in the individual market, beginning on or after January 1, 2014.

■ 22. A new § 156.155 is added to subpart B to read as follows:

§ 156.155 Enrollment in catastrophic plans.

(a) *General rule.* A health plan is a catastrophic plan if it meets the following conditions:

(1) Meets all applicable requirements for health insurance coverage in the individual market (including but not limited to those requirements described in parts 147 and 148 of this subchapter), and is offered only in the individual market.

(2) Does not provide a bronze, silver, gold, or platinum level of coverage described in section 1302(d) of the Affordable Care Act.

(3) Provides coverage of the essential health benefits under section 1302(b) of the Affordable Care Act once the annual limitation on cost sharing in section 1302(c)(1) of the Affordable Care Act is reached.

(4) Provides coverage for at least three primary care visits per year before reaching the deductible.

(5) Covers only individuals who meet either of the following conditions:

(i) Have not attained the age of 30 prior to the first day of the plan or policy year.

(ii) Have received a certificate of exemption for the reasons identified in section 1302(e)(2)(B)(i) or (ii) of the Affordable Care Act.

(b) *Coverage of preventive health services.* A catastrophic plan may not impose any cost-sharing requirements (such as a copayment, coinsurance, or deductible) for preventive services, in accordance with section 2713 of the Public Health Service Act.

(c) *Application for family coverage.* For other than self-only coverage, each individual enrolled must meet the requirements of paragraph (a)(5) of this section.

Dated: February 15, 2013.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: February 20, 2013.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

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